Filed Pursuant to Rule 424(b)(4)
Registration No. 333-282850

PROSPECTUS

155,000 Shares of Common Stock
956,111 Pre-Funded Warrants to Purchase up to 956,111 Shares of Common Stock
1,111,111 Common Warrants to Purchase up to 2,222,222 Shares of Common Stock
956,111 Shares of Common Stock issuable upon exercise of the Pre-Funded Warrants
2,222,222 Shares of Common Stock issuable upon exercise of the Common Warrants

We are offering 155,000 shares of our common stock and common warrants to purchase up to an aggregate of 2,222,222 shares of our common stock, par value $0.0001 per share (and the shares of common stock that are issuable from time to time upon exercise of the common warrants), at a combined public offering price of $4.50. We are also offering to those purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, pre-funded warrants to purchase up to an aggregate of 956,111 shares of our common stock, in lieu of shares of common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each share of common stock and pre-funded warrant is being sold together with a common warrant to purchase two shares of our common stock at an exercise price of $4.50 per share. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrant will be equal to the price at which a share of common stock and accompanying common warrant are sold to the public in this offering, minus $0.0001, and the exercise price of each pre-funded warrant will be $0.0001 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of the common warrants and any pre-funded warrants sold in this offering. The common warrants will be exercisable immediately and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

We effected a 1-for-8 reverse stock split on September 30, 2024, pursuant to which every 8 shares of our issued and outstanding common stock were reclassified as one share of common stock. The reverse stock split had no impact on the par value of our common stock or the authorized number of shares of our common stock. Unless otherwise indicated, all share and per share information in this prospectus has been adjusted to reflect the September 30, 2024 reverse stock split.

Our common stock is listed on The Nasdaq Capital Market LLC (the "The Nasdaq Capital Market") under the symbol "SONN." On November 5, 2024, the last reported sale price of our common stock on The Nasdaq Capital Market was $4.21 per share. There is no established public trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the pre-funded warrants or common warrants on any national securities exchange. Without an active trading market, the liquidity of the pre-funded warrants or common warrants will be limited.

You should read this prospectus, together with additional information described under the heading "Where You Can Find More Information," carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 7of this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

	Per Share and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Public offering price	$ 4.500	$ 4.4999	$ 4,999,904
Underwriting discounts and commissions (1)	$ 0.315	$ 0.3150	$ 349,993
Proceeds to us, before expenses	$ 4.185	$ 4.1849	$ 4,649,911

(1) See "Underwriting" for additional information regarding underwriting compensation.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the securities offered hereby on or about November 7, 2024.

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The date of this prospectus is November 6, 2024.

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You should rely only on the information contained in this prospectus. No one has been authorized to provide you with information that is different from that contained in this prospectus. This prospectus is dated as of the date set forth on the cover hereof. You should not assume that the information contained in this prospectus is accurate as of any date other than that date.

For investors outside the United States: We and the underwriter have not done anything that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about, and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information about our company, this offering and information contained in greater detail in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere. You should read the entire prospectus, the registration statement of which this prospectus is a part, the "Risk Factors" section in this prospectus and the financial statements included elsewhere in this prospectus, before purchasing our securities in this offering.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to "the Company," "we," "us" and "our" refer to Sonnet BioTherapeutics Holdings, Inc. and our consolidated subsidiaries.

Corporate Overview

Sonnet BioTherapeutics Holdings, Inc. ("we," "us," "our" or the "Company"), is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single- or bi-functional action. Sonnet's F_HAB™ (Fully Human Albumin Binding) technology utilizes a fully human single chain antibody fragment that binds to and "hitch-hikes" on human serum albumin for transport to target tissues. We designed the construct to improve drug accumulation in the tumor microenvironment and lymph nodes, as well as to extend the duration of activity in the body. F_HAB development candidates are produced in a mammalian cell culture, which enables glycosylation, thereby reducing the risk of immunogenicity. We believe our lock-and-load F_HAB technology, for which we received a U.S. patent in June 2021, is a distinguishing feature of our biopharmaceutical platform that is well suited for future drug development across a range of human disease areas, including in oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

Lead Clinical Programs Update

SON-1010

Phase 1 Trial (SB101 Trial): Solid Tumors (Monotherapy)

This first-in-human study is primarily designed to evaluate the safety of multiple ascending doses of SON-1010 in cancer patients. The final dose escalation cohort has been fully enrolled and the trial is being conducted at sites in the United States.

