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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): **May 16, 2020**

SONNET BIOTHERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35570**	**20-2932652**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Overlook Center, Suite 102
Princeton, New Jersey 08540

(Address of principal executive offices)
Registrant's telephone number, including area code: **(609) 375-2227**

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 Par Value	SONN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [ ]

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. [ ]

EXPLANATORY NOTE

This Current Report on Form 8-K (this "report") is filed by Sonnet BioTherapeutics Holdings, Inc. ("Sonnet," "we," "us," "our," or the "Company"), formerly known as Chanticleer Holdings, Inc. As of and for the period ending March 31, 2020, the Company was in the business of owning, operating and franchising fast casual dining concepts domestically and internationally. As reported in its Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on April 3, 2020 and as discussed in more detail in the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2020, filed or to be filed concurrently with this report (the "Form 10-Q"), on April 1, 2020, the Company completed its merger transaction with Sonnet BioTherapeutics, Inc. ("Sonnet Sub"), pursuant to which Sonnet Sub became a wholly-owned subsidiary of the Company (the "Merger"). On April 1, 2020, in connection with the Merger, the Company changed its name to "Sonnet BioTherapeutics Holdings, Inc."

The Merger was treated by the Company as a reverse merger and accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). For accounting purposes, Sonnet Sub is considered to have acquired the Company.

In connection with and prior to the Merger, the Company contributed and transferred to Amergent Hospitality Group, Inc. ("Amergent"), a newly formed, wholly owned subsidiary of the Company, all of the assets and liabilities relating to the Company's restaurant business. On March 16, 2020, the board of directors of the Company declared a dividend with respect to the shares of the Company common stock outstanding at the close of business on March 26, 2020 of one share of the Amergent common stock held by the Company for each outstanding share of the Company's common stock. The dividend was paid to the stockholders of the Company on April 1, 2020 immediately prior to the Merger. The dividend, which together with the contribution and transfer of the Company's restaurant business described above, is referred to as the "Spin-Off." Prior to the Spin-Off, Amergent engaged in no business or operations.

As a result of the Spin-Off and the Merger, since April 1, 2020 the Company has operated through Sonnet Sub and its direct and indirect subsidiaries and the ongoing business of the Company is the Sonnet Sub business. Sonnet Sub is a clinical-stage biopharmaceutical company with a proprietary technology for developing novel biologic medicines we refer to as FHAB™ (Fully Human Albumin Binding). FHAB utilizes a fully human single chain antibody fragment (scFv) linked to either one or two therapeutic molecules capable of affecting single- or bi-specific mechanisms of action.

In addition, in connection with and prior to the Merger, on April 1, 2020, Sonnet Sub completed its acquisition of the global development rights for Atexakin Alfa (low dose formulation of Interleukin-6, IL-6, now "SON-080") from Relief Therapeutics Holding SA ("Relief Holding") through its acquisition of Relief Holding's wholly-owned subsidiary, Relief Therapeutics SA ("Relief"), in exchange for the issuance to Relief Holding of shares of Sonnet Sub common stock that converted into an aggregate of 757,933 shares of Company common stock in the Merger.

This report includes financial statements of Sonnet Sub as of and for the three months and six months ended March 31, 2020, financial statements of Relief as of and for the three months ended March 31, 2020 and certain pro forma financial information. This report should be read in conjunction with the information in the Form 10-Q.

The financial condition and results of operations of the Company for the periods presented in the 10-Q are for periods prior to the Merger and Spin-Off and thus bear no relationship to the business, financial condition and results of operations of Sonnet Sub and are not indicative of the business, financial condition and results of operations of the Company for any future period. The Company's future business, financial condition and results of operations will reflect the business, financial condition and results of operations of Sonnet Sub and its consolidated subsidiaries.

Item 2.02. Results of Operations and Financial Condition.

On May 18, 2020, Sonnet BioTherapeutics Holdings, Inc. (the "Company" or the "Registrant") issued a press release regarding financial results and certain business updates for the fiscal quarter ended March 31, 2020. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 4.01 Changes in Registrant's Certifying Accountant

On May 16, 2020, the Audit Committee (the "Audit Committee") of the Board of the Company dismissed Cherry Bekaert LLP ("Cherry Bekaert") as the Company's independent registered public accounting firm, effectively immediately.

The reports of Cherry Bekaert on the Company's consolidated financial statements for the fiscal years ended December 31, 2019 and 2018 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles except that, the reports on the consolidated financial statements of the Company as of and for the years ended December 31, 2019 and 2018, each contained a separate explanatory paragraph regarding substantial doubt about the Company's ability to continue as a going concern.

During the fiscal years ended December 31, 2019 and 2018 and the subsequent interim period through May 16, 2020, there have been no "disagreements" (as defined in Item 304(a)(1)(iv) of Regulation S-K and related instructions) with Cherry Bekaert on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Cherry Bekaert, would have caused Cherry Bekaert to make reference thereto in their reports on the consolidated financial statements for such fiscal years.

During the fiscal years ended December 31, 2019 and 2018 and any subsequent interim period through May 16, 2020, there have been no "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K).

The Company has provided Cherry Bekaert with a copy of the disclosure it is making herein in response to Item 304(a) of Regulation S-K and requested that Cherry Bekaert furnish the Company with a copy of its letter addressed to the Securities and Exchange Commission (the "SEC"), pursuant to Item 304(a)(3) of Regulation S-K, stating whether Cherry Bekaert agrees with the statements made by the Company in response to Item 304(a) of Regulation S-K. A copy of Cherry Bekaert's letter to the SEC dated May 18, 2020, is filed as Exhibit 16.1 to this Current Report on Form 8-K.

On May 16, 2020, the Audit Committee approved the appointment of KPMG LLP ("KPMG") as the Company's new independent registered public accounting firm, effective immediately. During the fiscal years ended September 30, 2019 and 2018 and the subsequent interim period through May 16, 2020, neither the Company, nor anyone on its behalf, consulted KPMG regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the financial statements of the Company, and no written report or oral advice was provided to the Company by KPMG that KPMG concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a "disagreement" (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a "reportable event" (as that term is defined in Item 304(a)(1)(v) of Regulation S-K).

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

As previously reported, in April 2020, the Company acquired Sonnet BioTherapeutics, Inc. ("Sonnet Sub"), our wholly owned subsidiary, by way of a reverse merger transaction in which Sonnet Sub is treated as the acquirer for financial accounting purposes. On May 17, 2020, therefore, the Board of the Company approved a change in the Company's fiscal year end from December 31 to September 30, the fiscal year end of Sonnet Sub.

In accordance with SEC guidance, no transition report is required in connection with the change in the Company's fiscal year end. Accordingly, the Company intends to file a Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

Item 8.01 Other Events.

Business Update

As a result of the Merger, the Spin-Off and the transactions related thereto occurring on or about April 1, 2020, we are a clinical-stage biopharmaceutical company with a proprietary technology for developing novel biologic medicines we refer to as FHAB™ (Fully Human Albumin Binding). FHAB utilizes a fully human single chain antibody fragment (scFv) linked to either one or two therapeutic molecules capable of affecting single or bispecific mechanisms of action. The FHAB construct contains a domain that is designed to bind to and "hitch hike" on human serum albumin (HSA) for transport to and accumulation in target tissues, with an extended duration of therapeutic activity. FHAB development candidates are produced in a mammalian cell culture, which enables glycosylation, thereby reducing the risk of immunogenicity. Our current internal research and development activities are focused on cytokines, a class of cell signaling peptides that serve important immunomodulatory functions. We have a pipeline of therapeutic compounds focused on oncology indications of high unmet medical need and we recently announced an initiative to explore FHAB opportunities in virology. We believe our FHAB technology is well suited for future drug development across a range of human disease areas, including anti-infective, autoimmune, inflammatory, and hematological applications.

● SON-080, our most advanced candidate, is a low-dose formulation of Interleukin-6, in development for Chemotherapy Induced Peripheral Neuropathy (CIPN), an indication of high unmet medical need. Through Serono SA's original exploration of the cytokine as a potential treatment for thrombocytopenia in cancer, over 200 patients worth of Phase I clinical data were generated. After observing transient efficacy at doses approaching the estimated maximum tolerated dose (MTD) for thrombocytopenia, Serono elected to pursue CIPN using lower doses, but the program was de-prioritized by Merck KGaA after it acquired the company in 2006. We purchased the global development rights to SON-080 in August 2019 and will be applying the Merck Serono preclinical and clinical data package to our ongoing work in CIPN.

We are currently requalifying the legacy clinical batch product and updating the safety package to comply with current regulatory requirements. We are undertaking the qualification and validation of the product prior to entering a preclinical toxicology study for further refining the dosing parameters for a Phase Ia/IIb trial in CIPN patients. We are designing this trial to leverage data from prior studies. Although the CIPN program continues to progress forward, the COVID-19 pandemic has impacted workflow at our contract research partners such that we now estimate delays pushing a trial initiation into the first half of 2021 from late 2020. Additionally, we continue to explore business development opportunities for the Diabetic Peripheral Neuropathy (DPN) indication.

● SON-1010 (IL12- FHAB), our most advanced FHAB-derived compound, utilizes a fully human version of Interleukin-12 (IL-12) linked to FHAB. IL-12 is a well-known immune stimulator that we believe carries potential therapeutic utility in both immune oncology and antiviral applications. The Sonnet FHAB was designed to deliver low doses of conjugated drug candidates to target tissues such as solid tumors or the lymphatic system for oncology or virology indications, respectively.

We have filed updated intellectual property that includes provisions for three areas of antiviral drug development: (i) as an adjuvant to potentiate vaccine efficacy; (ii) as a broad spectrum antiviral that could be deployed against a wide array of viruses, particularly those that do not elicit Cytokine Release Syndrome (CRS); and (iii) as a platform for configuring bispecific, multifunctional vaccines comprising the FHAB construct conjugated with both a vaccine peptide and an immune stimulator (e.g., IL-12) that could enhance delivery to the lymphatic system.

We have successfully manufactured and initiated animal testing of SON-1010 for select virology applications. We have initiated work on preliminary viral challenge studies in mice using an H1N1 model with data expected during the second half of 2020. If successful, a mouse-adapted SARS-CoV-1 challenge model study is expected to follow, which we expect would help us develop a clinical trial strategy using FHAB in an adjuvant capacity, paired with a vaccine.

In immune oncology, we have completed in vitro pharmacology studies of affinity and binding kinetics that demonstrate species cross-reactivity of SON-1010 in serum albumin for hamster, rat, dog, cynomolgus monkey and human. The results verified that SON-1010 displays species specificity to cynomolgus monkey and human subjects, which will guide species selection for further preclinical toxicology work. A humanized mouse model (SCID) study designed to evaluate pK/pD and dose response is underway. This work will inform our decision about dosing in a forthcoming nonhuman primate study, scheduled to commence following analysis of the SCID mouse data.

Work on the master cell bank expressing SON-1010, formulation development and process development activities have all been completed, in addition to drug product formulation (liquid and lyophilized). Process transfer and cGMP product manufacturing are scheduled for the second half of 2020, followed by an IND-enabling toxicology study in the first half of 2021. An IND submission is expected in the second half of 2021.

● SON-1210 (IL15- FHAB-IL12), our first bi-specific construct, combines FHAB with fully human IL-12 and fully human Interleukin-15 (IL-15). This compound has demonstrated significant reduction in tumor volume compared to concomitantly administered naked IL-12 and IL-15. Cell line development is underway and final clone selection is expected in 2020. Early development material will be used in a humanized mouse model (SCID) study designed to evaluate PK/PD and dose response. This work will inform our decision about dosing in a forthcoming nonhuman primate study, expected to be initiated by mid-2021. We will also explore potential antiviral applications for SON-1210.

● SON-2014 (GMcSF- FHAB-IL18), is a bi-specific combination of Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) and Interleukin-18 (IL-18). Discrete GMcSF and IL-18 for preclinical studies have been manufactured and we are currently undertaking a proof-of-concept study in mice to evaluate the efficacy of the co-administered cytokines.

● SON-3015 (anti-IL6- FHAB-anti-TGFβ), is a bi-specific combination of anti-IL6 and anti-Tumor Growth Factor Beta. We expect to complete lead selection for this discovery-stage bispecific molecule around year-end 2020 followed by a preclinical proof-of-concept study in mice.

Risk Factors

Investing in Sonnet involves a high degree of risk. Before deciding whether to invest, you should carefully consider the following risks and uncertainties, together with all other information in this Current Report on Form 8-K, including Sonnet's consolidated financial statements and related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition", our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 19, 2020, as amended on April 22, 2020, and our definitive proxy statement/prospectus/information statement filed with the Securities and Exchange Commission on February 11, 2020 under Rule 424 of the Securities Act of 1933, as amended. All references in this section to "Sonnet," the "Company," "we," "us," or "our" mean Sonnet BioTherapeutics Holdings, Inc. unless we state otherwise or the context otherwise indicates. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and/or growth prospects. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward- looking statements. See "Forward-Looking Statements" in this Current Report on Form 8-K.

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of significant operating losses and expect to incur significant and increasing losses for the foreseeable future, and we may never achieve or maintain profitability.

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. Sonnet Sub incurred net losses of $5.0 million, $4.9 million and $0.9 million for the six months ended March 31, 2020 and years ended September 30, 2019 and 2018, respectively. In addition, Sonnet Stub's accumulated deficit as of March 31, 2020 was $17.4 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability in the future. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' (deficit) equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to our lead product candidate, SON-080, and our other product candidates;
- initiate and continue research, preclinical and clinical development efforts for any future product candidates;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek marketing and regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization;
- maintain, expand and protect our intellectual property portfolio;
- expand our research and development infrastructure, including hiring and retaining additional personnel, such as clinical, quality control and scientific personnel;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize products for which we obtain marketing approval, if any;

● add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization and help us comply with our obligations as a public company; and

● add equipment and physical infrastructure to support our research and development.

Our ability to become and remain profitable depends on our ability to license our products and generate revenue. Generating product revenue will depend on our ability to obtain marketing approval for, and successfully commercialize, one or more of our product candidates.

Successful commercialization will require achievement of key milestones, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any collaborators may never succeed in these activities and, even if we do, or any collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses, investors may not receive any return on their investment and may lose their entire investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our business commenced operations in 2015. Our operations to date have been limited to financing and staffing our company, developing our technology, conducting preclinical research and early-stage clinical trials for our product candidates and pursuing strategic collaborations to advance our product candidates. We have not yet demonstrated an ability to successfully conduct late-stage clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Sonnet Sub has incurred recurring losses and negative cash flows from operations activities since inception and it expects to generate losses from operations for the foreseeable future primarily due to research and development costs for its potential product candidates. As of March 31, 2020, Sonnet Sub had cash of $272,855 and stockholders' deficit of $3,541,258. The Company believes Sonnet Sub's cash at March 31, 2020 and approximately $8.3 million received in connection with the Merger and related transactions will fund the Company's projected operations through the end of the fiscal year ending September 30, 2020. Substantial additional financing will be needed by the Company to fund its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company will require additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources to carry out the Company's planned development activities. If additional capital is not secured when required, the Company may need to delay or curtail its operations until such funding is received. Various internal and external factors will affect whether and when the Company's product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company's products candidates, length of time and cost of developing and commercializing these product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations.

Operations since inception have consisted primarily of organizing the Company, securing financing, developing its technologies through performing research and development and conducting preclinical studies. The Company faces risks associated with companies whose products are in development. These risks include the need for additional financing to complete its research and development, achieving its research and development objectives, defending its intellectual property rights, recruiting and retaining skilled personnel, and dependence on key members of management.

Our ability to continue as a going concern is dependent on our ability to raise additional equity or debt capital or spin-off non-core assets to raise additional cash. Should we be unable to raise sufficient additional capital, we may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern.

While the potential economic impact brought by, and the duration of, COVID-19, discussed further below, may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. For example, in the six months ended March 31, 2020 and years ended September 30, 2019 and 2018, Sonnet Sub used $3.6 million, $2.2 million and $0.7 million, respectively, in net cash for its operating activities, substantially all of which related to research and development activities. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek marketing approval for, our current product candidates or any future product candidates. In addition, if we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a collaborator. Furthermore, as a result of the Merger, we incur significant costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We will be required to expend significant funds in order to advance the development of the product candidates in our pipeline, as well as other product candidates we may seek to develop. In addition, while we may seek one or more collaborators for future development of our product candidates, we may not be able to enter into a collaboration for any of our product candidates for such indications on suitable terms, on a timely basis or at all. In any event, our existing cash will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, our current and future product candidates;
- our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements;
- our ability to identify one or more future product candidates for our pipeline;
- the number of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the receipt of marketing approval, revenue, if any, received from commercial sales of our current and future product candidates;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances, licensing arrangements or monetization transactions. To the extent that we raise additional capital through the sale of equity, convertible debt securities or other equity-based derivative securities, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Any indebtedness we incur would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline and existing shareholders may not agree with our financing plans or the terms of such financings. If we raise additional funds through strategic partnerships and alliances, licensing arrangements or monetization transactions with third parties, we may have to relinquish valuable rights to our technologies, or our product candidates, or grant licenses on terms unfavorable to us. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

The coronavirus COVID-19 pandemic or the widespread outbreak of any other communicable disease could materially and adversely affect our business, financial condition and results of operations.