Phase 1 Trial (SB102 Trial): Healthy Volunteers (Single dose)

A blinded randomized study in healthy volunteers that was focused on the pharmacokinetics (PK) and pharmacodynamics (PD) of SON-1010 has been completed. This study was done in Australia and established a safe first dose that is used to allow higher subsequent maintenance doses in cancer patients. This data was published on February 29, 2024.

Phase 1b/2a Trial (SB221 Trial): PROC (Combo with Atezolizumab)

The second trial is a Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study being conducted in the United States and Australia that targets platinum-resistant ovarian cancer (PROC). The goal is to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered subcutaneously (SC), either alone or in combination with atezolizumab given intravenously (IV).

Program Highlights:

- Human PK data reveals about 10-fold extended half-life for SON-1010 compared with rhIL-12 and suggests tumor targeting by the F_HAB.
- A dose-related IFNγ response has been shown with controlled and sustained peak levels. Data in mice suggests this is important for tumor control.
- The SB101, SB102 and SB221 trials have collectively enrolled 70 subjects. To date, 8 of 23 cancer patients (35%) had Stable Disease at 4 months, suggesting clinical benefit of SON-1010.
- Patients have received up to 22 cycles of SON-1010 as monotherapy and up to 18 cycles of SON-1010 with atezolizumab (Tecentriq®) without dose-limiting toxicity at any dose level.
- Toxicity is minimized in both trials with the use of a 'desensitizing' first dose that takes advantage of the known tachyphylaxis with rhIL-12, which allows higher maintenance doses and potential improvements in efficacy.
- Favorable safety profile.

Upcoming Milestones:

- Phase 1: Solid Tumors (Monotherapy)
  - Q4 2024: Safety Data
  - H1 2025: Topline Efficacy Data

- Phase 1b/2a: PROC (Combo with Atezolizumab)
  - Q4 2024: Additional Safety Data
  - H2 2025: RP2D & Topline Efficacy Data

SON-080

Phase 1b/2a Trial (SB211 Trial): Chemotherapy Induced Peripheral Neuropathy (CIPN)

The SB211 study is a double-blind, randomized, controlled trial of SON-080 conducted at two sites in Australia in patients with persistent CIPN using a new proprietary version of recombinant human Interleukin-6 (rhIL-6) that builds upon previous work done with atexakin alfa (low-dosage formulation of interleukin-6). The goal of the Phase 1b portion of the SB211 study was to confirm safety and tolerability before continued development in Phase 2. As previously announced in March 2024, a data and safety monitoring board reviewed the unblinded safety and tolerability of SON-080 in the first nine patients and concluded that the symptoms were tolerable in the initial patients and the study could proceed to Phase 2.

Phase 1b Data Highlights:

- SON-080 was demonstrated to be well-tolerated at both 20 µg and 60 µg/dose, which was about 10-fold lower than the MTD for IL-6 that had been established in previous clinical evaluations.
- Pain and quality of life survey results suggest the potential for rapid improvement of peripheral neuropathy symptoms and post-dosing durability with both doses, compared to placebo controls.

Upcoming Milestones:

- Initiate strategic oversight meeting with Alkem Laboratories Limited, a company organized under the laws of India ("Alkem"), focused on clinical development activities, subsequent to the announced licensing transaction on October 8, 2024, in support of the initiation of a Phase 2 clinical trial in DPN, a mechanistically synergistic and larger, high-value indication with unmet medical need.

Recent Developments

Issuance of U.S. Patent

In November 2024, we announced that the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 12,134,635 entitled "Interleukin 18 (IL-18) Variants and Fusion Proteins Comprising Same," covering two of our novel drug candidates, SON-1411 (IL-18^{BPR}-F_HAB-IL12) and SON-1400 (IL-18^{BPR}-F_HAB), each containing a modified version of recombinant human interleukin-18 (IL-$18^{BPR\ =\ Binding\ Protein\ Resistant}$). The patent carries a term effective until June 2044.

Alkem Licensing Agreement

In October 2024, we announced the execution of a license agreement with Alkem (the "Alkem Agreement") for the treatment of peripheral neuropathy (DPN) in India as well as the and the manufacturing, marketing and commercialization of SON-080 for the treatment of chemotherapy-induced peripheral neuropathy (CIPN) and autonomic neuropathy in India. Pursuant to the terms of the Alkem Agreement, Alkem will bear the cost of certain expenses, including conducting clinical studies, preparing and filing regulatory applications and undertaking other developmental and regulatory activities for and commercializing SON-080 for DPN in India. Alkem has agreed to pay us, within 12 weeks of the Effective Date of the Alkem Agreement, a $1,000,000 upfront non-refundable cash payment, of which $500,000 has been paid, as well as potential additional milestone payments totaling up to $1,000,000 subject to the achievement of certain development and regulatory milestones. In addition, Alkem is obligated to pay us a royalty equal to a percentage in the low double digits of net sales less Alkem's actual cost of goods sold and Alkem's sales and marketing and related expenses of SON-080 in India until the first commercial sale of a competitive Intermitted Low Dose IL-6 compound as set forth in the Alkem Agreement.

SB101 Enrollment

On September 18, 2024, we announced the completion of enrollment for dose escalation and initiation of dosing in our Phase 1 SB101 clinical trial of SON-1010 in adult patients with advanced solid tumors. We expect to report topline safety data from this study in Q4 2024. SB101 is our open-label, adaptive-design dose-escalation study to assess the safety, tolerability, and PK/PD of SON-1010 administered to patients with advanced solid tumors. Twenty-four subjects have been enrolled to date. Primary outcome measures for the study are to evaluate the safety and tolerability of SON-1010 and establish the maximum tolerated dose (MTD) of SON-1010.

Sarcoma Oncology Center Agreement

On August 19, 2024, we announced that we had entered into a Master Clinical Collaboration Agreement (the "Sarcoma Agreement") with the Sarcoma Oncology Center, to advance the development of SON-1210, our bifunctional IL12-F_HAB-IL15 asset. Preclinical data published on December 20, 2023 demonstrated the potential of SON-1210 for solid tumor immunotherapy. An Innovative Immuno Oncology Consortium ("IIOC") led by oncology experts funded by the Sarcoma Oncology Center will conduct an investigator-initiated Phase 1b/2a study of SON-1210 in pancreatic cancer. Under the terms of the Sarcoma Agreement, the IIOC, in collaboration with us, will prepare a protocol and conduct an investigator-initiated Phase 1b/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents for the specific treatment of metastatic pancreatic cancer. We will provide the study drug, SON-1210, and support operational services for the planned Phase 1b/2a study.

Nasdaq Letters and Reverse Stock Split

On August 5, 2024, we received a letter from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("The Nasdaq Stock Market") indicating that, based upon our non-compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market (the "Bid Price Requirement"), the Staff had determined to delist our securities from The Nasdaq Capital Market unless we timely request a hearing before the Nasdaq Hearing Panel (the "Panel"). The Nasdaq Listing Rules require listed securities to maintain a minimum bid price of $1.00 per share and, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet this requirement. Because we effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, the Staff did not grant additional time for us to regain compliance with the Bid Price Requirement.

On August 28, 2024, we received notice from The Nasdaq Stock Market that the Panel had granted us an exception until October 15, 2024 (the "Exception") to effect a reverse stock split of our common stock once approved by our stockholders, and regain compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under the Bid Price Requirement. In the event we failed to regain compliance with the Bid Price Requirement by October 15, 2024, our securities would have been delisted from The Nasdaq Capital Market. The Exception was granted following the Panel's review of an expired review questionnaire submitted by us to Nasdaq on August 19, 2024.

At our annual meeting of stockholders held on September 12, 2024, our stockholders voted to approve an amendment to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to effect a reverse stock split of our issued and outstanding shares of common stock, at a specific ratio, ranging from one-for-two (1:2) to one-for-twelve (1:12), at any time prior to the one-year anniversary date of the Annual Meeting, with the exact ratio to be determined by our board of directors. On September 25, 2024, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware, effected at 12:01 a.m. Eastern Time on September 30, 2024, a one-for-eight (1:8) reverse stock split of our issued and outstanding shares of common stock. On October 16, 2024, we received a letter from The Nasdaq Stock Market stating that because our shares had a closing bid price above $1.00 per share for 11 consecutive trading days, our common stock had regained compliance with the Bid Price Requirement of $1.00 per share for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2). We will be subject to a mandatory panel monitor for a period of one year from October 16, 2024. If, within that one-year monitoring period, the Staff finds us again out of compliance with the Minimum Bid Price Requirement, notwithstanding Nasdaq Listing Rule 5810(c)(2), then the Staff will issue a delist determination letter and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Panel if the initial Panel is unavailable.