We face risks related to health epidemics or outbreaks of communicable diseases, for example, the recent outbreak around the world of the highly transmissible and pathogenic coronavirus COVID-19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and on March 11, 2020 was declared a pandemic by the World Health Organization. The extent to which COVID-19 may impact our preclinical and clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of the outbreak, the severity of COVID-19, and the effectiveness of actions to contain and treat COVID-19.

To date, many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of COVID-19 and have closed non-essential businesses. As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

This pandemic or outbreak could result in difficulty securing clinical trial site locations, CROs, and/or trial monitors and other critical vendors and consultants supporting the trial. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the Company's ability to enroll patients. These situations, or others associated with Covid-19, could cause delays in the Company's clinical trial plans and could increase expected costs, all of which could have a material adverse effect on the Company's business and its financial condition.

In particular, although our CIPN program with SON-080 continues to progress forward, the COVID-19 pandemic has impacted workflow at our contract research partners such that we now estimate delays pushing a trial initiation into the first half of 2021 from our previous plan of late 2020.

While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares.

The COVID-19 outbreak may also affect the ability of our staff and the parties we work with to carry out our non-clinical, clinical, and drug manufacturing activities. We rely or may in the future rely on clinical sites, investigators and other study staff, consultants, independent contractors, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our nonclinical studies and clinical trials. We also rely or may in the future rely on consultants, independent contractors, contract manufacturing organizations, and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our API production, formulation, and drug manufacturing activities. COVID-19 may affect the ability of any of these external people, organizations, or companies to devote sufficient time and resources to our programs or to travel to perform work for us.

Potential negative impacts of the COVID-19 outbreak on the conduct of current or future clinical studies include delays in gaining feedback from regulatory agencies, starting new clinical studies, and recruiting subjects to studies that are enrolling. The potential negative impacts also include inability to have study visits at study sites, incomplete collection of safety and efficacy data, and higher rates of drop-out of subjects from ongoing studies, delays in site entry of study data into the data base, delays in monitoring of study data because of restricted physical access to study sites, delays in site responses to queries, delays in data-base lock, delays in data analyses, delays in time to top-line data, and delays in completing study reports. New or worsening COVID-19 disruptions or restrictions could have the potential to further negatively impact our non-clinical studies, clinical trials, and drug manufacturing activities.

We are substantially dependent on the success of our internal development programs and our product pipeline candidates may not successfully complete clinical trials, receive regulatory approval or be successfully commercialized.

Our future success will depend heavily on the success of our internal development programs and of product candidates from our pipeline program.

Our ability to successfully commercialize our pipeline and our other product candidates will depend on, among other things, our ability to:

- successfully complete preclinical studies and clinical trials;

- receive regulatory approvals from the FDA, the EMA and other similar regulatory authorities;

- establish and maintain collaborations with third parties for the development and/or commercialization of our product candidates, or otherwise build and maintain strong development, sales, distribution and marketing capabilities that are sufficient to develop products and launch commercial sales of any approved products;

- obtain coverage and adequate reimbursement from payors such as government health care systems and insurance companies and achieve commercially attractive levels of pricing;

- secure acceptance of our product candidates from physicians, health care payors, patients and the medical community;

- produce, through a validated process, in manufacturing facilities inspected and approved by regulatory authorities, including the FDA, sufficiently large quantities of our product candidates to permit successful commercialization;

- manage our spending as expenses increase due to clinical trials and commercialization; and

- obtain and enforce sufficient intellectual property rights for any approved products and product candidates.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a new drug application, or NDA, or biologics licensing application, or BLA, to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market our product candidates, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. If we are unable to develop, or obtain regulatory approval for, or, if approved, to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

We are at a very early stage in our development efforts, our product candidates represent a new category of medicines and may be subject to heightened regulatory scrutiny until they are established as a therapeutic modality.

Our pipeline product candidates represent a new therapeutic modality of including engaging a Fully Human Albumin Binding Domain to deliver therapeutic products. Our product candidates may not demonstrate in patients any or all of the pharmacological benefits we believe they may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for these or any other product candidates in clinical trials or in obtaining marketing approval thereafter.

Regulatory authorities do not have experience with our product candidate and may require evidence of safety and efficacy that goes beyond what we have included in our development plans. In such a case, development of our product candidates may be more costly or time-consuming than expected, and our candidate products may not prove to be viable.

If we are unsuccessful in our development efforts, we may not be able to advance the development of our product candidates, commercialize products, raise capital, expand our business or continue our operations.

Our product candidates and those of any collaborators will need to undergo preclinical and clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If preclinical or clinical trials of our or their product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA, the EMA and any other comparable regulatory authority, additional costs may be incurred or delays experienced in completing, the development of these product candidates, or their development may be abandoned.

The FDA in the United States, the EMA in the European Union and the European Economic Area, and other comparable regulatory authorities in other jurisdictions must approve new product candidates before they can be marketed, promoted or sold in those territories. We have not previously submitted an IND or BLA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. We must provide these regulatory authorities with data from preclinical studies and clinical trials that demonstrate that our product candidates are safe and effective for a specific indication before they can be approved for commercial distribution. We cannot be certain that our clinical trials for our product candidates will be successful or that any of our product candidates will receive approval from the FDA, the EMA or any other comparable regulatory authority.

Preclinical studies and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years and require significant expenditures to complete the preclinical studies and clinical trials necessary to commercialize a product candidate, and delays or failure are inherently unpredictable and can occur at any stage. We may also be required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we contemplate, which may lead to us incurring additional unplanned costs or result in delays in clinical development. In addition, we may be required to redesign or otherwise modify our plans with respect to an ongoing or planned clinical trial, and changing the design of a clinical trial can be expensive and time consuming. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us. An unfavorable outcome in one or more trials may require us to delay, reduce the scope of or eliminate one or more product development programs, which could have a material adverse effect on our business, financial position, results of operations and future growth prospects.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates. The FDA, EMA or any other comparable regulatory authority may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

In connection with clinical trials of our product candidates, we face a number of risks, including risks that:

- a product candidate is ineffective or inferior to existing approved products for the same indications;
- a product candidate causes or is associated with unacceptable toxicity or has unacceptable side effects;
- patients may die or suffer adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier trials;

● the results may not meet the level of statistical significance required by the FDA, the EMA or other relevant regulatory agencies to establish the safety and efficacy of our product candidates for continued trial or marketing approval; and

● our collaborators may be unable or unwilling to perform under their contracts.

Furthermore, we sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, the receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, we may not be entitled to receive certain contractual payments, which could have a material adverse effect on our business, financial position, results of operations and future growth prospects.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit patients to participate as well as the completion of required follow-up periods. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments or for other reasons. Enrollment risks are heightened with respect to certain indications that we may target for one or more of our product candidates that may be rare diseases, which may limit the pool of patients that may be enrolled in our planned clinical trials. The timeline for recruiting patients, conducting trials and obtaining regulatory approval of our product candidates may be delayed, which could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics, to complete our clinical trials in a timely manner. For example, due to the nature of the indications that we are initially targeting, patients with advanced disease progression may not be suitable candidates for treatment with our product candidates and may be ineligible for enrollment in our clinical trials. Therefore, early diagnosis in patients with our target diseases is critical to our success. Patient enrollment and trial completion is affected by factors including the:

● size of the patient population and process for identifying subjects;

● design of the trial protocol;

● eligibility and exclusion criteria;

● safety profile, to date, of the product candidate under study;

● perceived risks and benefits of the product candidate under study;

● perceived risks and benefits of our approach to treatment of diseases;

● availability of competing therapies and clinical trials;

● severity of the disease under investigation;

● degree of progression of the subject’s disease at the time of enrollment;

- proximity and availability of clinical trial sites for prospective subjects;
- ability to obtain and maintain subject consent;
- risk that enrolled subjects will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

In addition, clinical development for pilot scale feasibility study of SON-080 is currently planned to take place outside of the U.S. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with academic partners or contract research organizations, or CROs, and physicians;
- different standards for the conduct of clinical trials;
- the absence in some countries of established groups with sufficient regulatory expertise for review of protocols related to our novel approach;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. For example, the Phase IIa trial of SON-080 will be conducted outside of the U.S., and the findings may not be replicated in future trials at global clinical trial sites in a later stage clinical trial conducted by us or our collaborators. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support marketing approval.

Preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or any collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.

Undesirable or clinically unmanageable side effects could occur and cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the Institutional Review Boards, or IRBs, or independent ethics committees at the institutions in which our studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may be required to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following consequences could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any collaborators, may need to recall the product, or be required to change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- we, or any collaborators, may be required to create a medication guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed. Any of these events could harm our business and operations, and could negatively impact the price of our common stock.

We may not be successful in our efforts to identify or discover additional product candidates.

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify other product candidates for clinical development for a number of reasons. For example, our research methodology may not be successful in identifying potential product candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Additional product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development. If we fail to identify and develop additional potential product candidates, we may be unable to grow our business and our results of operations could be materially harmed.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the impairment of our business reputation;
- the withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants;
- costs due to related litigation;
- the distraction of management's attention from our primary business;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We intend to acquire product liability insurance coverage in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage each time we commercialize an additional product; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by certain of our product candidates, such as our lead indications in oncology, are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We may seek designations for our product candidates with the FDA and other comparable regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway, but there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and other comparable regulatory authorities offer certain designations for product candidates that are intended to encourage the research and development of pharmaceutical products addressing conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. There can be no assurance that we will successfully obtain such designation for any of our other product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Breakthrough Therapy Designation for one or more of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, if preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

We may also seek Fast Track Designation for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of ultimate FDA approval. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, in particular if such product candidate has received a Breakthrough Therapy Designation, the FDA may decide not to grant it. Moreover, a priority review designation does not result in expedited development and does not necessarily result in expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We do not have experience in obtaining reimbursement or pricing approvals in international markets.

Obtaining marketing approvals and compliance with regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries outside of the United States. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Risks Related to Commercialization of Our Product Candidates and Other Regulatory Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us or any collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any collaborators, will obtain marketing approval to commercialize a product candidate.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product commercially unviable.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. For example, regulatory agencies may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. Regulators may approve a product candidate for a smaller patient population, a different drug formulation or a different manufacturing process, than we are seeking. If we are unable to obtain necessary regulatory approvals, or more limited regulatory approvals than we expect, our business, prospects, financial condition and results of operations may suffer.

Any delay in obtaining or failure to obtain required approvals could negatively impact our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact the price of our common stock.

We currently have no marketing, sales or distribution infrastructure with respect to our product candidates. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities and have limited sales or marketing experience within our organization. If one or more of our product candidates is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize that product candidate, or to outsource this function to a third party. There are risks involved with either establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services.

Recruiting and training an internal commercial organization is expensive and time consuming and could delay any product launch. Some or all of these costs may be incurred in advance of any approval of any of our product candidates. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States or other target market that is sufficient in size or has adequate expertise in the medical markets that we intend to target.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- the inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future product that we may develop;

- the lack of complementary treatments to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability to us from these revenue streams is likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and therefore may be small.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy, immunotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We may initially seek approval of SON-080 and any other product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including use as first- or second-line therapy.

Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.

Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include, among others, prohibitions on the promotion of an approved product for uses not included in the product's approved labeling, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, and Good Clinical Practice, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- untitled and warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapeutics that will compete, if approved, with other products and therapies that currently exist, are being developed or will in the future be developed, some of which we may not currently be aware.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, 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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

There is a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, such as traditional chemotherapy, as well as novel immunotherapies. For example, a number of multinational companies as well as large biotechnology companies, including Astellas Pharma Inc., Seattle Genetics, Inc., AstraZeneca, and GlaxoSmithKline plc, are developing programs for the targets that we are exploring for our pipeline programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidate we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

Smaller and other early stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. 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 product candidates obsolete, less competitive or not economical.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, payors and others in the medical community.

We have never commercialized a product, and even if we obtain any regulatory approval for our product candidates, the commercial success of our product candidates will depend in part on the medical community, patients, and payors accepting our product candidates as effective, safe and cost-effective. Any product that we bring to the market may not gain market acceptance by physicians, patients, payors and others in the medical community. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

The degree of market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the frequency and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the frequency and severity of any side effects resulting from follow-up requirements for the administration of our product candidates;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and adequate reimbursement.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product, if approved for commercial sale, will not be known until after it is launched. Our efforts to educate the medical community and payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors, particularly due to the novelty of our *Sonnet* approach. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable.

If the market opportunities for our product candidates are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer.

We currently focus our research and product development on treatments for oncology indications and our product FHAB candidates are designed to target solid tumors. Our understanding of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. Patient identification efforts also influence the ability to address a patient population. If efforts in patient identification are unsuccessful or less impactful than anticipated, we may not address the entirety of the opportunity we are seeking.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

We expect the cost of our product candidates to be substantial, when and if they achieve market approval. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by private payors, such as private health coverage insurers, health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health care programs, such as Medicare and Medicaid. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize our product candidates, even if approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as the CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for novel products such as ours, as there is no body of established practices and precedents for these new products. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: (1) a covered benefit under its health plan; (2) safe, effective and medically necessary; (3) appropriate for the specific patient; (4) cost-effective; and (5) neither experimental nor investigational. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, or medicinal products, as they are commonly referred to in the European Union. These countries have broad discretion in setting prices and we cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Additionally, some countries require approval of the sale price of a product before it can be lawfully marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we, or any collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, efforts by governments and payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate reimbursement for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our product candidates that receive marketing approval, or such authorities do not grant such products appropriate periods of data exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.

In the United States, manufacturers may seek approval of biosimilar versions of biologics approved by the FDA under a BLA through submission of abbreviated biologic license applications, or ABLAs. In support of an ABLA, a biosimilar manufacturer generally must show that its product is similar to the original biologic product. Biosimilar products may be less costly to bring to market than the original biologic and companies that produce biosimilar products are sometimes able to offer them at lower prices. Thus, following the introduction of a biosimilar product, a significant percentage of the sales of the original biologic may be lost to the biosimilar product, and the price of the original biologic product may be lowered.

The FDA may not accept for review or approve an ABLA for a biosimilar product until any applicable period of non-patent exclusivity for the original biologic has expired. The Public Health Service (PHS) Act provides a period of twelve years of non-patent exclusivity for a biologic approved under a BLA.

Competition that our products may face from biosimilar versions of our products could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, or Anti-Kickback Statute, the federal civil and criminal False Claims Act and Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to:

- the Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. "Remuneration" has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA, or federal civil money penalties. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which impose criminal and civil penalties against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the beneficiary inducement provisions of the CMP Law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective business associates, individuals and entities that perform services on their behalf that involve the use or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the U.S. federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payer. Many U.S. states have adopted laws similar to the Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Healthcare legislative reform measures and constraints on national budget social security systems may have a material adverse effect on our business and results of operations.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in the United States, the ACA was enacted in 2010 which, among other things, subjects biologic products to potential competition by lower-cost biosimilars; addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extends the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjects manufacturers to new annual fees and taxes for certain branded prescription drugs; and provides incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current administration to repeal or replace certain aspects of the ACA. Further, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. In addition, CMS recently issued a final rule that will give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Concurrently, Congress has considered legislation that would repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, 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." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device exercise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress also could consider additional legislation to repeal or replace other elements of the ACA. Thus, the full impact of the ACA, any law repealing or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.5 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and due to subsequent legislative amendments, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the current administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. For example, in November 2018, CMS issued a proposed rule for comment that would, among other things, provide Medicare prescription drug plans under Part D more transparency in pricing and greater flexibility to negotiate discounts for, and in certain circumstances exclude, drugs in the six "protected" formulary classes and allow Medicare Advantage plans to use certain drug management tools such as step therapy for physician-administered drugs. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of these governments and other payors to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

We are subject to the the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the FCPA, the U.S. domestic bribery statute contained in 18 §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our International Operations

As one of our subsidiaries, Relief, is based outside of the United States, we are subject to economic, political, regulatory and other risks associated with international operations.

As Relief is based in the Switzerland, our business is subject to risks associated with conducting business outside of the United States. Many of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the pound sterling, U.S. dollar, euro and currency controls;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our share option schemes or equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal health data in the European Union is was governed by the provisions of the Data Protection Directive, and which, as of May 25, 2018, has been superseded by the GDPR. These directives impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any potential clinical trial activities in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or € 20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the pound sterling and the U.S. dollar, may adversely affect us. Although we are based in the United Kingdom, we source research and development, manufacturing, consulting and other services from the United States and the European Union. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the euro, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Risks Related to Our Dependence on Third Parties

For certain product candidates, we may depend on development and commercialization collaborators to develop and conduct clinical trials with, obtain regulatory approvals for, and if approved, market and sell product candidates. If such collaborators fail to perform as expected, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be harmed.

For certain products candidates, we depend, or will depend, on our development and commercial collaborators to develop, conduct clinical trials of, and, if approved, commercialize product candidates.

Our current collaborations and any future collaborations that we enter into are subject to numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to the collaborations;
- collaborators may not perform their obligations as expected or fail to fulfill their responsibilities in a timely manner, or at all;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay preclinical studies or clinical trials, provide insufficient funding for clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our shareholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- The collaborations may not result in product candidates to develop and/or preclinical studies or clinical trials conducted as part of the collaborations may not be successful;
- product candidates developed with collaborators may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to stop commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; and
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation.

In addition, certain collaboration and commercialization agreements provide our collaborators with rights to terminate such agreements, which rights may or may not be subject to conditions, and which rights, if exercised, would adversely affect our product development efforts and could make it difficult for us to attract new collaborators. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidates or products; we would likely be required to seek additional financing to fund further development or identify alternative strategic collaborations; our potential to generate future revenue from royalties and milestone payments from such product candidates or products would be significantly reduced, delayed or eliminated; and it could have an adverse effect on our business and future growth prospects. Our rights to recover tangible and intangible assets and intellectual property rights needed to advance a product candidate or product after termination of a collaboration may be limited by contract, and we may not be able to advance a program post- termination.

If conflicts arise with our development and commercialization collaborators or licensors, they may act in their own self-interest, which may be adverse to the interests of our company.

We may in the future experience disagreements with our development and commercialization collaborators or licensors. Conflicts may arise in our collaboration and license arrangements with third parties due to one or more of the following:

- disputes with respect to milestone, royalty and other payments that are believed due under the applicable agreements;
- disagreements with respect to the ownership of intellectual property rights or scope of licenses;
- disagreements with respect to the scope of any reporting obligations;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities; and
- disputes with respect to a collaborator's or our development or commercialization efforts with respect to our products and product candidates.

Conflicts with our development and commercialization collaborators or licensors could materially adversely affect our business, financial condition or results of operations and future growth prospects.

We will rely on third parties, including independent clinical investigators and CROs, to conduct and sponsor some of the clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.

We will be relying upon and plan to continue to rely upon third parties, including independent clinical investigators, academic partners, regulatory affairs consultants and third-party CROs, to conduct our preclinical studies and clinical trials, including in some instances sponsoring such clinical trials, and to engage with regulatory authorities and monitor and manage data for our ongoing preclinical and clinical programs. Given the breadth of clinical therapeutic areas for which we believe our product candidates may have utility, we intend to continue to rely on external service providers rather than build internal regulatory expertise.

Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

We remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our academic partners or CROs or if we or any of our academic partners or CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us, our academic partners or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable CGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, with respect to investigator-sponsored trials that may be conducted, we would not control the design or conduct of these trials, and it is possible that the FDA or EMA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator- sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Additionally, the FDA or EMA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

We intend to rely on third parties to manufacture product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third- party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our product candidates may shorten the expiry of our product candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of our product candidates as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our product candidates. Even after a third-party manufacturer has gained significant experience in manufacturing our product candidates or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of our product candidates in a timely manner or continuously over time, or at all.

We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used.

We operate an outsourced model for the manufacture of our product candidates, and contract with good manufacturing practice, or GMP, licensed pharmaceutical contract development and manufacturing organizations. While we have engaged several third-party vendors to provide clinical and non-clinical supplies and fill-finish services, we do not currently have any agreements with third-party manufacturers for long-term commercial supplies. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third- party manufacturers entails risks, including:

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. In addition, some of the product candidates we intend to develop, including SON-080, use toxins or other substances that can be produced only in specialized facilities with specific authorizations and permits, and there can be no guarantee that we or our manufacturers can maintain such authorizations and permits. These specialized requirements may also limit the number of potential manufacturers that we can engage to produce our product candidates, and impair any efforts to transition to replacement manufacturers.

Our future product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our products and product candidates, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our technology and manufacturing processes. We rely on research, manufacturing and other know-how, patents, trade secrets, license agreements and contractual provisions to establish our intellectual property rights and protect our products and product candidates. These legal means, however, afford only limited protection and may not adequately protect our rights. As of May 18, 2020, our intellectual property portfolio includes six patent applications.

In certain situations and as considered appropriate, we have sought, and we intend to continue to seek to protect our proprietary position by filing patent applications in the United States and, in at least some cases, one or more countries outside the United States relating to current and future products and product candidates that are important to our business. However, we cannot predict whether the patent applications currently being pursued will issue as patents, or whether the claims of any resulting patents will provide us with a competitive advantage or whether we will be able to successfully pursue patent applications in the future relating to our current or future products and product candidates. Moreover, the patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to seek additional patent protection. It is possible that defects of form in the preparation or filing of patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents.

Even if they are unchallenged, our patents and patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected.

As discussed in “Business of Sonnet,” Sonnet’s WO/2018/151868 patent application was not timely filed in the PCT receiving office due to a computer issue at the filing office. Despite the restoration of priority by the PCT as “unintentional”, some countries in which this application was foreign filed did not accept this restoration. Canada and China do not allow for such priority restoration. Brazil, Europe, India and Japan allow priority restoration under a more rigorous “due care” standard, and such restoration procedures are pending in these jurisdictions. However, if priority is not restored, these patent applications will face both Sonnet’s own publications as well as any additional prior art published by third parties in the year preceding the PCT filing. This could affect the scope or breadth of the patent claims we are pursuing in these specific jurisdictions, or could result in no ability to receive patents in these countries.

Other parties, many of whom have substantially greater resources and have made significant investments in competing technologies, have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same compositions, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, any patents we may obtain in the future may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our products and product candidates.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

In the future, one or more of our products and product candidates may be in-licensed from third parties. Accordingly, in some cases, the availability and scope of potential patent protection is limited based on prior decisions by our licensors or the inventors, such as decisions on when to file patent applications or whether to file patent applications at all. Our failure to obtain, maintain, enforce or defend such intellectual property rights, for any reason, could allow third parties, in particular, other established and better financed competitors having established development, manufacturing and distribution capabilities, to make competing products or impact our ability to develop, manufacture and market our products and product candidates, even if approved, on a commercially viable basis, if at all, which could have a material adverse effect on our business.

In addition to patent protection, we expect to rely heavily on trade secrets, know-how and other unpatented technology, which are difficult to protect. Although we seek such protection in part by entering into confidentiality agreements with our vendors, employees, consultants and others who may have access to proprietary information, we cannot be certain that these agreements will not be breached, adequate remedies for any breach would be available, or our trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or be independently developed by our competitors. If we are unsuccessful in protecting our intellectual property rights, sales of our products may suffer and our ability to generate revenue could be severely impacted.

Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in court or in administrative proceedings. We may not be able to protect our trade secrets in court.

If we initiate legal proceedings against a third-party to enforce a patent covering one of our products or product candidates, should such a patent issue, the defendant could counterclaim that the patent covering our product or product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions. An adverse determination in any of the foregoing proceedings could result in the revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our products and product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors and other third parties could purchase our products and product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

We may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we own or that we may own or license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignments may not be self-executing or may be breached. We could be subject to ownership disputes arising, for example, from conflicting obligations of employees, consultants or others who are involved in developing our products or product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we or fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required 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 applications. 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 and after a patent has issued. There are situations in which non- compliance 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. The terms of one or more licenses that we enter into the future may not provide us with the ability to maintain or prosecute patents in the portfolio, and must therefore rely on third parties to do so.

If we do not obtain patent term extension and data exclusivity for our products and product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the future, if we obtain an issued patent covering one of our present or future product candidates, depending upon the timing, duration and specifics of any FDA marketing approval of such product candidates, such patent may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. A patent may only be extended once and only based on a single approved product. However, we may not be granted an extension because of, for example, failure to obtain a granted patent before approval of a product candidate, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or otherwise our failure to satisfy applicable requirements. A patent licensed to us by a third party may not be available for patent term extension. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products and product candidates.

Changes in either the patent laws or the interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. When implemented, the Leahy-Smith Act included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy-Smith Act also included provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allowed third- party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. It remains unclear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We cannot assure you that our efforts to seek patent protection for one or more of our products and product candidates will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact courts' decisions in historical and future cases may have on the ability of life science companies to obtain or enforce patents relating to their products in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on our existing patent rights and our ability to protect and enforce our intellectual property in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending and enforcing patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. There can be no assurance that we will obtain or maintain patent rights in or outside the United States under any future license agreements. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Proceedings to enforce our patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. While we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, we and our collaborators or sublicensees may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all. We may also be required to indemnify our collaborators or sublicensees in such an event.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and 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 the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product.

However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees may be subject to proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In addition, our patents may become, involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time-consuming, and our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both.

In an infringement proceeding, a court may decide that a patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we fail to comply with our obligations under any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

In connection with our efforts to build our product candidate pipeline, we may enter into license agreements in the future. We expect that such license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or our licensors may convert the license to a non-exclusive license, which could negatively impact the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. 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 foreign 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 are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Employee Matters and Managing Growth

We only have a limited number of employees to manage and operate our business.

As of May 18, 2020, we had about seven full-time U.S. employees and two Swiss employees on contract. Additionally, we utilize independent contractors and other third parties to assist with various aspects of our business. Our focus on the development of our product candidates requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire or retain adequate staffing levels to develop our product candidates or run our operations or to accomplish all of the objectives that we otherwise would seek to accomplish.

Cyber-attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team and key employees, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with certain of our executive officers, any of them could leave our employment at any time. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical trials may make it more challenging to recruit and retain qualified personnel.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

The inability to recruit or the loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, and (4) laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, bribery and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or collaborator misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. While we have a code of conduct and business ethics, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug manufacturing, regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Moreover, our expected growth could require us to relocate to geographic areas beyond those where we have been historically located. For example, we maintain an office in Princeton, New Jersey, at which many of our finance, management and administrative personnel work. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Sonnet has material weaknesses in its internal control systems and will need to hire additional personnel and develop and maintain proper and effective internal control over financial reporting, or the accuracy and timeliness of its financial reporting will be adversely affected.

Our management is required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. We were informed by our independent registered public accounting firm that Sonnet Sub had a material weakness in its internal control over financial reporting as it did not maintain a sufficient complement of personnel commensurate with its accounting and reporting requirements. The material weakness had not been remediated as of September 30, 2019. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified relate to controls to address segregation of certain accounting duties, timely reconciliation and analysis of certain key accounts and the review of journal entries. Sonnet has concluded that these material weaknesses arose because, as a pre-revenue private company, Sonnet did not have the necessary business processes, systems, personnel and related internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

To address these material weaknesses, the Company intends to (a) hire additional accounting personnel with appropriate expertise in accounting and reporting under U.S. GAAP and SEC regulations and to be better aligned with segregation of duties, (b) institute quarterly meetings to identify significant infrequent and unusual transactions as well as ensure timely reporting (c) continue to engage an accounting advisory firm to assist with, among other areas, the analysis of complex, infrequent and unusual transactions and (d) initiate a preliminary assessment of management's internal controls over financial reporting in accordance with the 2013 integrated framework, as prescribed by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO.

Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting for so long as we remain a "smaller reporting company" as defined in applicable SEC regulations. Our management team is required to disclose changes made in our internal controls and procedures on a quarterly basis. To comply with the requirements of Sonnet Sub's financial statements becoming those of the Company now that the Merger has closed, we will need to undertake various actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Our audit committee must also be advised and regularly updated on management's review of internal controls. We are only now beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation of our internal control over financial reporting needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Related to Our Common Stock

The market price of our common stock may be significantly volatile.

The market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agencies;
- developments or disputes concerning a company's intellectual property rights;
- technological innovations of such companies or their competitors;
- changes in market valuations of similar companies;
- announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing a product.

The securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.

In the past, we have issued common stock, convertible securities (such as convertible notes) and warrants in order to raise capital. We have also issued common stock as compensation for services and incentive compensation for our employees, directors and certain vendors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our common stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our common stock), or could obligate us to issue additional shares of common stock to certain of our stockholders.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, stockholders who have been non-affiliates for the preceding three months may sell shares of our common stock freely after six months subject only to the current public information requirement. Affiliates may sell shares of our common stock after six months subject to the Rule 144 volume, manner of sale, current public information and notice requirements. Any substantial sales of our common stock pursuant to Rule 144 may have a material adverse effect on the market price of our common stock.

We do not expect to pay cash dividends in the foreseeable future and therefore investors should not anticipate cash dividends on their investment.

Our board of directors does not intend to pay cash dividends in the foreseeable future but instead intends to retain any and all earnings to finance the growth of the business. To date, we have not paid any cash dividends and there can be no assurance that cash dividends will ever be paid on our common stock.

We may issue additional shares of our common stock, which could depress the market price of our common stock and dilute your ownership.

Market sales of large amounts of our common stock, or the potential for those sales even if they do not actually occur, may have the effect of depressing the market price of our common stock. In addition, if our future financing needs require us to issue additional shares of common stock or securities convertible into common stock, the amount of common stock available for resale could be increased which could stimulate trading activity and cause the market price of our common stock to drop, even if our business is doing well. Furthermore, the issuance of any additional shares of our common stock, or securities convertible into our common stock could be substantially dilutive to holders of our common stock.

Anti-takeover provisions under Delaware law could make an acquisition of the combined company more difficult and may prevent attempts by the combined company stockholders to replace or remove the combined company management.

Because the combined company will be incorporated in Delaware, it is governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding combined company voting stock from merging or combining with the combined company. Although Chanticleer and Sonnet believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with the combined company's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the combined company's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Director and officer liability is limited.

As permitted by Delaware law, our bylaws limit the liability of our directors for monetary damages for breach of a director's fiduciary duty except for liability in certain instances. As a result of our bylaw provisions and Delaware law, stockholders may have limited rights to recover against directors for breach of fiduciary duty.

Forward-Looking Statements

This report, including Exhibits 99.1 and 99.2 furnished herewith, contains forward-looking statements within the meaning of the federal securities laws. Forward-looking statements typically are identified by use of terms such as "may," "will," "should," "plan," "expect," "anticipate," "estimate" and similar words, and the opposites of such words, although some forward-looking statements are expressed differently. Forward-looking statements involve known and unknown risks and uncertainties that exist in the Registrant's operations and business environment, which may be beyond the Registrant's control, and which may cause actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward- looking statements. For example, forward-looking statements include, without limitation: statements regarding the Registrant's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. The risks and uncertainties referred to above include, but are not limited to, risks detailed from time to time in the Registrant's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2019, Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, proxy statement/prospectus/information statement filed with the Securities and Exchange Commission on February 11, 2020 under Rule 424 of the Securities Act of 1933, as amended, and this report. These risks could cause actual results to differ materially from those expressed in any forward- looking statements made by, or on behalf of, the Registrant. Forward-looking statements represent the judgment of management of the Registrant regarding future events. Although the Registrant believes that the expectations reflected in such forward-looking statements are reasonable at the time that they are made, the Registrant can give no assurance that such expectations will prove to be correct. Unless otherwise required by applicable law, the Registrant assumes no obligation to update any forward-looking statements, and expressly disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(a) ***Financial Statements of Business Acquired***

Sonnet Sub's unaudited interim financial statements for the three and six months ended March 31, 2020, and the notes related thereto, filed herewith and attached hereto as Exhibit 99.2, are incorporated herein by reference.

Relief Therapeutics SA's unaudited interim financial statements for the three months ended March 31, 2020, and the notes related thereto, filed herewith and attached hereto as Exhibit 99.3, are incorporated herein by reference.

(b) ***Pro Forma Financial Information***

The Company's unaudited pro forma condensed consolidated financial statements for the three months ended March 31, 2020 and for the year ended December 31, 2019, and the notes related thereto, filed herewith and attached hereto as Exhibit 99.4, are incorporated herein by reference.

(d) Exhibits.

Exhibit No.	Exhibit
16.1	Letter from Cherry Bekaert LLP, dated May 18, 2020.
99.1	Press Release dated May 18, 2020
99.2	The unaudited interim financial statements of Sonnet Sub for the three and six months ended March 31, 2020, and the notes related thereto and accompanying Management's Discussion and Analysis of Financial Condition and Results of Operations.
99.3	Relief Therapeutics SA's unaudited interim financial statements for the three months ended March 31, 2020, and the notes related thereto.
99.4	Unaudited pro forma condensed consolidated financial statements of Sonnet BioTherapeutics Holdings, Inc,

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sonnet BioTherapeutics Holdings, Inc.
a Delaware corporation
(Registrant)

Date: May 18, 2020

By: */s/ Pankaj Mohan, Ph.D.*
Name: Pankaj Mohan, Ph.D.
Title: Chief Executive Officer

Exhibit 16.1

Cherry Bekaert LLP
CPAs & Advisors

May 18, 2020

United States Securities & Exchange Commission
Division of Corporate Finance
100 F Street, NE
Washington, D.C. 20549
Via email @ DCAOLetters@sec.gov

To Whom It May Concern:

We have read the following paragraphs of Item 4.01 included in the Form 8-K filed May 18, 2020 of Sonnet BioTherapeutics Holdings, Inc., and we are in agreement with the statements contained in these paragraphs related to our firm.

We have no basis to agree or disagree with other statements made under Item 4.01.

Very truly yours,

Cherry Bekaert LLP

CHERRY BEKAERT LLP

Exhibit 99.1

Sonnet BioTherapeutics Holdings Provides Business and Earnings Update

Company successfully completes merger with private Sonnet BioTherapeutics

Company Launches Initiative to Explore FHAB Technology in Antiviral Applications

PRINCETON, N.J., May 18, 2020 – Sonnet BioTherapeutics Holdings, Inc. (Nasdaq: SONN) ("Sonnet" or the "Company"), a biopharmaceutical company developing innovative targeted biologic drugs, announced today its financial results for the three and six months ended March 31, 2020 and provided updates on its internal product development pipeline. In addition to the Company's ongoing activities in immune oncology, a new initiative has been launched to evaluate the proprietary F_HAB technology for antiviral applications.

Pankaj Mohan, Ph.D., Founder and CEO commented, "We are excited to have successfully completed the merger transaction and look forward to progressing our operations as a public company. We will continue to advance our immune oncology pipeline alongside our newly announced initiative to explore applications in virology. We believe Sonnet maintains a promising technology platform capable of benefiting patients, as well as our new shareholders."