Warrant Inducement Offering

On June 19, 2024, we entered into inducement offer letter agreements with holders of certain existing warrants issued in October 2023 having an original exercise price of $12.80 per share to purchase up to an aggregate of 353,562 shares of our common stock at a reduced exercise price of $9.60 per share (the "Warrant Inducement Offering"). The Warrant Inducement Offering closed on June 21, 2024, resulting in gross proceeds to us of $3.4 million and net proceeds of $2.9 million. Also, in connection with the Warrant Inducement Offering, we (i) issued to holders who participated in the transaction new common stock warrants to purchase an aggregate of 703,125 shares of common stock, (ii) reduced the exercise price of existing warrants to purchase 355,000 shares of common stock for those holders who did not exercise warrants in the transaction from $12.80 per share to $9.60 per share for the remaining term of the warrants, and (iii) reduced the exercise price of certain existing warrants issued in June 2023 to purchase 28,409 shares of common stock from $118.7824 per share to $12.40 per share and extended the expiration date of these warrants from December 30, 2026 to June 21, 2029. The new common stock warrants are immediately exercisable at a price of $12.40 per share and expire five years from the date of issuance. Warrants to purchase 14,142 shares of common stock were issued to the placement agent as compensation for its services related to the Warrant Inducement Offering. These common stock warrants are immediately exercisable at a price of $14.88 per share and expire five years from the date of issuance.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "*Risk Factors*" in this prospectus. These risks include, but are not limited to, the following:

- 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.
- Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.
- We will need significant additional capital, 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.
- 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.
- We are at an 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.
- We may not satisfy The Nasdaq Capital Market's requirements for continued listing of our common stock in the future. If we cannot satisfy these requirements, The Nasdaq Capital Market could delist our common stock.
- 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.
- 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 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.
- 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.
- 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.
- 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.
- We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We do not expect to pay cash dividends in the foreseeable future and therefore investors should not anticipate cash dividends on their investment.
- We may not satisfy The Nasdaq Capital Market's requirements for continued listing of our common stock in the future. If we cannot satisfy these requirements, The Nasdaq Capital Market could delist our common stock.

Corporate Information

We were organized on October 21, 1999, under the name Tulvine Systems, Inc., under the laws of the State of Delaware. On April 25, 2005, Tulvine Systems, Inc. formed a wholly owned subsidiary, Chanticleer Holdings, Inc., and on May 2, 2005, Tulvine Systems, Inc. merged with, and changed its name to, Chanticleer Holdings, Inc. On April 1, 2020, we completed our business combination with Sonnet BioTherapeutics, Inc. ("Sonnet"), in accordance with the terms of the Agreement and Plan of Merger, dated as of October 10, 2019, as amended, by and among us, Sonnet and Biosub Inc., a wholly-owned subsidiary of the Company ("Merger Sub") (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Sonnet, with Sonnet surviving as a wholly owned subsidiary of us (the "Merger"). Under the terms of the Merger Agreement, we issued shares of common stock to Sonnet's stockholders at an exchange rate of 0.106572 shares for each share of Sonnet common stock outstanding immediately prior to the Merger. In connection with the Merger, we changed our name from "Chanticleer Holdings, Inc." to "Sonnet BioTherapeutics Holdings, Inc.," and the business conducted by us became the business conducted by Sonnet.

Our principal executive offices are located at 100 Overlook Center, Suite 102, Princeton, New Jersey 08540, and our telephone number is (609) 375-2227. Our website is

www.sonnetbio.com. Our website and the information contained on, or that can be accessed through, our website shall not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on any such information in making your decision whether to purchase our securities.

THE OFFERING

The following summary contains basic information about this offering. This summary is qualified in its entirety by the more detailed information included in this prospectus. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus, including the information under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the financial statements included elsewhere in this prospectus.

Common Stock to be Offered	155,000 shares.
Pre-funded Warrants to be Offered	We are also offering pre-funded warrants to purchase up to an aggregate of 956,111 shares of common stock to those purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded warrants to purchase shares of common stock, in lieu of shares of common stock that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrant will equal the price at which the share of common stock and accompanying common warrant are being sold to the public in this offering, minus $0.0001, and the exercise price of each pre-funded warrant will be $0.0001 per share. The pre-funded warrants will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants.
Common Warrants to be Offered	Common warrants to purchase up to an aggregate of 2,222,222 shares of our common stock. Each share of our common stock and each pre-funded warrant to purchase one share of our common stock is being sold together with a common warrant to purchase two shares of our common stock. Each common warrant will have an exercise price of $4.50 per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The shares of common stock and pre-funded warrants, and the accompanying common warrants, as the case may be, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.