First Quarter and Recent Corporate Updates

Sonnet is pleased to provide the following updates on its pipeline assets:

SON-1010 (IL12-F_HAB)

IL-12 is a well-known immune stimulator that Sonnet believes carries potential therapeutic utility in immune oncology (IO) and other indications, including virology. The Sonnet F_HAB was designed to deliver low doses of conjugated drug candidates to target tissues such as solid tumors or the lymphatic system for oncology or virology indications, respectively.

John Cini, Sonnet co-founder and Chief Scientific Officer added, "Enhancing innate immunity is one of the keys to treating cancer, as well as viral infections. Our most advanced FHAB-derived compound, SON-1010, is being developed as an innate immunity enhancer, where it has shown significant tumor volume reduction in preclinical models. SON-1010 has been tested in cancerous mice and has shown to be over 30-fold more efficacious compared to wildtype IL-12, thus demonstrating the therapeutic potential of F_HAB-based cytokine delivery."

Sonnet has filed updated intellectual property that includes provisions for three areas of antiviral drug development: (i) as an adjuvant to potentiate vaccine efficacy; (ii) as a broad spectrum antiviral that could be deployed against a wide array of viruses, particularly those where Cytokine Release Syndrome (CRS) is not observed; and (iii) as a platform for configuring bispecific, multifunctional vaccines comprising the F_HAB construct conjugated with both a vaccine peptide and an immune stimulator (e.g., IL-12) that could enhance delivery to the lymphatic system.

Sonnet has successfully manufactured and initiated animal testing of SON-1010 for select virology applications. The Company has initiated work on preliminary viral challenge studies in mice using an H1N1 model with data expected during the second half of 2020. If successful, a mouse-adapted SARS-CoV-1 challenge model study will follow, which we expect would help the Company develop a clinical trial strategy using F_HAB in an adjuvant capacity, paired with a vaccine.

In IO, the Company has completed *in vitro* pharmacology studies of affinity and binding kinetics that demonstrate species cross-reactivity of SON-1010 in serum albumin for hamster, rat, dog, cynomolgus monkey and human. The results verified that SON-1010 displays species specificity to cynomolgus monkey and human subjects, which will guide species selection for further preclinical toxicology work. A humanized mouse model (SCID) study designed to evaluate PK/PD and dose response is underway. This work will inform our decision about dosing in a forthcoming nonhuman primate study, scheduled to commence following analysis of the SCID mouse data.

Work on the master cell bank expressing SON-1010, formulation development and process development activities have all been completed, in addition to drug product formulation (liquid and lyophilized). Process transfer and cGMP product manufacturing are scheduled for the second half of 2020, followed by an IND-enabling toxicology study in the first half of 2021. An IND submission is expected in the second half of 2021.

SON-080 (low dose IL-6)

Sonnet is currently requalifying the legacy clinical batch product and updating the safety package to comply with current regulatory requirements. The Company is undertaking the qualification and validation of the product prior to entering a preclinical toxicology study for further refining the dosing parameters for a Phase Ia/IIb trial in CIPN patients. Sonnet is designing this trial to leverage data from the prior studies conducted by Serono SA. Although the CIPN program continues to progress forward, the COVID-19 pandemic has impacted workflow at the Company's contract research partners such that the Company now estimate delays pushing a trial initiation into the first half of 2021 from late 2020. Additionally, the Company continues to explore business development opportunities for the Diabetic Peripheral Neuropathy (DPN) indication.

SON-1210 (IL12-F_HAB-IL15)

SON-1210 is a highly differentiated bispecific compound that has demonstrated significant reduction in tumor volume compared to concomitantly administered naked IL-12 and IL-15. Cell line development is underway and final clone selection is expected in 2020. Early development material will be used in a humanized mouse model (SCID) study designed to evaluate PK/PD and dose response. This work will inform our decision about dosing in a forthcoming nonhuman primate study, expected to be initiated by mid-2021. We will also explore potential antiviral applications for SON-1210.

SON-2014 (GMcSF-F_HAB-IL18)

Discrete GMcSF and IL-18 for preclinical studies have been manufactured and the Company is currently undertaking a proof-of-concept study in mice to evaluate the efficacy of the co-administered cytokines.

SON-3015 (anti-IL6-F_HAB-anti-TGFβ)

We expect to complete lead selection for this discovery-stage bispecific molecule around year-end 2020 followed by a preclinical proof-of-concept study in mice.

Merger Transaction

On April 1, 2020, the Company, formerly known as Chanticleer Holdings, Inc., completed its merger transaction with privately-held Sonnet BioTherapeutics, Inc. ("Sonnet Sub"), and on the same day spun-off its restaurant business through a dividend to its stockholders of the common stock of its newly-formed wholly-owned subsidiary, Amergent Hospitality Group, Inc. ("Amergent").

Fiscal 2020 Second Quarter Ended March 31, 2020 Financial Results

As previously reported, on April 1, 2020, the Company completed its merger transaction with Sonnet Sub, whereby Sonnet Sub became a wholly owned subsidiary of the Company, and the business of Sonnet Sub became that of the Company. On April 2, 2020, the Company's common stock began trading on The Nasdaq Capital Market under the symbol "SONN."

Since the merger transaction occurred subsequent to March 31, 2020, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the Securities and Exchange Commission on or about May 18, 2020 reflects the historical restaurant business of the Company, which was spun off in conjunction with and prior to the merger. As a result, the financial condition and results of operations of the Company for the periods presented in the 10-Q bear no relationship to the business, financial condition and results of operations of Sonnet Sub and are not indicative of the business, financial condition and results of operations of the Company for any future period. Sonnet Sub's historical financial statements, along with pro forma financial information which give effect to the spin off and the merger, can be found in the exhibits to the Company's Current Report on Form 8-K to be filed on or about May 18, 2020.

- As of March 31st, 2020, Sonnet had $272k cash on hand. As previously reported, on April 1st, in conjunction with the close of the merger, Sonnet announced the close of a $19M private placement to institutional investors, which complemented an existing $20M share subscription facility, access to which is subject to certain conditions. The Company has $20 million remaining in this facility.
- Research and development expenses for the six months ended March 31st, 2020, were $2.7M, compared to $0.2M for the same period in 2019. The increase was primarily driven by an increase in preclinical activities and a broadening of the company's F_HAB pipeline.
- General and administrative expenses increased to $2.3M for the six months ended March 31st, 2020 from $0.3M for the same period in 2019. The increase was primarily driven by activities relating to the merger into Chanticleer.
- On a pro forma basis, Sonnet ended the quarter with 9,180,001 shares of common stock outstanding.

About Sonnet BioTherapeutics Holdings, Inc.

Founded in 2011, Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of single or bispecific action. Known as FHAB™ (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. FHAB™ is the foundation of a modular, plug-and-play construct for potentiating a range of large molecule therapeutic classes, including cytokines, peptides, antibodies and vaccines.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential, "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Sonnet Biotherapeutics Investor Contact
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SOURCE: Sonnet BioTherapeutics Holdings, Inc.

Sonnet Biotherapeutics, Inc.
Balance Sheets
(unaudited)

	March 31, 2020	September 30, 2019
Assets		
Current assets:		
Cash	$ 272,855	$ 35,653
Prepaid expenses other current assets	19,484	4,101
Related-party receivable	214,142	—
Total current assets	506,481	39,754
Property and equipment	63,134	—
Operating lease right-of-use asset	243,733	—
Other assets	82,959	—
Total assets	$ 896,307	$ 39,754
Liabilities and stockholders' deficit		
Current liabilities:		
Related-party notes	$ 919	$ 217,380
Accounts payable	3,678,318	1,842,996
Accrued expenses	514,275	824,865
Operating lease liability	76,366	—
Total current liabilities	4,269,878	2,885,241
Operating lease liability	167,687	—
Total liabilities	4,437,565	2,885,241
Commitments and contingencies (note 7)		
Stockholders' deficit:		
Preferred stock; no par value: 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock; no par value: 100,000,000 shares authorized; 53,881,250 and 52,055,250 issued and outstanding at March 31, 2020 and September 30, 2019, respectively	13,864,685	9,594,655
Accumulated deficit	(17,405,943)	(12,440,142)
Total stockholders' deficit	(3,541,258)	(2,845,487)
Total liabilities and stockholders' deficit	$ 896,307	$ 39,754

Sonnet BioTherapeutics, Inc.
Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 1,302,515	$ 166,426	$ 2,710,663	$ 224,411
General and administrative	1,208,374	102,234	2,269,280	200,298
Loss from operations	(2,510,889)	(268,660)	(4,979,943)	(424,709)
Interest income (expense)	14,142	(15,020)	14,142	(151,018)
Net loss	$ (2,496,747)	$ (283,680)	$ (4,965,801)	$ (575,727)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.05)	$ (0.01)	$ (0.09)	$ (0.01)
Weighted average shares outstanding, basic and diluted	53,672,415	49,560,056	53,068,157	48,786,299

Exhibit 99.2

SONNET BIOTHERAPEUTICS, INC.

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Sonnet Biotherapeutics, Inc.
Balance Sheets
(unaudited)

	March 31, 2020	September 30, 2019
Assets		
Current assets:		
Cash	$ 272,855	$ 35,653
Prepaid expenses other current assets	19,484	4,101
Related-party receivable	214,142	—
Total current assets	506,481	39,754
Property and equipment	63,134	—
Operating lease right-of-use asset	243,733	—
Other assets	82,959	—
Total assets	$ 896,307	$ 39,754
Liabilities and stockholders' deficit		
Current liabilities:		
Related-party notes	$ 919	$ 217,380
Accounts payable	3,678,318	1,842,996
Accrued expenses	514,275	824,865
Operating lease liability	76,366	—
Total current liabilities	4,269,878	2,885,241
Operating lease liability	167,687	—
Total liabilities	4,437,565	2,885,241
Commitments and contingencies (note 7)		
Stockholders' deficit:		
Preferred stock; no par value: 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock; no par value: 100,000,000 shares authorized; 53,881,250 and 52,055,250 issued and outstanding at March 31, 2020 and September 30, 2019, respectively	13,864,685	9,594,655
Accumulated deficit	(17,405,943)	(12,440,142)
Total stockholders' deficit	(3,541,258)	(2,845,487)
Total liabilities and stockholders' deficit	$ 896,307	$ 39,754

See accompanying notes to unaudited interim financial statements.

Sonnet BioTherapeutics, Inc.
Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 1,302,515	$ 166,426	$ 2,710,663	$ 224,411
General and administrative	1,208,374	102,234	2,269,280	200,298
Loss from operations	(2,510,889)	(268,660)	(4,979,943)	(424,709)
Interest income (expense)	14,142	(15,020)	14,142	(151,018)
Net loss	$ (2,496,747)	$ (283,680)	$ (4,965,801)	$ (575,727)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.05)	$ (0.01)	$ (0.09)	$ (0.01)
Weighted average shares outstanding, basic and diluted	53,672,415	49,560,056	53,068,157	48,786,299

See accompanying notes to unaudited interim financial statements.

Sonnet BioTherapeutics, Inc.
Statements of Changes in Stockholders' Deficit
(unaudited)

	Common stock		Accumulated	
	Shares	Amount	deficit	Total
Balance at September 30, 2019	52,055,250	$ 9,594,655	$ (12,440,142)	$ (2,845,487)
Sale of common stock and warrants, net of issuance cost	1,204,000	2,715,030	—	2,715,030
Issuance of common stock to settle related-party notes	80,000	200,000	—	200,000
Net loss	—	—	(2,469,054)	(2,469,054)
Balance at December 31, 2019	53,339,250	$ 12,509,685	$ (14,909,196)	$ (2,399,511)
Sale of common stock and warrants, net of issuance cost	542,000	1,355,000	—	1,355,000
Net loss	—	—	(2,496,747)	(2,496,747)
Balance at March 31, 2020	53,881,250	$ 13,864,685	$ (17,405,943)	$ (3,541,258)

	Common stock		Accumulated	
	Shares	Amount	deficit	Total
Balance at September 30, 2018	47,104,500	$ 5,177,655	$ (7,568,931)	$ (2,391,276)
Sale of common stock, net of issuance cost	812,500	629,000	—	629,000
Conversion of convertible promissory notes into common stock	1,250,000	1,000,000	—	1,000,000
Issuance of common stock to settle related-party notes	275,000	220,000	—	220,000
Net loss	—	—	(292,047)	(292,047)
Balance at December 31, 2018	49,442,000	$ 7,026,655	$ (7,860,978)	$ (834,323)
Sale of common stock, net of issuance cost				
Net Loss	312,500	250,000	—	250,000
Net Loss	—	—	(283,680)	(283,680)
Balance at March 31, 2019	49,754,500	$ 7,276,655	$ (8,144,658)	(868,003)

See accompanying notes to unaudited interim financial statements.

Sonnet BioTherapeutics, Inc.
Statements of Cash Flows
(unaudited)

	Six Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (4,965,801)	$ (575,727)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,131	—
Amortization of right of use asset	12,205	—
Noncash interest	(14,142)	86,233
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(15,383)	—
Other assets	(82,959)	
Accounts payable	1,835,322	40,759
Accrued expenses	(310,590)	6,687
Operating lease liability	(11,885)	
Net cash used in operating activities	(3,551,102)	(442,048)
Cash flows from investing activities:		
Purchases of property and equipment	(65,265)	—
Net cash used in investing activities	(65,265)	—
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants, net of issuance costs	4,070,030	879,000
Related-party receivable	(200,000)	—
Proceeds received from related-party notes	30,000	86,000
Repayments of related-party notes	(46,461)	(520,554)
Net cash provided by financing activities	3,853,569	444,446
Net increase in cash	237,202	2,398
Cash, beginning of period	35,653	5,419
Cash, end of period	$ 272,855	$ 7,817
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible promissory note into common stock	$ —	$ 1,000,000
Issuance of common stock to settle related-party notes	$ 200,000	$ 220,000
Right of use asset and liability recorded upon adoption of ASC 842	$ 255,938	$ —

See accompanying notes to unaudited interim financial statements.

(1) Nature of Business and Liquidity

Sonnet BioTherapeutics, Inc. (the Company or Sonnet) was incorporated as a New Jersey corporation on April 6, 2015. The Company is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single- or bi-specific action. Known as F_HAB™ (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. The Company's pipeline of therapeutic compounds for oncology indications of high unmet medical need includes lead candidate, SON-080, a fully human version of low dose Interleukin-6 (IL-6) that has successfully completed Phase I clinical trials and will advance to a pilot efficacy study in patients with chemotherapy-induced peripheral neuropathy (CIPN) during 2020.

The Company has incurred recurring losses and negative cash flows from operations activities since inception and it expects to generate losses from operations for the foreseeable future primarily due to research and development costs for its potential product candidates. As of March 31, 2020, the Company had cash of $272,855 and stockholders' deficit of $3,541,258. The Company believes its cash at March 31, 2020 and approximately $8.3 million received in connection with the transaction discussed in Note 9 will fund the Company's projected operations through the end of the fiscal year ending September 30, 2020. Substantial additional financing will be needed by the Company to fund its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company will require additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources to carry out the Company's planned development activities. If additional capital is not secured when required, the Company may need to delay or curtail its operations until such funding is received. Various internal and external factors will affect whether and when the Company's product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company's products candidates, length of time and cost of developing and commercializing these product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations.

Operations since inception have consisted primarily of organizing the Company, securing financing, developing its technologies through performing research and development and conducting preclinical studies. The Company faces risks associated with companies whose products are in development. These risks include the need for additional financing to complete its research and development, achieving its research and development objectives, defending its intellectual property rights, recruiting and retaining skilled personnel, and dependence on key members of management.

(2) Summary of Significant Accounting Policies

(a) *Basis of presentation*

The accompanying unaudited interim financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information as found in the Accounting Standard Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"). In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2020, its results of operations and cash flows for the three and six months ended March 31, 2020 and 2019. The unaudited interim financial statements presented herein do not contain the required disclosures under GAAP for annual financial statements and should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended September 30, 2019.

(b) 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 expenses during the reporting period. Actual results could differ from those estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary.

(c) Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of the asset. Expenditures for repairs and maintenance that do not extend the estimated useful life or improve an asset are expensed as incurred. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts, and any resulting gain or loss is included in the statement of operations. As of March 31, 2020, the plant property and equipment balance was comprised of leasehold improvements and computer equipment associated with the Princeton office lease discussed in Note 8.

(d) Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company views and manages its business in one segment.

(e) Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The standard was effective for the Company beginning October 1, 2019. See Note 8 for further discussion of adoption of ASU 2016-02.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurements,*which changes the fair value measurement disclosure requirements of ASC 820. The goal of the ASU is to improve the effectiveness of ASC 820's disclosure requirements. The standard is applicable to public business entities for fiscal years beginning after December 15, 2019, and interim periods within those years. The Company is currently evaluating the potential impact of the adoption of this standard on its related disclosures.

(3) Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2020	September 30, 2019
Compensation and benefits	$ 48,395	$ 166,951
Professional fees	465,880	657,914
	$ 514,275	$ 824,865

(4) Debt

Related-party notes

During the six months ended March 31, 2020 and 2019, the Company issued unsecured notes payable to various related parties resulting in cash proceeds of $30,000 and $86,000, respectively. These notes are payable on demand and payments of $46,461 and $520,554 were made during the six months ended March 31, 2020 and 2019, respectively. The interest on these notes was de minimis during each of those periods.

In October 2019 and December 2018, the Company issued 80,000 and 275,000 shares of common stock to settle $200,000 and $220,000 of related-party notes, respectively.

The total amount of related-party notes outstanding was $919 and $217,380 at March 31, 2020 and September 30, 2019, respectively.

(5) Stockholders' Deficit

Common stock

During the six months ended March 31, 2020, the Company sold 1,746 equity units to investors for net proceeds of $4,070,030. Each unit was comprised of 100 shares of common stock and 50 warrants to purchase shares of the Company's common stock with an exercise price of $3.125. As of March 31, 2020, the Company had 993,000 warrants outstanding which expire three years from the date of their issuance and each warrant has an exercise price of $3.125.

During the six months ended March 31, 2019, the Company sold 1,437,500 shares of common stock to investors for net proceeds of $879,000.

(6) Related-Party Transactions

During the six months ended March 31, 2020 and 2019, the Company entered into various debt agreements with several officers of the Company. The terms of the debt and related components are further described in more detail in Note 4.

On January 21, 2019, the Company provided Chanticleer Holdings, Inc. ("Chanticleer") $200,000 in connection with the issuance of a promissory note for $210,000 issued at a discount of $10,000. The note accrued interest at 10% per year. The note was settled on April 1, 2020, in connection with the merger with Chanticleer as discussed in Note 9.

(7) Commitments and Contingencies

(a) Legal Proceedings

From time to time, the Company is a party to various lawsuits, claims, and other legal proceedings that arise in the ordinary course of its business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company's financial position, results of operations, or cash flows.

(b) Employment Agreements

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the contract. In addition, in the event of termination of employment following a change in control, as defined, either by the Company without cause or by the employee for good reason, any unvested portion of the employee's initial stock option grant becomes immediately vested. Through March 31, 2020 no stock options have been granted.

(8) Leases

The Company adopted ASC 842 – *Leases* on October 1, 2019. Through September 30, 2019, the Company only leased office space under various operating leases with terms of one year or less. These leases qualified as short-term leases, and as such, there was no cumulative impact from the adoption of ASC 842.

In December 2019, the Company entered a 36-month lease for office space in Princeton, New Jersey, which commenced February 1, 2020. At that time, the Company terminated its existing month-to-month leases for office space.

The components of lease expense for the six months ended March 31, 2020 are as follows:

Lease expense:		
Operating lease expense	$	17,027
Short-term lease expense		49,395
Total lease cost	$	66,422

The weighted-average remaining lease term was 2.8 years and the weighted average discount rate was 12%

Cash flow information related to operating leases for the six months ended March 31, 2020:

Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	16,708

Future minimum lease payments under non-cancellable leases at March 31, 2020 are as follows:

Fiscal year		
2020 (excluding the six months ended March 31, 2020)	$	75,188
2021		101,991
2022		103,924
2023		8,674
Total undiscounted lease payments		289,777
Less: imputed interest		(45,724)
Total lease liabilities	$	244,053

(9) Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through May 18, 2020, the date at which the interim financial statements were available to be issued, and there are no other items requiring disclosure except for the following:

Relief Therapeutics SA

In August 2019, the Company executed a Share Exchange Agreement with Relief Therapeutics SA ("Relief"), in which the Company agreed to acquire the outstanding shares of Relief by issuing 7,111,947 shares of the Company's common stock. The Company will assume the development of Relief's asset, atexakin alfa, together with its proprietary experimental drugs. The acquisition of Relief closed on April 1, 2020.

Merger with Sonnet BioTherapeutics Holdings, Inc

On October 10, 2019, Sonnet BioTherapeutics Holdings, Inc. (formerly known as Chanticleer) ("Sonnet Holdings"), its wholly owned subsidiary, Biosub Inc., and the Company entered into a Merger Agreement, as amended on February 7, 2020, pursuant to which Biosub Inc. will merge with and into the Company, with the Company continuing as a wholly-owned subsidiary of Sonnet Holdings and the surviving corporation of the merger. The merger closed on April 1, 2020.

In connection with the transactions contemplated by the merger, on February 7, 2020, the Company and Sonnet Holdings entered into a securities purchase agreement with certain accredited investors (the "Investors") pursuant to which, among other things, the Company agreed to issue to the Investors shares of the Company's common stock immediately prior to the merger and Sonnet Holdings agreed to issue to the Investors warrants to purchase shares of Sonnet Holdings common stock on the tenth trading day following the consummation of the merger in a private placement transaction for an aggregate purchase price of approximately $19.0 million (which amount is comprised of (x) a $4.0 million credit to Chardan Capital Markets, LLC ("Chardan"), in lieu of certain transaction fees otherwise owed to Chardan by the Company, and (y) $15.0 million in cash from the other Investors). From the $15.0 million of cash received, $5.8 million was paid to Sonnet Holdings at the time of close and approximately $0.9 million of transaction costs were paid, resulting in net cash proceeds to the Company of $8.3 million.

The Company entered into a common stock purchase agreement with GEM Global Yield Fund LLC SCS ("GEM") on August 6, 2019, as amended on September 25, 2019 and January 31, 2020, (the "GEM Agreement"). Pursuant to the GEM Agreement, GEM agreed to purchase up to $20.0 million ("Aggregate Limit") of the Company's common stock over a three-year period commencing on the date the original agreement was executed; provided that during any period when the Company's public float is less than $75.0 million, the Aggregate Limit will instead be equal to one-third of the amount of the Company's public float over any consecutive 12-month period. No common stock has been issued to date under the GEM Agreement.

Coronavirus Pandemic

On March 10, 2020, the World Health Organization characterized the novel COVID-19 virus as a global pandemic. There is significant uncertainty as to the likely effects of this disease which may, among other things, materially impact the Company's planned clinical trials. This pandemic or outbreak could result in difficulty securing clinical trial site locations, CROs, and/or trial monitors and other critical vendors and consultants supporting the trial. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the Company's ability to enroll patients. These situations, or others associated with Covid-19, could cause delays in the Company's clinical trial plans and could increase expected costs, all of which could have a material adverse effect on the Company's business and its financial condition. At the current time, the Company is unable to quantify the potential effects of this pandemic on its future operations.

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

Overview

Sonnet BioTherapeutics, Inc. ("Sonnet" or the "Company") is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single- or bi-specific action. Known as F_HAB™ (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues.

Since Sonnet's inception in 2015, Sonnet has devoted substantially all of its efforts and financial resources to organizing and staffing the company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights and conducting discovery, research and development activities for its product candidates. Sonnet does not have any products approved for sale and has not generated any revenue from product sales. Sonnet has funded its operations to date primarily with proceeds from sales of common stock, warrants and proceeds from the issuance of convertible debt. Through March 31, 2020, Sonnet had received net proceeds of $13.2 million from sales of its common stock, warrants and convertible promissory notes.

Sonnet has incurred recurring operating losses and negative cash flows since inception. Sonnet's ability to generate product or licensing revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of Sonnet's current or future product candidates. Sonnet's net losses were $5.0 million for the six months ended March 31, 2020. As of March 31, 2020, Sonnet had stockholder's deficit of $3.5 million. Sonnet expects to continue to incur significant expenses and increasing operating losses for at least the next several years. Sonnet expects that its expenses and capital requirements will increase substantially in connection with its ongoing activities, particularly if and as Sonnet:

- conducts additional clinical trials for its product candidates;
- continues to discover and develop additional product candidates;
- acquires or in-licenses other product candidates and technologies;
- maintains, expands and protects its intellectual property portfolio;
- hires additional clinical, scientific and commercial personnel;
- establishes a commercial manufacturing source and secures supply chain capacity sufficient to provide commercial quantities of any product candidates for which it may obtain regulatory approval;
- seeks regulatory approvals for any product candidates that successfully complete clinical trials;
- establishes a sales, marketing and distribution infrastructure to commercialize any products for which it may obtain regulatory approval; and
- adds operational, financial and management information systems and personnel, including personnel to support its product development and planned future commercialization efforts, as well as to support its transition to a public reporting company.

Sonnet will not generate revenue from product sales, if any, unless and until Sonnet receives licensing revenue and/or successfully completes clinical development and obtains regulatory approval for its product candidates. If Sonnet obtains regulatory approval for any of its product candidates and does not enter into a commercialization partnership, Sonnet expects to incur significant expenses related to developing Sonnet's internal commercialization capability to support product sales, marketing and distribution. As a result of the Merger, as described below, Sonnet will incur additional costs associated with operating as a public company.

As a result, Sonnet will need substantial additional funding to support its continuing operations and pursue its growth strategy. Until such time as Sonnet can generate significant revenue from product sales, if ever, Sonnet expects to finance its operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. Sonnet may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If Sonnet fails to raise capital or enter into such agreements as and when needed, Sonnet may have to significantly delay, reduce or eliminate the development and commercialization of one or more of its product candidates or delay its pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, Sonnet is unable to predict the timing or amount of increased expenses or when or if it will be able to achieve or maintain profitability. Even if Sonnet is able to generate product sales, Sonnet may not become profitable. If Sonnet fails to become profitable or is unable to sustain profitability on a continuing basis, then Sonnet may be unable to continue its operations at planned levels and be forced to reduce or terminate its operations.

Merger with Sonnet Holdings and Acquisition of Relief

On October 10, 2019, Sonnet BioTherapeutics Holdings, Inc. (formerly known as Chanticleer) ("Sonnet Holdings"), its wholly owned subsidiary, Biosub Inc., and the Company entered into a Merger Agreement, as amended on February 7, 2020, pursuant to which Biosub Inc. will merge with and into the Company, with the Company continuing as a wholly-owned subsidiary of Sonnet Holdings and the surviving corporation of the merger (the "Merger"). The Merger closed on April 1, 2020.

The business combination will be accounted for as a reverse merger in accordance with U.S. generally accepted accounting principles ("GAAP"). Under GAAP, Sonnet is the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectations that, immediately following the Merger: (1) Sonnet stockholders own a substantial majority of the voting rights of the combined company; (2) Sonnet has designated all of the initial members of the board of directors of the combined company; and (3) Sonnet's senior management hold all key positions in senior management of the combined organization. Accordingly, for accounting purposes, the business combination will be treated as the equivalent of Sonnet issuing common stock to acquire the net assets of Sonnet Holdings. As a result of the Merger, the net assets of Sonnet Holdings will be recorded at their acquisition-date fair values in the financial statements of Sonnet and the reported operating results prior to the business combination will be those of Sonnet.

On August 9, 2019, Sonnet executed a Share Exchange Agreement with Relief Therapeutics Holding SA ("Relief Holding"), in which Sonnet agreed to acquire the outstanding shares of Relief Therapeutics SA ("Relief") by issuing 7,111,947 shares of Sonnet common stock to Relief Holding. The Share Exchange Agreement with Relief will be accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired is concentrated Relief's atexakin alfa asset. The closing occurred immediately prior to the Merger on April 1, 2020.

Pre-Merger Financing

On February 7, 2020, Sonnet Holdings and Sonnet entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain accredited investors (the "Investors") pursuant to which, among other things, Sonnet agreed to issue to the Investors shares of Sonnet's common stock immediately prior to the Merger and Sonnet Holdings agreed to issue to the Investors warrants to purchase shares of Sonnet Holdings' common stock on the tenth trading day following the consummation of the Merger in a private placement transaction for an aggregate purchase price of approximately $19.0 million, which is comprised of a $4.0 million credit to Chardan Capital Markets, LLC ("Chardan") in lieu of certain transaction fees otherwise owed to Chardan, and $15.0 million in cash from the other Investors (the "Pre-Merger Financing"). From the $15.0 million cash received, $5.8 million was paid to Sonnet Holdings at the closing of the Merger for use by its spinoff entity and approximately $0.9 million of transaction costs were paid, resulting in net cash proceeds to Sonnet of $8.3 million.

The Merger and the transactions related thereto were consummated on April 1, 2020, including the Pre-Merger Financing. Sonnet expects that proceeds from the Merger and Pre-Merger Financing and its existing cash will be sufficient to fund its operating expenses and capital expenditure requirements through the end of the fiscal year ending September 30, 2020. Sonnet has based this estimate on assumptions that may prove to be wrong, and Sonnet could exhaust its available capital resources sooner than it expects. See "*-Liquidity and Capital Resources.*" Beyond that point, Sonnet will need to raise additional capital to finance its operations, which cannot be assured.

GEM

Sonnet entered into a Common Stock Purchase Agreement with GEM Global Yield Fund LLC SCS ("GEM") on August 6, 2019 (the "Purchase Agreement"). The GEM Agreement was further amended on September 25, 2019 by an Amendment to Common Stock Purchase Agreement (the "2019 GEM Amendment"), and subsequently amended again on January 31, 2020 (the "2020 GEM Amendment" and, together with the Purchase Agreement and the 2019 GEM Amendment, the "GEM Agreement"). The rights and obligations under the GEM Agreement were assigned to Sonnet Holdings prior to the effective time of the Merger, and Sonnet Holdings assumed all obligations thereunder. Pursuant to the GEM Agreement, GEM agreed to purchase up to $20,000,000 of Sonnet's common stock (the "Aggregate Limit") over a three-year period commencing on the date the Purchase Agreement was executed (the "Investment Period"); provided that during any period when Sonnet's public float is less than $75,000,000, the Aggregate Limit will instead be equal to one-third of the amount of Sonnet's public float over any consecutive 12-month period. Under the GEM Agreement, during the Investment Period, Sonnet may, by delivering a Draw Down Notice (as defined in the Purchase Agreement") direct GEM to purchase shares of Sonnet common stock in an amount up to 400% of the average daily trading volume for the ten (10) trading days immediately preceding the date the Draw Down Notice is delivered. GEM is not obligated to purchase any shares of Sonnet common stock which would result in GEM beneficially owning, directly or indirectly, at the time of the proposed issuance, more than 4.99% of the number of common shares issued and outstanding of Sonnet. GEM will pay a purchase price per share equal to 90% of the average market closing price of the common stock during the ten consecutive trading days commencing with the first trading day on which a Draw Down Notice is delivered (the "Draw Down Pricing Period").

GEM represented to Sonnet, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act), and Sonnet will rely upon an exemption from registration contained in Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder when issuing shares of its common stock under the GEM Agreement. Sonnet has agreed to file a Registration Statement with the SEC to register the shares of common stock to be issued to GEM pursuant to the GEM Agreement. The GEM Agreement contains customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. Sonnet has the right to terminate the GEM Agreement at any time, at no cost or penalty. Unless Sonnet informs GEM of an event resulting in a Materially Adverse Effect or Material Change in Ownership (all defined in the GEM Agreement) GEM does not have the right to terminate the GEM Agreement. No sales under the GEM Agreement have been made to date.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of Sonnet's product candidates. Sonnet expenses research and development costs as incurred and such costs include:

- employee-related expenses, including salaries and related benefits, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of Sonnet's product candidates, including under agreements with third parties, such as consultants and clinical research organizations;
- the cost of manufacturing drug products for use in Sonnet's preclinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance;
- costs related to compliance with regulatory requirements; and
- payments made under third-party licensing agreements.

Sonnet recognizes external development costs based on an evaluation of the progress to completion of specific tasks using information provided to Sonnet by its service providers. This process involves reviewing open contracts and purchase orders, communicating with its personnel to identify services that have been performed on its behalf, and estimating the level of service performed and the associated cost incurred for the service when Sonnet has not yet been invoiced or otherwise notified of actual costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense when the goods have been delivered or the services have been performed.

Sonnet's direct research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with its preclinical development, process development, manufacturing and clinical development activities. Sonnet's direct research and development expenses also include fees incurred under third-party license agreements. Sonnet does not allocate employee costs and costs associated with its discovery efforts, laboratory supplies and facilities, including depreciation or other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. Sonnet uses internal resources primarily to conduct its research and discovery as well as for managing its preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, Sonnet does not track its costs by product candidate.

Sonnet expects its research and development expense will increase for the foreseeable future as it expects to advance development of its product candidates. The successful development of Sonnet's product candidates is highly uncertain. At this time, Sonnet cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of its current pipeline or any future product candidates Sonnet may develop due to the numerous risks and uncertainties associated with clinical development, including risk and uncertainties related to:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs that Sonnet decides to pursue;
- Sonnet's ability to maintain its current research and development programs and to establish new ones;
- establishing an appropriate safety profile with investigational new drug-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- Sonnet's ability to establish new licensing or collaboration arrangements;
- establishing agreements with third-party manufacturers for clinical supply for Sonnet's clinical trials and commercial manufacturing, if any of Sonnet's product candidates is approved;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in Sonnet's clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of Sonnet's product candidates, if approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.
- The potential impact of COVID-19 on operations which may affect among other things, the timing of clinical trials, availability of raw materials, and the ability to access and secure testing facilities.

A change in the outcome of any of these variables with respect to the development of Sonnet's product candidates could significantly change the costs and timing associated with the development of that product candidate. Sonnet may never succeed in obtaining regulatory approval for any of its product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting, and audit services.

Sonnet's general and administrative expenses will increase in the future as it increases its headcount to support its continued research activities and development of its product candidates. Sonnet will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Interest Income (Expense)

Interest expense consists of amounts amortized, accrued and paid under Sonnet's notes payable.