Common Stock to be Outstanding Immediately After this Offering (1)	837,659 shares, assuming none of the pre-funded warrants or the common warrants offered hereby are exercised.
Use of Proceeds	We estimate that the net proceeds from this offering will be approximately $4.2 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants and pre-funded warrants in this offering. We currently intend to use the net proceeds from this offering for research and development, including clinical trials, working capital, the repayment of all or a portion of our liabilities, and general corporate purposes. See "*Use of Proceeds*" for additional information.
Risk Factors	An investment in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 7 of this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities.
National Securities Exchange Listing	Our common stock is listed on The Nasdaq Capital Market under the symbol "SONN." There is no established public trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or common warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants or common warrants will be limited.

(1) The number of shares of our common stock that will be outstanding immediately after this offering is based on 682,659 shares of common stock outstanding as of November 1, 2024, and excludes:

- 9,175 shares of common stock underlying restricted stock units outstanding as of November 1, 2024;
- 7,977 shares of common stock subject to restricted stock awards granted as of November 1, 2024 but not yet issued;
- 1,265,972 shares of common stock issuable upon the exercise of warrants outstanding as of November 1, 2024, with a weighted average exercise price of $55.71 per share;
- 956,111 shares of common stock issuable upon the exercise of the pre-funded warrants issued in this offering; and
- 2,222,222 shares of common stock issuable upon the exercise of the common warrants issued in this offering.

Unless otherwise indicated, this prospectus reflects and assumes no issuances or exercises of any other outstanding shares, options, restricted stock units or warrants after November 1, 2024.

RISK FACTORS

An investment in our securities involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this prospectus and the other reports filed by us with the Securities and Exchange Commission (the "SEC"). The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our securities.

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. Our net losses for the fiscal years ended September 30, 2023 and 2022 were approximately $18.8 million and $29.7 million, respectively, and the nine months ended June 30, 2024 and 2023 were approximately $4.3 million and $15.2 million, respectively. As of June 30, 2024, we had an accumulated deficit of approximately $114.6 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.

We have incurred recurring losses and negative cash flows from operations activities since inception and we expect to generate losses and negative cash flows from operations for the foreseeable future primarily due to research and development costs for our potential product candidates. As of June 30, 2024, we had cash of $3,554,331 and stockholders' equity of $2,618,106. We believe our cash at June 30, 2024, together with the $4.4 million in net proceeds received from this offering, will fund our projected

operations through approximately March 2025, notwithstanding receipt of the following: we expect to receive a $0.7 million net cash refund from the research and development tax incentive program in Australia and recently received preliminary approval of our application to sell up to $8 million of our New Jersey state net operating losses for proceeds of up to $0.795 million through the Technology Business Tax Certificate Transfer Program, subject to execution of such sale; Alkem has also agreed to pay us a $1,000,000 upfront non-refundable cash payment within 12 weeks of the effective date of the Alkem Agreement, of which $500,000 has been paid.

Substantial additional financing will be needed by us to fund our operations. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We will require additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources to carry out our planned development activities. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. Various internal and external factors will affect whether and when our product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of our 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 our financial condition and future operations.

Operations since inception have consisted primarily of organizing us, securing financing, developing its technologies through performing research and development and conducting preclinical studies. We face 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.

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, for the nine months ended June 30, 2024 and 2023, we used $5,437,553 and $16,782,729, respectively, in net cash for our operating activities, substantially all of which related to research and development activities. For the fiscal years ended September 30, 2023 and 2022, we used $21,341,842 and $27,723,528, respectively, in net cash for our 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 will continue to 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

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 U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("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 an 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 was 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.

The widespread outbreak of communicable diseases 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 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. Many countries around the world may impose quarantines and restrictions on travel and mass gatherings to slow the spread of communicable diseases and close non-essential businesses. 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.

A 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 our ability to enroll patients. These situations could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and its financial condition. In particular, manufacturing of our pipeline products may be delayed by related supply chain issues, specifically supply of raw materials, including media, resins, and analytical kits, compounded by international shipping delays.

While the potential economic impact brought by, and the duration of the widespread outbreak of communicable diseases 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 any communicable disease could materially affect our business and the value of our common stock.

An 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 Active Pharmaceutical Ingredients (APIs) production, formulation, and drug manufacturing activities. A widespread pandemic would 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 widespread outbreak of communicable diseases 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 communicable disease disruptions or restrictions could have the potential to negatively impact our non-clinical studies, clinical trials, and drug manufacturing activities.