Interest income consists of amounts earned on a note receivable from Sonnet Holdings.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

The following table summarizes Sonnet's results of operations for the three months ended March 31, 2020 and 2019:

	Three months ended March 31,		
	2020	**2019**	**Change**
Operating expenses:			
Research and development	$ 1,302,515	$ 166,426	$ 1,136,089
General and administration	1,208,374	102,234	1,106,140
Loss from operations	(2,510,889)	(268,660)	(2,242,229)
Interest income (expense)	14,142	(15,020)	29,162
Net loss	$ (2,496,747)	$ (283,680)	$ (2.213,067)

Research and Development Expenses

Research and development expenses were $1.3 million for the three months ended March 31, 2020, compared to $0.2 million for the three months ended March 31, 2019. The increase of $1.1 million was primarily due to the development of the cell line for IL12-ABD and IL12-ABD-IL15 manufacturing.

General and Administrative Expenses

General and administrative expenses were $1.2 million for the three months ended March 31, 2020, compared to $0.1 million for the three months ended March 31, 2019. The increase of $1.1 million was primarily due to a $0.3 million increase in personnel-related expenses and $0.7 million increase in professional fees. Personnel-related costs increased as Sonnet hired a full time CEO and CFO starting in January and May 2019, respectively. Professional fees increased due to higher legal costs and other costs incurred in connection with the Merger, the financing and the transactions related thereto and costs associated with Sonnet's ongoing business operations.

Interest Income (Expense)

Sonnet earned interest income of $14,142 during the three months ended March 31, 2020 on a receivable due from Sonnet Holdings compared to $15,020 of interest expense for the three months ended March 31, 2019 on interest-bearing debt.

Results of Operations

Comparison of the Six Months Ended March 31, 2020 and 2019

The following table summarizes Sonnet's results of operations for the six months ended December 31, 2019 and 2018:

	Six months ended March 31,		
	2020	**2019**	**Change**
Operating expenses:			
Research and development	$ 2,710,663	$ 224,411	$ 2,486,252
General and administration	2,269,280	200,298	2,068,982
Loss from operations	(4,979,943)	(424,709)	(4,555,234)
Interest income (expense)	14,142	(151,018)	165,160
Net loss	$ (4,965,801)	$ (575,727)	$ (4,390,074)

Research and Development Expenses

Research and development expenses were $2.7 million for the six months ended March 31, 2020, compared to $0.2 million for the six months ended March 31, 2019. The increase of $2.5 million was primarily due to the development of the cell line for IL12-ABD and IL12-ABD-IL15 manufacturing.

General and Administrative Expenses

General and administrative expenses were $2.3 million for the six months ended March 31, 2020, compared to $0.2 million for the six months ended March 31, 2019. The increase of $2.1 million was primarily due to a $0.6 million increase in personnel-related expenses, $1.3 million increase in professional fees, $0.1 million increase in rent and facility related expenses and a $0.1 million increase in travel expenses. Personnel-related costs increased as Sonnet hired a full time CEO and CFO starting in calendar 2019. Professional fees increased due to higher legal costs and other costs incurred in connection with the Merger, the financing and the transactions related thereto and costs associated with Sonnet's ongoing business operations.

Interest Income (Expense)

Sonnet earned interest income of $14,142 during the six months ended March 31, 2020 on a receivable due from Sonnet Holdings compared to $151,018 of interest expense for the six months ended March 31, 2019 on interest-bearing debt.

Liquidity and Capital Resources

Since its inception, Sonnet has not generated any revenue from any sources, including from product sales, and has incurred recurring losses and negative cash flows from its operations. Sonnet has funded its operations to date primarily with proceeds from sales of common stock, warrants and proceeds from the issuance of convertible debt. Through March 31, 2020, Sonnet had received net proceeds of $13.1 million from sales of its common stock, warrants and convertible promissory notes. The following table summarizes Sonnet's sources and uses of cash for each of the periods presented:

	Six Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (3,551,102)	$ (442,048)
Net cash used in investing activities	(65,265)	—
Net cash provided by financing activities	3,853,569	444,446
Net increase in cash	$ 237,202	$ 2,398

Operating Activities

During the six months ended March 31, 2020, Sonnet used $3.6 million of cash in operating activities. Cash used in operating activities reflected Sonnet's net loss of $5.0 million offset by a net change in operating assets and liabilities of $1.4 million. The net change in Sonnet's operating assets and liabilities was primarily attributable to an increase in accounts payable due to continued research and development efforts.

During the six months ended March 31, 2019, Sonnet used $0.4 million of cash in operating activities. Cash used in operating activities reflected Sonnet's net loss of $0.6 million offset by noncash interest of $0.1 million. The net change in Sonnet's operating assets and liabilities was insignificant.

Investing Activities

During the six months ended March 31, 2020, net cash used in investing activities was $65,265, consisting of purchases of office furniture and computer equipment.

Financing Activities

During the six months ended March 31, 2020, net cash provided by financing activities was $3.8 million, consisting primarily of $4.1 million of net proceeds from Sonnet's sale of common stock and warrants partially offset by a $0.2 million loan to Sonnet Holdings.

During the six months ended March 31, 2019, net cash provided by financing activities was $0.4 million, consisting of proceeds of $0.9 million from Sonnet's sale of common stock, partially offset by $0.5 million in net repayments of related party notes.

Funding Requirements

Sonnet expects its expenses to increase substantially in connection with its ongoing activities, particularly as it advances the preclinical activities and clinical trials of its product candidates in development. In addition, Sonnet expects to incur additional costs associated with operating as a public company. The timing and amount of Sonnet's operating expenditures will depend largely on:

- the scope, number, initiation, progress, timing, costs, design, duration, any potential delays, and results of clinical trials and nonclinical studies for Sonnet's current or future product candidates;
- the clinical development plans Sonnet establishes for these product candidates;
- the number and characteristics of product candidates and programs that Sonnet develops or may in-license;
- the outcome, timing and cost of regulatory reviews, approvals or other actions to meet regulatory requirements established by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that Sonnet perform more studies for its product candidates than those that Sonnet currently expects;
- Sonnet's ability to obtain marketing approval for its product candidates;
- the cost of filing, prosecuting, defending and enforcing Sonnet's patent claims and other intellectual property rights covering its product candidates;
- Sonnet's ability to maintain, expand and defend the scope of its intellectual property portfolio, including the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against Sonnet or its product candidates;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities with respect to Sonnet's product candidates;
- Sonnet's ability to establish and maintain licensing, collaboration or similar arrangements on favorable terms and whether and to what extent Sonnet retains development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Sonnet may receive regulatory approval in regions where Sonnet chooses to commercialize its products on its own;
- the success of any other business, product or technology that Sonnet acquires or in which Sonnet invests;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- Sonnet's need and ability to hire additional management and scientific and medical personnel;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for Sonnet's business;
- market acceptance of Sonnet's product candidates, to the extent any are approved for commercial sale; and
- the effect of competing technological and market developments; and
- the potential impact of the COVID-19 pandemic on Sonnet's clinical trials and operations.

Until such time, if ever, as Sonnet can generate substantial product revenue, Sonnet expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that Sonnet raises additional capital through the sale of equity or convertible debt securities, the ownership interest of Sonnet may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of the Sonnet stockholders and the rights of the stockholders of the combined organization following the closing of the merger. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit Sonnet's ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Sonnet raises funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, Sonnet may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to Sonnet. If Sonnet is unable to raise additional funds through equity or debt financings or other arrangements when needed, Sonnet may be required to delay, reduce or eliminate its product development or future commercialization efforts, sell off assets, or grant rights to develop and market product candidates that Sonnet would otherwise prefer to develop and market themselves.

Contractual Obligations and Commitments

The following table summarizes Sonnet's contractual obligations as of March 31, 2020 and the effects that such obligations are expected to have on its liquidity and cash flows in future periods:

	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years	Total
Operating Leases (1)	$ 75,188	$ 205,915	$ 8,674		$ 289,777
Debt Obligations (2)	919	—	—	—	919
Total	$ 76,107	$ 205,915	$ 8,674	$ —	$ 290,696

(1) Reflects obligations pursuant to Sonnet's office lease in Princeton, New Jersey.

(2) Reflects unsecured notes payable issued to various other related parties.

In addition to the contracts with payment commitments that Sonnet has reflected in the table above, Sonnet has entered into other contracts in the normal course of business with certain CROs, CMOs and other third-parties for preclinical research studies and testing, clinical trials and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by Sonnet upon prior notice and, as a result, are not included in the table of contractual obligations and commitments above. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of Sonnet's service providers, up to the date of cancellation.

Critical Accounting Policies

Sonnet's financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP") which requires Sonnet to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in its financial statements. Sonnet bases its estimates on historical experience, known trends and events and various other factors that Sonnet believes are 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. Sonnet evaluates its estimates and assumptions on an ongoing basis. Sonnet's actual results may differ from these estimates under different assumptions or conditions.

While Sonnet's significant accounting policies are described in more detail in the notes to its financial statements included elsewhere in this 8-K, Sonnet believes that the following accounting policies are those most critical to the judgments and estimates used in the preparation of its financial statements.

Research and development expenses

Research and development expense consist primarily of costs incurred in connection with the development of Sonnet's product candidates. Sonnet expenses research and development costs as incurred.

At the end of each reporting period, Sonnet compares payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that Sonnet estimates has been made as a result of the service provided, Sonnet may record net prepaid or accrued expense relating to these costs. As of March 31, 2020, Sonnet has not made any material adjustments to its prior estimates of accrued research and development expenses.

Off-Balance Sheet Arrangements

Sonnet does not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. Sonnet does not engage in off-balance sheet financing arrangements. In addition, Sonnet does not engage in trading activities involving non-exchange traded contracts. Sonnet therefore believes that it is not materially exposed to any financing, liquidity, market or credit risk that could arise if it had engaged in these relationships.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Sonnet's financial position and results of operations is disclosed in Note 2 to Sonnet's financial statements included elsewhere in this 8-K.

Exhibit 99.3

Relief Therapeutics SA, Geneva

Interim condensed financial statements for the three months period ended 31 March 2020

Table of content

Relief Therapeutics SA (interim condensed financial statements)

Relief Therapeutics SA, Geneva

Interim condensed balance sheet

TCHF	Notes	31 March 2020 *Unaudited*	31 December 2019
ASSETS			
Property, plant and equipment	5	-	-
Non-current assets		**-**	**-**
Financial assets due from shareholder	6	897	1,009
Financial assets due from related parties		1	1
Other current assets and other receivables	7	27	27
Cash and cash equivalents		16	9
Current assets		**941**	**1,046**
Total assets		**941**	**1,046**
EQUITY AND LIABILITIES			
Share capital	8	208	208
Reserves		597	597
Accumulated losses		(31)	(104)
Equity		**774**	**701**
Defined benefit obligation	9	-	136
Non-current liabilities		**-**	**136**
Trade payables		51	55
Financial liabilities due to related parties		14	14
Tax liabilities		10	10
Other current payables and liabilities	10	92	130
Current liabilities		**167**	**209**
Total equity and liabilities		**941**	**1,046**

The accompanying notes form an integral part of the financial statements.

Relief Therapeutics SA, Geneva

Interim condensed statement of comprehensive income

TCHF	Notes	01.01. - 31.03.2020 *Unaudited*	01.01. - 31.03.2019 *Unaudited*
CONTINUING OPERATIONS			
Service expense		(8)	(10)
Personnel expense		(3)	(6)
Other administrative expense	11	(54)	(7)
Other gains	12	2	-
EBITDA		**(63)**	**(23)**
Depreciation and amortisation expense		-	(1)
Operating loss		**(63)**	**(24)**
Finance income		-	-
Finance expense		-	-
Loss before income taxes		**(63)**	**(24)**
Income taxes		-	-
Loss for the period		**(63)**	**(24)**
Remeasurement of defined benefit obligation	9	136	-
Total items that will not be reclassified subsequently to profit or loss		**136**	**-**
Total items that may be reclassified subsequently to profir or loss		-	-
Total other comprehensive income for the period		**136**	**-**
Total comprehensive income for the period		**73**	**(24)**

The accompanying notes form an integral part of the financial statements.

Relief Therapeutics SA, Geneva

Interim condensed cash flow statement

TCHF	01.01. - 31.03.2020 *Unaudited*	01.01. - 31.03.2019 *Unaudited*
Cash flow used in operating activities	**7**	**(111)**
Interest received	-	-
Cash flow from investing activities	**-**	**-**
Proceeds from shareholder's loan		85
Cash flow from financing activities	**-**	**85**
Net (decrease)/increase in cash and cash equivalents	7	(26)
Cash and cash equivalents at beginning of period	9	37
Net effect of currency translation on cash and cash equivalents	-	-
Cash and cash equivalents at end of period	**16**	**11**

The accompanying notes form an integral part of the financial statements.

Relief Therapeutics SA, Geneva

Interim condensed statement of changes in equity

TCHF	Notes	Share capital	Reserves	Accumulated loss	Total
Balance at 1 January 2019		**208**	**597**	**(1,825)**	**(1,020)**
Loss for the period		-	-	(24)	**(24)**
Other comprehensive income for the period, net of income tax		-	-	-	
Total comprehensive income for the period		**-**	**-**	**(24)**	**(24)**
Balance at 31 March 2019 (*Unaudited)*		**208**	**597**	**(1,849)**	**(1,044)**
Balance at 1 January 2020		**208**	**597**	**(104)**	**701**
Loss for the period		-	-	(63)	(63)
Other comprehensive income for the period, net of income tax		-	-	136	136
Total comprehensive income for the period		**-**	**-**	**73**	**73**
Balance at 31 March 2020 *(Unaudited)*		**208**	**597**	**(31)**	**774**

The accompanying notes form an integral part of the financial statements.

1 General information

Relief Therapeutics SA ("Relief" or the "Company") is an unlisted Swiss stock corporation whose registered office is Avenue de Sécheron 15, 1202 Geneva, Switzerland.

The mission of the Company is to develop innovative treatments to address high-unmet medical needs. In particular, the most advanced program aims at providing significant improvements for the debilitating affections that are associated with the degeneration of the peripheral nervous system (neuropathies). To achieve this goal, the Company is planning to conduct a clinical trial with the recombinant human protein, atexakin alfa, that proved, in previous clinical trial for a different indication, safe in patients and efficient at reconstructing nerves and reinstating normal blood flow in relevant animal models.

The interim condensed financial statements are presented in thousands of Swiss Francs (CHF).

2 Basis of preparation

These interim condensed financial statements for the three months ended 31 March 2020 have been prepared in accordance with IAS 34 Interim Financial Reporting. They do not include all the information and disclosures required in the annual financial statements and should be read in conjunction with the Company's annual financial statements as at 31 December 2019.

3 Summary of significant accounting policies

3.1 Amendments to IFRSs and the new Interpretation that are mandatorily effective for the current year

The accounting policies adopted in the preparation of the interim condensed financial statements are consistent with those followed in the preparation of the Company's annual financial statements for the year ended 31 December 2019, except for the adoption of new standards effective as of 1 January 2020. The Company has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

None of the new or revised Standards mentioned below has had a material impact on these interim condensed financial statements. The details of each of the new or revised Standards adopted by the Company are detailed below.

	New, amended and revised Standards and Interpretations
Various	The amendments in Definition of Material (Amendments to IAS 1 and IAS 8) clarify the definition of "material" and align the definition used in the Conceptual Framework and the standards.

3.2 Standards and Interpretations in issue but not yet effective

At the date of authorisation of these financial statements, the Company has not adopted the following amendments to a Standard that have been issued but are not yet effective. They will be effective on or after the dates described below.

	New, amended and revised Standards and Interpretations	**Effective from**
IAS 1	The amendments in Classification of Liabilities as Current or Non-Current (Amendments to IAS 1) affect only the presentation of liabilities in the statement of financial position — not the amount or timing of recognition of any asset, liability income or expenses, or the information that entities disclose about those items. They:	Annual periods beginning on or after 1 January 2022
	● clarify that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period and align the wording in all affected paragraphs to refer to the "right" to defer settlement by at least twelve months and make explicit that only rights in place "at the end of the reporting period" should affect the classification of a liability;	
	● clarify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability; and	
	● make clear that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services.	

The Company is currently assessing whether these changes will impact the financial statements in the period of initial application, however the Company does not expect any significant impact from the amended Standards mentioned above.

4 Summary of critical accounting judgements and key sources of estimation uncertainty

The preparation of the financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income, expenses and related disclosures. The estimates and underlying assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making the judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below.

4.1 Critical judgements in applying accounting policies

Critical judgements in applying accounting policies were the same as those applied to the financial statements of the year ended 31 December 2019 except for the following:

Going concern

The Company has been facing some financial difficulties by having some operating losses thus questioning the capacity to continue as a going concern. Indeed, the Company had negative operating results of TCHF (63) for the 3 months ended at 31.03.20, TCHF (235) for the year 2019 and TCHF (136) for the year 2018 thus resulting in an operating cash outflows for both years.

In 2020 and 2019, as well as in previous years, Relief reduced its capital needs significantly. The Company operated with a single part time manager, and external resources and relocated to an office with reduced costs. The Company mainly relied on its current cash balance and financial support from its Parent company Relief Therapeutics Holding SA ("RTH") which has injected capital via loans. While these loans have generated some debt (principal and interest) towards RTH, discussions with the RTH board have resulted in the write-off in 2019 of the corresponding amount and relieved the Company from its financial obligations towards RTH.

On 2 April 2020, RTH and Sonnet BioTherapeutics Inc. ("Sonnet") completed a share exchange agreement resulting in the transfer of control of the Company. From that date, the Company is a fully owned subsidiary of Sonnet. Sonnet envisions a long-term strategy based on the development of the Company's main asset Atexakin alfa ("Atexakin", SON-080 as fully integrated in Sonnet's pipeline of projects). Sonnet has already invested significantly in the initial phase of Atexakin's development that resulted in the delivery of a complete analysis of the available supporting information, of regulatory documents and in the establishment of collaborative interactions with service providers to progress the project. Sonnet will pursue its investment in the clinical development of Atexakin and will commit funding into the clinical testing of Atexakin for safety and efficacy to treat Chemotherapy-Induced Peripheral Neuropathy (CIPN). Positive results may support progression into subsequent development phases either internally of via sub-licensing to an external company until clearance for market entry. This is expected to provide funds to the Company, in addition to those coming from Sonnet, under the form of upfront and milestone fees.

In the current context of coronavirus pandemic, as the Company's reliance on local or global supply chains is low, and as it does not operate any production facilities, it has a low risk of being forced to interrupt its operations due to the on-going Covid-19 pandemic. Due to the average age of collaborators involved in the daily activities of the Company, no loss of personnel is expected as a consequence of potential infection. Government-imposed travel restrictions and quarantines may lead the Company to adapt to this novel environment by reducing its face-to-face interactions and by favoring video and teleconferences which already support the majority of its in-house and external business interactions. At the present time, a precise quantitative evaluation of the impact of the pandemic on the Company's planned activities is almost impossible to establish. Indeed, there is uncertainty about the effects of Covid-19 on the Company's ability to get appropriate financing in the future. The Company is closely monitoring its global evolution.

Sonnet intends to hire executive(s) and to renew the Board of Directors of the Company in the coming months. Some resigning former executives have been hired as part time consultants to occupy such position(s). Management hence considers that all the elements are or will soon be in place to ensure the Company will remain in a going concern.

4.2 Key sources of estimation uncertainty

Key sources of estimation uncertainty were the same as those applied to the financial statements of the year ended 31 December 2019.

5 Property, plant and equipment

There were no additions or disposals in the first three months of 2020. As at 31 March 2020, the remaining property, plant and equipment is fully depreciated.

6 Financial assets due from shareholder

At 31 March 2020, TCHF 897 is due from Relief Therapeutics Holding SA ("RTH"), the sole shareholder of the Company (31 December 2019: TCHF 1'009), earned by the Company in exchange of service provided such as payroll or general overhead paid by the Company on behalf of RTH. During the financial period, RTH recharged various expenses in relation to administrative costs which it paid on behalf of the Company. The current account is non-interest bearing, does not have a fixed term and is not impaired. The fair value of this financial asset is close to its carrying amount.

7 Other current assets and other receivables

At 31 March 2020, other current assets and other receivables mainly relate to receivables from social security institutions, prepaid expenses and recharged expenses to Sonnet.

8 Share capital

8.1 Issued share capital

At 31 March 2020, the issued share capital amounts to TCHF 208, consisting of 208'163 registered shares with a par value of CHF 1. They entitle the holder to participate in dividends and to share in the proceeds of winding up the Company in proportion to the number of shares and amounts paid on the shares held. There were no changes to the share capital in the first three months of 2020.

8.2 Authorized and conditional share capital

At 31 March 2020, the Company had no authorized share capital, but conditional share capital of TCHF 23, consisting of 23'129 shares with a par value of CHF 1.00 each.

9 Defined benefit obligation

The Company participates in a Swiss pension plan which qualifies as defined benefit plan under the requirements of IAS 19. The Company exercises judgement in determining whether a full remeasurement of the plan assets and the defined benefit obligation is required at the end of an interim period. As there were no remaining employees within the Company as at 31 March 2020, the entire defined benefit obligation was derecognised through other comprehensive income. Additional information is disclosed in Note 17.

10 Other current payables and liabilities

As at 31 March 2020, other current payables and liabilities mainly consist of accrued expenses (TCHF 31), sales taxes (TCHF 56), deferred income (TCHF 3) and accrued holiday provisions (TCHF 2).

11 Other administrative expense

TCHF	01.01. - 31.03.2020	01.01. - 31.03.2019
Office expense	1	1
Accounting, legal and consulting expense	53	2
Travel expense	-	2
IT expense	-	1
Other operating expense	-	1
Total general and administrative expense	**54**	**7**

12 Other gains

TCHF	01.01. - 31.03.2020	01.01. - 31.03.2019
Expenses recharged to Sonnet	2	-
Total other gains	**2**	**-**

13 Related party balances and transactions

As at 31 March 2020, the only outstanding related party balances are financial assets due from the shareholder (note 6) and insignificant receivables and payables with other related parties.

The only significant transactions in the first three months of 2020 were the recharged expenses as detailed on note 6.

As the change of control of the Company was effective after the current period, Sonnet is not disclosed as a related party as of 31 March 2020.

14 Fair value measurement

Unchanged to 31 December 2019, there are no assets or liabilities measured at fair value. For all financial assets and liabilities their carrying amount at amortised cost approximates fair value.

15 Non-cash transactions

There were no significant non-cash transactions during the first three months of 2020 or 2019.

16 Contingent liabilities

Litigation

The Company is not, and does not foresee to become party to any legal, administrative or arbitral proceedings, the outcome of which, if adverse to the Company, may be material to its business, financial condition and results of operation taken as a whole.

Uncertain tax position

The forgiveness of the loan of the Company's mother company has been recorded as taxable profit for the financial year 2019 giving the uncertainty due to the lack of information faced by the Company as at 31 December 2019. Indeed, the Company was seeking confirmation from the Swiss tax authorities whether the debt forgiveness from its direct shareholder could be viewed as a capital restructuring ("mesure d'assainissement in French") with the debt being converted as equity thus being viewed as a capital injection. If the Cantonal Tax authorities validate the capital restructuring, the loss carried forward would not be consumed by the income resulting from the debt forgiveness of the direct shareholder as such income is tax exempted. Balance sheet and comprehensive income statement is not impacted by this consideration.

In case this will be approved by the Federal Tax authorities as well, the capital injection made by the direct shareholder is subject to the payment of the Federal Stamp of 1%, except if all the tax requirements are fulfilled to get an exemption of the issuance stamp tax. If stamp tax was due, the Company would record a tax payable and a tax expense of TCHF 14.

Nevertheless, there is uncertainty as to whether the payment of this federal stamp would still be due as the Company might be exempted due to the capital restructuring. A confirmation from the Swiss Tax authorities is expected later in 2020.

17 Subsequent events

Sale of the Company to Sonnet

On 2 April 2020, Relief Therapeutics Holding SA announced the closing of the share exchange agreement between Sonnet BioTherapeutics, Inc. ("Sonnet"), now a subsidiary of Sonnet BioTherapeutics Holdings, Inc. (formerly known as Chanticleer Holdings, Inc.) (Nasdaq:SONN, "Sonnet Holdings") and Relief Therapeutics Holding SA. Consequently, Sonnet acquires all outstanding shares of the Company that becomes a wholly owned Geneva-based subsidiary of Sonnet.

Departure of personnel

The sole remaining employee of the Company has resigned from his position with effective date 31 March 2020. From an operational perspective, management of the Company is conducted by Sonnet with the support of external consultants who were previously part of the former executive team.

Board of Directors composition

As a result of the acquisition of the Company by Sonnet, the former administrator Mr. Thomaz Burckhardt resigned and was replaced by Mr. Gael Hedou, registered as Board member ("*administrateur*") at the Geneva commercial register as of 27 April 2020.

There were no other significant events subsequent to 31 March 2020.

18 Approval of financial statements

These interim condensed financial statements were approved by the Board of Directors on 13 May 2020.

Exhibit 99.4

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

Sonnet BioTherapeutics, Inc. ("Sonnet Sub") and Sonnet BioTherapeutics Holdings, Inc. ("Sonnet" or the "Company"), formerly known as "Chanticleer Holdings, Inc.", entered into an Agreement and Plan of Merger dated October 10, 2019 (the "Merger Agreement"), as amended by Amendment No. 1 thereto made and entered into as of February 7, 2020 (the "First Amendment") (the Merger Agreement, as amended by the First Amendment, the "Amended Merger Agreement") as approved by the Sonnet stockholders on March 18, 2020, pursuant to which Sonnet Sub became a wholly owned subsidiary of Sonnet (the "Merger").

Following stockholder approval on March 18, 2020, but prior to the Merger, Sonnet consummated a reverse stock split of its issued and outstanding common stock (the "Common Stock") in a ratio of 1 for 26. All pro forma numbers and per share amounts of Common Stock have been retroactively restated to reflect the reverse split. On April 1, 2020, in connection with the Merger, the Company changed its name from Chanticleer Holdings, Inc. to Sonnet BioTherapeutics Holdings, Inc.

The following selected unaudited pro forma condensed combined financial data gives effect to (i) the Merger, (ii) the Pre-Merger Financing, (iii) proceeds from Sonnet Sub's Pre-Closing Private Placement Transactions, (iv) Sonnet Sub's acquisition of Relief, and (v) the Spin-Off (collectively, the "Pro Forma Events").

The Merger is accounted for as a reverse recapitalization under U.S. GAAP because Sonnet had nominal operations and assets at the time of the Merger. Sonnet Sub was determined to be the accounting acquirer based upon the terms of the Merger and other factors including: (i) Sonnet Sub shareholders own approximately 92% of the Fully Diluted Common Stock, (ii) Sonnet Sub holds all of the board seats of the combined company and (iii) Sonnet Sub's management will hold all key positions in the management of the combined company.

The Sonnet and Sonnet Sub unaudited pro forma condensed combined balance sheet data assume that the Pro Forma Events took place on March 31, 2020 and combines the Sonnet, Relief and Sonnet Sub historical balance sheets at March 31, 2020. The Sonnet and Sonnet Sub unaudited pro forma condensed combined statements of operations data assume that the Pro Forma Events took place as of January 1, 2019, and combines the historical results of Sonnet and Relief for the year ended December 31, 2019 and of Sonnet Sub for the year ended September 30, 2019. The historical financial statements of Sonnet Sub are provided in Exhibit 99.2 to the Current Report on Form 8-K of which this Exhibit 99.4 forms a part. The historical financial statements of Relief are provided in Exhibit 99.3 thereto. These financial statements have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

Sonnet and Sonnet Sub have different fiscal year ends. As Sonnet's fiscal year ended December 31 is within 93 days of Sonnet Sub's fiscal year ended September 30, pro forma condensed combined statement of operations for the year ended December 31, 2019 includes Sonnet Sub's operating results for its respective fiscal year ended September 30, 2019 as permitted by Rule 11-02 of Regulation S-X. Following the completion of the Merger, the continuing reporting entity will have a fiscal year ended September 30.

The unaudited pro forma condensed combined financial statements are based on the assumptions and adjustments that are described in the accompanying notes. The unaudited pro forma condensed combined financial statements and pro forma adjustments have been prepared based on preliminary estimates of fair value of assets acquired and liabilities assumed as of the date of completion of the transaction. Differences between these preliminary estimates and the final fair value of assets and liabilities acquired may occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial statements and the combined organization's future results of operations and financial position.

The unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the acquisition. The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Sonnet, Relief and Sonnet Sub been a combined organization during the specified period. The unaudited pro forma condensed combined financial statements, including the notes thereto, should be read in conjunction with the separate Sonnet Sub, Relief and Sonnet historical financial statements.

Unaudited Pro Forma Condensed Combined Balance Sheet

As of March 31, 2020

(In thousands)

	Sonnet BioTherapeutics, Inc.	Relief Therapeutics SA	Pro Forma Adjustments	Notes	Pro Forma Sonnet BioTherapeutics, Inc.	Sonnet BioTherapeutics Holdings, Inc.	Pro Forma Adjustments	Notes	Pro Forma Combined
Assets									
Current assets:									
Cash and cash equivalents	$ 273	$ 17	$ —		$ 290	$ 549	$ 8,115	C	$ 8,954
Accounts receivable	—	—	—		—	63	(63)	D	—
Related party receivable	214	933	—		1,147	—	(214)	B	933
Inventories	—	—	—		—	272	(272)	D	—
Prepaid expenses and other current assets	19	28	—		47	934	(934)	D	47
Total current assets	506	978	—		1,484	1,818	6,632		9,934
Property and equipment, net	63	—	—		63	5,325	(5,325)	D	63
Operating lease right-of-use asset	244	—	—		244	11,257	(11,257)	D	244
Goodwill	—	—	—		—	8,513	(8,513)	D	—
Intangible assets, net	—	—	—		—	3,565	(3,565)	D	—
Investments	—	—	—		—	390	(390)	D	—
Deposits and other assets	83	—	—		83	302	(302)	D	83
Assets of discontinued operations	—	—	—			149	(149)	D	—
Total assets	$ 896	$ 978	$ —		$ 1,874	$ 31,319	$ (22,869)		$ 10,324
Liabilities and stockholders' equity (deficit)									
Current liabilities:									
Current portion of long-term debt and noted payable	$ —	$ —	$ —		$ —	$ 6,348	$ (6,348)	E	$ —
Related-party notes	1	—	—		1	—	—		1
Accounts payable	3,678	53	—		3,731	3,782	(3,782)	D	3,731
Other accrued expenses	514	106	—		620	4,038	(3,861)	D,F	797
Operating lease liabilities, current	76	—	—		76	3,183	(3,183)	D	76
Derivative liability	—	—	—		—	826	(826)	D	—
Related party payable	—	15	—		15	—	—		15
Total current liabilities	4,269	174	—		4,443	18,177	(18,000)		4,620
Redeemable preferred stock	—	—	—		—	718	(718)	G	—
Operating lease liabilities	168	—	—		168	14,065	(14,065)	D	168
Deferred revenue	—	—	—		—	936	(936)	D	—
Deferred tax liabilities	—	—	—		—	102	(102)	D	—
Liabilities of discontinued operations	—	—	—		—	248	(248)	D	—
Total liabilities	4,437	174	—		4,611	34,246	(34,069)		4,788
Convertible preferred stock	—	—	—		—	460	(460)	H	—
Stockholders' equity (deficit):									
Common stock	13,865	216	6,423	A	20,504	1	(20,504)	I	1
Additional paid-in capital	—	620	(620)	A	—	73,499	(39,996)	I	33,503
Accumulated other comprehensive income	—	—	—		—	(128)	128	I	—
Accumulated deficit	(17,406)	(32)	(5,803)	A	(23,241)	(77,344)	72,617	I	(27,968)
Total stockholders' equity (deficit)	(3,541)	804	—		(2,737)	(3,972)	12,245		5,536
Equity attributable to non-controlling interest	—	—	—		—	585	(585)	I	—
Total liabilities and stockholders' equity	$ 896	$ 978	$ —		$ 1,874	$ 31,319	$ (22,869)		$ 10,324

Unaudited Pro Forma Condensed Combined Statement of Operations

For the Three Months Ended March 31, 2020

(In thousands, except share and per share data)

	Sonnet BioTherapeutics, Inc.	Relief Therapeutics SA	Pro Forma Adjustments	Notes	Pro Forma Sonnet BioTherapeutics, Inc.	Sonnet BioTherapeutics Holdings, Inc.	Pro Forma Adjustments	Notes	Pro Forma Combined
Revenues	$ —	$ —	$ —		$ —	$ 5,681	$ (5,681)	D	$ —
Costs and expenses:									
Cost of revenues	—	—	—		—	5,445	(5,445)	D	—
Research and development	1,303	8	—		1,311	—	—		1,311
Selling, general and administrative	1,208	57	(43)	J	1,222	1,175	(909)	M	1,488
Depreciation and amortization	—	—	—	K	—	416	(416)	D	—
Total costs and expenses	2,511	65	(43)		2,533	7,036	(6,770)		2,799
(Loss) income from operations	(2,511)	(65)	43		(2,533)	(1,355)	1,089		(2,799)
Interest income (expense)	14	—	—		14	(163)	149	L	—
Other income (expense)	—	—	—		—	(279)	279	D	—
Total other income (expenses)	14	—	—		14	(442)	428		—
(Loss) income before taxes	(2,497)	(65)	43		(2,519)	(1,797)	1,517		(2,799)
Income tax benefit	—	—	—		—	4	(4)	D	—
Net (loss) income	(2,497)	(65)	43		(2,519)	(1,793)	1,513		(2,799)
Net (loss) income attributable to non-controlling interest	—	—	—		—	(129)	129	D	—
Net (loss) income attributable to the Company	(2,497)	(65)	43		(2,519)	(1,922)	1,642		(2,799)
Dividends on redeemable preferred stock	—	—	—		—	(28)	28	D	—
Net (loss) income attributable to common stockholders	$ (2,497)	$ (65)	$ 43		$ (2,519)	$ (1,950)	$ 1,670		$ (2,799)
Net loss per share, basic and diluted	$ (1.21)				$ (1.08)	$ (4.26)			$ (0.30)
Weighted average common shares outstanding, basic and diluted	2,064,324			N	2,337,859	458,065		O	9,180,001

Unaudited Pro Forma Condensed Combined Statement of Operations

For the Year Ended December 31, 2019*

(In thousands, except share and per share data)