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 our 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., AstraZeneca, Pfizer, Eli Lilly, Gilead Sciences, Immunity Bio, GlaxoSmithKline plc, Xilio and Werewolf Therapeutics 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, Congressional and executive challenges to certain aspects 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.

On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

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. In August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that may impact our business if we ultimately have approved drugs. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delaying the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. In August 2023, the government selected the first 10 drugs to be put through the Medicare drug price negotiation program, which is currently subject to several constitutional challenges. The outcomes of most of these challenges on the IRA, and the effect of the IRA on our business and the healthcare industry in general, are not yet known.

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 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.

Recently enacted and future policies and legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the reimbursement made for any product candidate for which we receive marketing approval.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United. States, for example, the Patient Protection and Affordable Care Act ("PPACA") was enacted in 2010 to expand healthcare coverage and made significant changes to drug reimbursement. Other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since PPACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes Centers for Medicare and Medicaid Services ("CMS") to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. Complying with any new legislation could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services. Moreover, the Biden administration, including the Secretary of the United States Department of Human and Health Services, has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the United States, but our results of operations may be adversely

affected.

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 Therapeutics SA ("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 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.

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 November 5, 2024, our intellectual property portfolio includes 22 total pending patent applications and issued patents, inclusive of 2 issued patent in the U.S., 1 Decision to Grant in each of Japan, Russia and New Zealand, and 9 PCT applications within the 5007 patent family - also, 11 pending provisional and non-provisional applications covering formulations, manufacturing processes, novel fusion proteins and methods of use.

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 under the heading "BUSINESS", our PCT patent application having international patent application number PCT/US2018/00085 received an application filing date of February 20, 2018, which is four days after the one year anniversary of the filing date of U.S. provisional patent applications U.S. 62/459,975 and U.S. 62/459,981 to which the PCT patent application claims a priority benefit due to a computer issue at the PCT receiving office. Despite the restoration of the priority benefit to the filing date of U.S. provisional patent applications (U.S. 62/459,975 and U.S. 62/459,981) by the PCT, some countries in which national stage patent applications were filed from this PCT patent application did not accept this restoration including Canada and China, and the restoration procedure is pending in Brazil. In the event that priority is not restored, prior art may be available to these patent applications that may otherwise not be available to other patent applications filed from PCT/US2018/00085. This could affect the scope or breadth of the patent claims we are pursuing in Brazil, Canada, and China, 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 November 1, 2024, we had 13 full-time employees. 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.

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.

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.

We may not satisfy The Nasdaq Capital Market's requirements for continued listing of our common stock in the future. If we cannot satisfy these requirements, The Nasdaq Capital Market could delist our common stock.

Our common stock is listed on The Nasdaq Capital Market under the symbol "SONN." To continue to be listed on The Nasdaq Capital Market, we are required to satisfy a number of conditions. We cannot assure you that we will be able to satisfy The Nasdaq Capital Market listing requirements in the future. If we are delisted from The Nasdaq Capital Market, trading in our shares of common stock may be conducted, if available, on the "OTC Bulletin Board Service" or, if available, via another market. In the event of such delisting, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of the shares of our common stock, and our ability to raise future capital through the sale of the shares of our common stock or other securities convertible into or exercisable for our common stock could be severely limited. This could have a long-term impact on our ability to raise future capital through the sale of our common stock.

On August 5, 2024, we received a letter from the Staff of The Nasdaq Stock Market indicating that, based upon our non-compliance with the Bid Price Requirement, the Staff had determined to delist our securities from The Nasdaq Capital Market unless we timely request a hearing before the Panel. The letter stated that the Nasdaq Listing Rules require listed securities to maintain a minimum bid price of $1.00 per share and, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet this requirement. Because we effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, the Staff did not grant additional time for us to regain compliance with the Bid Price Requirement. On August 28, 2024, we received notice from The Nasdaq Stock Market that the Panel had granted us the Exception to effect a reverse stock split of our common stock once approved by our stockholders, and regain compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under the Bid Price Requirement. In the event we failed to regain compliance with the Bid Price Requirement by October 15, 2024, our securities would have been delisted from The Nasdaq Capital Market. The Exception was granted following the Panel's review of an expired review questionnaire submitted by us to Nasdaq on August 19, 2024. At our annual meeting of stockholders held on September 12, 2024, our stockholders approved an amendment to the Certificate of Incorporation and to effect a reverse stock split of our issued and outstanding shares of common stock, at a specific ratio, ranging from one-for-two (1:2) to one-for-twelve (1:12), at any time prior to the one-year anniversary date of the Annual Meeting, with the exact ratio to be determined by our board of directors. On September 25, 2024, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware, effected at 12:01 a.m. Eastern Time on September 30, 2024, a one-for-eight (1:8) reverse stock split of our issued and outstanding shares of common stock. On October 16, 2024, we received a letter from The Nasdaq Stock Market stating that because our shares had a closing bid price above $1.00 per share for 11 consecutive trading days, our common stock had regained compliance with the Bid Price Requirement of $1.00 per share for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2). However, we are still subject to a mandatory panel monitor for a period of one year from October 16, 2024. If, within that one-year monitoring period, the Staff finds us again out of compliance with the Minimum Bid Price Requirement, notwithstanding Nasdaq Listing Rule 5810(c)(2), then the Staff will issue a delist determination letter and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Panel if the initial Panel is unavailable.