	Sonnet BioTherapeutics, Inc. *Year Ended September 30, 2019	Relief Therapeutics SA	Pro Forma Adjustments	Notes	Pro Forma Sonnet BioTherapeutics, Inc.	Sonnet BioTherapeutics Holdings, Inc.	Pro Forma Adjustments	Notes	Pro Forma Combined
Revenues	$ —	$ —	$ —		$ —	$ 30,143	$ (30,143)	D	$ —
Costs and expenses:									
Cost of revenues	—	—	—		—	29,263	(29,263)	D	—
Research and development	2,199	39	—		2,238	—	—		2,238
Selling, general and administrative	2,509	196	(107)	J	2,598	5,966	(5,873)	M	2,691
Asset impairment charge	—	—	—		—	9,150	(9,150)	D	—
Depreciation and amortization	—	1	(1)	K	—	1,842	(1,842)	D	—
Total costs and expenses	4,708	236	(108)		4,836	46,221	(46,128)		4,929
Loss (income) from operations	(4,708)	(236)	108		(4,836)	(16,078)	15,985		(4,929)
Interest income (expense)	(163)	—	—		(163)	(674)	674	D	(163)
Other income (expense)	—	1,507	—		1,507	(617)	617	D	1,507
Total other income (expenses)	(163)	1,507	—		1,344	(1,291)	1,291		1,344
(Loss) income before taxes	(4,871)	1,271	108		(3,492)	(17,369)	17,276		(3,585)
Income tax expense	—	(10)	—		(10)	(74)	74	D	(10)
Net (loss) income	(4,871)	1,261	108		(3,502)	(17,443)	17,350		(3,595)
Net (loss) income attributable to non-controlling interest	—	—	—		—	402	(402)	D	—
Net loss (income) attributable to the Company	(4,871)	1,261	108		(3,502)	(17,041)	16,948		(3,595)
Dividends on redeemable preferred stock	—	—	—		—	(112)	112	D	—
Net (loss) income attributable to common stockholders	$ (4,871)	$ 1,261	$ 108		$ (3,502)	$ (17,153)	$ 17,060		$ (3,595)
Net loss per share, basic and diluted	$ (2.52)				$ (1.59)	$ (63.90)			$ (0.40)
Weighted average common shares outstanding, basic and diluted	1,931,396			N	2,204,932	268,417		O	9,006,276

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

(1) Description of Transactions

Merger

Sonnet BioTherapeutics, Inc. ("Sonnet Sub") and Sonnet BioTherapeutics Holdings, Inc. ("Sonnet" or "the Company), formerly known as "Chanticleer Holdings, Inc.", entered into an Agreement and Plan of Merger dated October 10, 2019 (the "Merger Agreement"), as amended by Amendment No. 1 thereto made and entered into as of February 7, 2020 (the "First Amendment") (the Merger Agreement, as amended by the First Amendment, the "Amended Merger Agreement") as approved by the Sonnet stockholders on March 18, 2019, pursuant to which Sonnet Sub became a wholly owned subsidiary of Sonnet (the "Merger").

In connection with, and immediately prior to the completion of, the Merger, the Company effected a reverse stock split of the Company's common stock, par value $0.0001 per share (the "Common Stock"), at a ratio of 1-for-26 (the "Reverse Stock Split"). In connection with the Merger, the Company changed its name to "Sonnet BioTherapeutics Holdings, Inc.," focused on advancing Sonnet Sub's pipeline of oncology candidates and the strategic expansion of Sonnet Sub's technology platform into other human diseases. Additionally, as part of the transaction, on April 1, 2020, the Company spun-off its restaurant operations into a newly-created wholly-owned subsidiary, Amergent Hospitality Group, Inc. (the "Spin-Off Entity" or "Amergent"), the equity of which was distributed out on April 1, 2020 to the stockholders of record of the Company as of the close of business on March 26, 2020.

Under the terms of the Amended Merger Agreement, the Company issued shares of Common Stock to Sonnet Sub's stockholders at an exchange ratio (the "Exchange Ratio") of approximately 0.106572 shares of Common Stock, after taking into account the Reverse Stock Split (2.770872 prior to the reverse split), for each share of Sonnet Sub's common stock outstanding immediately prior to the Merger. The Company also assumed all outstanding and unexercised warrants to purchase shares of Sonnet Sub's common stock, and in connection with the Merger they were converted into warrants (the "Converted Warrants") to purchase Common Stock, with the number of shares subject to such warrants, and the exercise price, being appropriately adjusted to reflect the Exchange Ratio. As a result, immediately following the Merger, there were outstanding Converted Warrants to purchase an aggregate of approximately 106,000 shares of Common Stock, all with terms of three years from their respective dates of issuance, between October 2019 and February 2020, and with an exercise price of $29.32 per share.

Immediately following the Merger, former stockholders and warrant holders of Sonnet Sub own, or hold rights to acquire, in aggregate, approximately 92% of the fully-diluted Common Stock, which for these purposes is defined as the outstanding Common Stock, plus outstanding warrants of the Company (the "Fully-Diluted Common Stock"), the Company's stockholders and warrant holders immediately prior to the Merger own or hold the right to own approximately 6% of the Fully-Diluted Common Stock and the Spin-Off Entity holds a warrant to purchase 2% of the number of shares of issued and outstanding Common Stock. The Spin-Off Entity warrant holders cannot exercise the warrant until 180 days after the closing date.

Pre-Merger Financing

On February 7, 2020, Sonnet Sub and Sonnet entered into a securities purchase agreement (the "Securities Purchase Agreement"), with certain accredited investors (the "Investors") pursuant to which, among other things, Sonnet Sub agreed to issue to the Investors shares of Sonnet Sub common stock immediately prior to the Merger and Sonnet agreed to issue to the Investors warrants to purchase shares of Common Stock on the tenth trading day following the consummation of the Merger in a private placement transaction for an aggregate purchase price of approximately $19 million which is comprised of a $4 million credit to Chardan Capital Markets, LLC ("Chardan"), in lieu of certain transaction fees otherwise owed to Chardan by Sonnet Sub, and $15 million in cash from the other Investors (the "Pre-Merger Financing").

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

GEM

Sonnet Sub entered into a Common Stock Purchase Agreement with GEM Global Yield Fund LLC SCS ("GEM") on August 6, 2019 (the "Purchase Agreement"). The Purchase Agreement was amended on September 25, 2019 by an Amendment to Common Stock Purchase Agreement (the "2019 GEM Amendment"), and subsequently amended again on February 7, 2020 (the "2020 GEM Amendment" and, together with the Purchase Agreement and the 2019 GEM Amendment, the "GEM Agreement"). Pursuant to the GEM Agreement, GEM has agreed to purchase up to $20,000,000 (the "Aggregate Limit") of the Company's common stock, par value $0.0001 per share (the "Common Stock") over a three-year period commencing on the date the Purchase Agreement was executed (the "Investment Period"); provided that during any period when the Company's public float is less than $75,000,000, the Aggregate Limit will instead be equal to one-third of the amount of the Company's public float over any consecutive 12-month period. Under the GEM Agreement, during the Investment Period, the Company may, by delivering a Draw Down Notice (as defined in the GEM Agreement) direct GEM to purchase shares of Common Stock in an amount up to 400% of the average daily trading volume for the ten (10) trading days immediately preceding the date the Draw Down Notice is delivered. GEM is not obligated to purchase any shares Common Stock which would result in GEM beneficially owning, directly or indirectly, at the time of the proposed issuance, more than 4.99% of the shares of Common Stock issued and outstanding. GEM will pay a purchase price per share equal to 90% of the average market closing price of the Common Stock during the ten consecutive trading days commencing with the first trading day on which a Draw Down Notice is delivered (the "Draw Down Pricing Period").

GEM represented to the Company, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act), and the Company will rely upon an exemption from registration contained in Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder when issuing shares of Common Stock under the GEM Agreement. The Company has agreed to file a Registration Statement with the Securities and Exchange Commission (the "SEC") to register the shares of Common Stock to be issued to GEM pursuant to the GEM Agreement. The GEM Agreement contains customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the GEM Agreement at any time, at no cost or penalty. Unless the Company informs GEM of an event resulting in a Materially Adverse Effect or Material Change in Ownership (all defined in the GEM Agreement) GEM does not have the right to terminate the GEM Agreement.

Acquisition of Relief

In connection with and prior to the Merger, on April 1, 2020, Sonnet Sub completed its acquisition of the global development rights for atexakin alfa from Relief Therapeutics Holding SA ("Relief Holding") through its acquisition of Relief Holding's wholly-owned subsidiary, Relief Therapeutics SA ("Relief"), in exchange for the issuance to Relief Holding of shares of Sonnet Sub common stock that converted into an aggregate of 757,933 shares of Common Stock in the Merger.

The Share Exchange Agreement with Relief is accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired is concentrated Relief's atexakin alfa asset. The closing occurred immediately prior to the Merger.

Amergent Spin-Off

In connection with and prior to the Merger, on March 30, 2020, the Company contributed and transferred (the "Contribution") to Amergent all of the assets and liabilities relating to the Company's restaurant business conducted prior to the Merger. Previously, on March 16, 2020, the Company's Board of Directors (the "Board") declared a dividend with respect to the shares of Common Stock outstanding at the close of business on March 26, 2020 of one share of the Amergent common stock for each outstanding share of Common Stock. Such dividend, which together with the Contribution is referred to as the "Spin-Off," was paid on April 1, 2020.

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

(2) Basis of Presentation

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC. The unaudited pro forma condensed combined balance sheet as of March 31, 2020 is presented as if the Pro Forma Events had been completed on March 31, 2020. The unaudited pro forma condensed combined statement of operations for the three months ended March 31, 2020 and the year ended December 31, 2019 assume that the Pro Forma Events occurred on January 1, 2019.

Sonnet and Relief have different fiscal year ends than Sonnet Sub. As Sonnet and Relief's fiscal year ended December 31 is within 93 days of Sonnet Sub's fiscal year ended September 30, Sonnet and Relief's pro forma condensed combined statement of operations for the year ended December 31, 2019 includes Sonnet Sub's operating results for its respective fiscal year ended September 30, 2019 as permitted by Rule 11-02 of Regulation S-X.

Additionally, the unaudited pro forma condensed combined statements of operations data reflect the acquisition by Sonnet Sub of Relief concurrent with the Merger by giving pro forma effect to the consummation of the acquisition as if it occurred on January 1, 2019. The historical financial information of Relief was prepared in accordance with IFRS and presented in Swiss francs. The historical financial information was translated from Swiss francs to U.S. dollars using an average exchange rate of 1.00 CHF to $1.03 for the three months ended March 31, 2020 and 1.00 CHF to $1.01 for the year ended December 31, 2019 and a spot exchange rate of 1.00 CHF to $1.04 as of March 31, 2020. There were no adjustments to convert Relief's financial information from IFRS to U.S. GAAP.

For accounting purposes, Sonnet Sub is considered to be the acquiring company and the Merger will be accounted for as a reverse recapitalization of Sonnet by Sonnet Sub because on the Merger date, Sonnet had nominal assets and operations as a result of the Spin-Off.

Under reverse recapitalization accounting, the assets and liabilities, if any, of Sonnet will be recorded, as of the completion of the Merger, at their book value because of the short-term nature of the instruments. No goodwill or intangible assets will be recognized and any excess consideration transferred over the value of the net assets, if any, of Sonnet following determination of the actual purchase consideration for Sonnet will be reflected as a reduction to equity. Consequently, the combined financial statements of Sonnet reflect the operations of Sonnet Sub, the acquirer for accounting purposes, together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of Sonnet, the legal acquirer, and a recapitalization of the equity of the accounting acquirer. The historical financial statements of Sonnet Sub are provided in Exhibit 99.2 to the Current Report on Form 8-K of which this Exhibit 99.4 forms a part. The historical financial statements of Relief are provided in Exhibit 99.3. These financial statements have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

To the extent there are significant changes to the business following completion of the merger, the assumptions and estimates set forth in the unaudited pro forma condensed combined financial statements could change significantly. Accordingly, the pro forma adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted following the completion of the Merger. There can be no assurances that these additional analyses will not result in material changes to the estimates of fair value.

(3) Pro Forma Adjustments

A. Reflects accounting for the acquisition of Relief as an asset acquisition and expensing the fair value allocated to the atexakin alfa program as in-process research and development since Sonnet Sub determined the asset has no alternative future use without further development and regulatory approval.

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

B. Reflects the settlement of the related party receivable upon consummation of Merger.

C. Reflects (i) $15.0 million in proceeds from the Pre-Merger Financing, (ii) $(6) million payment of "Payoff Amount" due to the Company for use by Amergent under the Amended Merger Agreement, and (iii) settlement of the related party note receivable upon consummation of the Merger.

(amounts in thousands)		**March 31, 2020**
Elimination of Sonnet cash as a result of Spin-Off	$	(549)
Pre-Merger Financing		15,000
Payment of Payoff Amount		(6,000)
Settlement of certain transaction costs at close		(550)
Settlement of related party receivable		214
Pro forma adjustment	$	8,115

D. To eliminate the operating accounts of Sonnet as a result of the Spin-Off.

E. Reflects the settlement of long-term debt and notes payable as required by the Amended Merger Agreement.

F. Reflects elimination of Sonnet other accrued expenses as result of Spin-Off and accrual of transaction costs in connection with the Merger.

(amounts in thousands)		**March 31, 2020**
Elimination of Sonnet other accrued expenses as a result of the Spin-Off	$	(4,038)
Transaction costs		177
Pro forma adjustment	$	(3,861)

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

G. Reflects settlement of Sonnet redeemable preferred stock as required by the Amended Merger Agreement.

H. Reflects cancellation of Series 2 Preferred Stock upon consummation of the Merger.

I. To record (i) the elimination of Sonnet's historical equity, (ii) sale of Sonnet Sub common stock in connection with the Pre-Merger Financing, (iii) issuance of Common Stock and warrants including the conversion of Series 2 Preferred Stock issued pursuant to a financing of Sonnet and disbursement of Payoff Amount in connection with reverse recapitalization, (iv) transaction costs associated with the Merger, (v) issuance of Common Stock to financial adviser upon consummation of the Merger and (vi) Exchange Ratio adjustment to Sonnet Sub's common stock outstanding.

(amounts in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity	Non-Controlling Interest
Elimination of Sonnet's historical carrying value	—	(1)	(73,499)	128	77,344	3,972	(585)
Sale of common stock, net of issuance costs, in connection with Pre-Merger Financing	1,699,232	—	15,000	—	—	15,000	—
Issuance of common stock and warrants to Chanticleer including the conversion of bridge preferred stock and disbursement of Payoff Amount in connection with reverse recapitalization	549,721	—	(6,000)	—	—	(6,000)	—
To record transaction costs	—	—	—	—	(727)	(727)	—
Issuance of common stock to financial adviser upon consummation of the Merger	453,128	—	4,000	—	(4,000)	—	—
Exchange ratio adjustment to Sonnet Sub's common stock outstanding	4,356,951	(20,503)	20,503	—	—	—	—
Pro forma adjustment	7,059,032	$ (20,504)	$ (39,996)	$ 128	$ 72,617	$ 12,245	$ (585)

J. Reflects elimination of Relief transaction costs recorded in historical period that will not have a continuing impact on the pro forma statement of operations.

K. Reflects elimination of the historical Relief depreciation expense in the historical period that will not have a continuing impact on the pro forma statement of operations.

L. Reflects elimination of Sonnet interest expense as a result of the Spin-Off and interest income earned on Sonnet note receivable.

(amounts in thousands)	Three Months Ended March 31, 2020
Elimination of Sonnet interest expense as a result of the Spin-Off	$ 163
Sonnet Sub interest income	(14)
Pro forma adjustment	$ 149

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

M. Reflects elimination of Sonnet selling, general and administrative expense as a result of the Spin-Off and Sonnet transaction costs recorded in historical period that will not have a continuing impact on the pro forma statements of operations.

(amounts in thousands)	Three Months Ended March 31, 2020	Year Ended December 31, 2019
Elimination of Sonnet selling, general and administrative expenses as a result of the Spin-Off	$ (1,175)	$ (5,966)
Sonnet Sub transaction costs	266	93
Pro forma adjustment	$ (909)	$ (5,873)

N. The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net income for the three months ended March 31, 2020 and the year ended December 31, 2019. In addition, the number of shares used in calculating the pro forma combined basic and diluted net income per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding as of the acquisition of Relief. The following table sets forth the calculation of the pro forma weighted average number of common shares outstanding – basic and diluted.

	Three Months Ended March 31, 2020	Year Ended December 31, 2019
Historical Sonnet Sub weighted average shares outstanding	2,064,324	1,931,396
Shares issued to Relief shareholders upon consummation of acquisition	273,535	273,536
Pro forma weighted average shares outstanding	2,337,859	2,204,932

O. The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net income for the three months ended March 31, 2020 and the year ended December 31, 2019. In addition, the number of shares used in calculating the pro forma combined basic and diluted net income per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding as of the closing of the Merger. The following table sets forth the calculation of the pro forma weighted average number of common shares outstanding – basic and diluted.

	Three Months Ended March 31, 2020	Year Months Ended December 31, 2019
Effect of applying the 2.7709 exchange ratio to historical Sonnet Sub weighted average shares outstanding	5,719,987	5,351,662
Shares issued to Relief shareholders upon consummation of acquisition	757,933	757,933
Shares issued in connection with pre-merger financing	1,699,232	1,699,232
Shares issued in connection with Pre-Closing Private Placement Transactions	—	194,600
Shares issued to Sonnet shareholders upon consummation of the Merger	549,721	549,721
Shares issued to financial adviser upon consummation of the Merger	453,128	453,128
Pro forma weighted average shares outstanding	9,180,001	9,006,276