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 incur significant costs and devote substantial management time as a result of operating as a public company, and we expect those costs to increase.

As a public company, we incur significant legal, accounting and other expenses. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. We currently do not have an internal audit function, and we have contracted for additional accounting and financial staff and may need to hire or contract for additional accounting and financial staff in the future with appropriate public company experience and technical accounting knowledge.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. 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 annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to detect or prevent error or fraud could materially adversely impact us.

Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We may not be able to complete our evaluation and testing of our internal control over financial reporting. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

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 we 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.

General Risk Factors

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 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. As of November 1, 2024, we have 9,175 shares of common stock reserved for issuance underlying restricted stock units and 1,265,972 shares of common stock reserved for issuance upon the exercise of outstanding warrants. We 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.

Risks Related to This Offering

If you purchase shares of common stock in this offering, you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity or equity-linked securities in the future.

Because the price per share of our common stock being offered is substantially higher than the as adjusted net tangible book value per share of our common stock, you will suffer immediate and substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on a combined public offering price of $4.50 per share of common stock and accompanying common warrant being sold in this offering, and our as adjusted net tangible book value as of June 30, 2024 of $3.87 per share, if you purchase securities in this offering, you will suffer immediate and substantial dilution of $0.63 per share with respect to the as adjusted net tangible book value of the common stock. See the section entitled "*Dilution*" for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

If we issue additional shares of common stock, or securities convertible into or exchangeable or exercisable for shares of common stock, our stockholders, including investors who purchase shares of common stock and/or pre-funded warrants and accompanying common warrants in this offering, will experience additional dilution, and any such issuances may result in downward pressure on the price of our common stock. We also cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

Future sales of substantial amounts of our common stock or securities convertible into or exchangeable or exercisable for shares of common stock, either by us or by our existing stockholders, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock or securities convertible into or exchangeable or exercisable for shares of common stock, including shares referred to in the foregoing risk factor, shares held by our existing stockholders or shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

There is no public market for the pre-funded warrants or common warrants being offered in this offering.

There is no established public trading market for the pre-funded warrants or common warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or common warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants and common warrants will be limited.

Holders of pre-funded warrants and common warrants purchased in this offering will have no rights as common stockholders until such holders exercise such warrants and acquire our common stock.

Until holders of pre-funded warrants or common warrants acquire shares of our common stock upon exercise of such warrants, holders of pre-funded warrants or common warrants will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the pre-funded warrants or common warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

We will have broad discretion in the use of our existing cash and cash equivalents, including the proceeds from this offering, and may invest or spend our cash in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of our cash and cash equivalents, including the proceeds from this offering. You may not agree with our decisions, and our use of cash may not yield any return on your investment. We intend to use the net proceeds from this offering for research and development, including clinical trials, working capital, the repayment of all or a portion of our liabilities, and general corporate purposes. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this prospectus other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, liquidity, future revenue, projected expenses, results of operations, expectations concerning the timing and our ability to commence and subsequently report data from planned non-clinical studies and clinical trials, prospects, plans and objectives of management are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in "*Risk Factors*" in this prospectus. These factors include, but are not limited to:

- our lack of operating history and history of operating losses;
- our need for significant additional capital and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our products and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- our ability to maintain the listing of our common stock on The Nasdaq Capital Market;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the emergence and effect of competing or complementary products, including the ability of our future products to compete effectively;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this prospectus. All forward-looking statements are qualified in their entirety by this cautionary statement.

You should also read carefully the factors described in the "*Risk Factors*" section of this prospectus to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised to consult any further disclosures we make on related subjects in our future public filings.

MARKET PRICE OF OUR COMMON STOCK

Market Information

Our common stock trades on The Nasdaq Capital Market under the symbol "SONN."

Holders of Record

As of November 1, 2024, we had 51 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $4.2 million from the sale of the securities offered by us in this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, excluding the proceeds, if any, from the exercise of the common warrants issued in this offering.

We currently intend to use the net proceeds from this offering for research and development, including clinical trials, working capital, general corporate purposes, and the repayment of all or a portion of our liabilities. See "*Risk Factors*" for a discussion of certain risks that may affect our intended use of the net proceeds from this offering.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for the purposes specified above, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our preclinical and clinical development programs, and whether we are able to enter into future licensing or collaboration arrangements.

Pending the use of the net proceeds from this offering, we intend to invest the net proceeds in investment-grade, interest-bearing instruments, certificates of deposit or direct or guaranteed obligations of the U.S.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2024, as follows:

- on an actual basis; and
- on an "as adjusted" basis to give further effect to our sale of shares of our common stock in this offering at a combined public offering price of $4.50 per share of common stock and accompanying common warrant, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and assuming solely for this purpose the full exercise of all of the pre-funded warrants sold in this offering and no exercise of the common warrants sold in this offering.

You should read this table together with the information under the heading "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included elsewhere in this prospectus. We are unable to predict the actual level of participation in the offering.

	As of June 30, 2024 (in thousands)	
(In Thousands)	**Actual**	**As Adjusted**
Cash	$ 3,554	$ 7,756
Total liabilities	3,179	3,179
Stockholders' equity (deficit):		
Common stock, 125,000,000 authorized shares; $0.0001 par value; 652,313 shares issued and outstanding, actual, 1,763,424 shares issued and outstanding, on an as adjusted basis		
Additional paid-in capital	117,170	121,372
Accumulated deficit	(114,552)	(114,552)
Total stockholders' equity (deficit)	$ 2,618	$ 6,820

The table and discussion above is based on 652,313 shares of common stock outstanding as of June 30, 2024 and excludes:

- 9,175 shares of common stock underlying unvested restricted stock units outstanding as of June 30, 2024;
- 7,977 shares of common stock subject to restricted stock awards granted as of June 30, 2024 but not yet issued;
- 1,265,972 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2024, with a weighted average exercise price of $55.71 per share; and
- 2,222,222 shares of common stock issuable upon the exercise of the common warrants issued in this offering.

Except as indicated otherwise, the discussion and table above assume solely for this purpose the full exercise of all of the pre-funded warrants sold in this offering and no exercise of the common warrants sold in this offering.

DILUTION

If you invest in our securities, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after the closing of this offering.

Our historical net tangible book value as of June 30, 2024 was $2,618,106, or $4.01 per share of common stock. Our historical net tangible book value is the amount of our total tangible assets less our liabilities. Historical net tangible book value per common share is our historical net tangible book value divided by the number of shares of common stock outstanding as of June 30, 2024.

After giving effect to the sale of 155,000 shares of common stock and accompanying common warrants at a combined public offering price of $4.50 per share and accompanying common warrants and pre-funded warrants to purchase up to an aggregate of 956,111 shares of common stock and accompanying common warrants at a combined public offering price of $4.4999 per pre-funded warrant and accompanying warrants in this offering, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, excluding the proceeds, if any, from the exercise of the common warrants issued in this offering, and assuming all of the pre-funded warrants offered in this offering are exercised, our as adjusted net tangible book value as of June 30, 2024 would have been approximately $6.8 million, or $3.87 per share of common stock. This amount represents an immediate decrease in net tangible book value of $0.14 per share to our existing stockholders and an immediate dilution of $0.63 per share to investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting as adjusted net tangible book value per share after this offering from the combined public offering price per share paid by investors participating in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Combined public offering price per share and accompanying common warrant			$	4.50
Historical net tangible book value per share as of June 30, 2024	$	4.01		
Decrease in net tangible book value per share attributable to this offering	$	0.14		
Net tangible book value per share after giving effect to this offering			$	3.87
Dilution per share to new investors in this offering			$	0.63

The table and discussion above is based on 652,313 shares of common stock outstanding as of June 30, 2024 and excludes:

- 9,175 shares of common stock underlying unvested restricted stock units outstanding as of June 30, 2024;
- 7,977 shares of common stock subject to restricted stock awards granted as of June 30, 2024 but not yet issued;
- 1,265,972 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2024, with a weighted average exercise price of $55.71 per share; and
- 2,222,222 shares of common stock issuable upon the exercise of the common warrants issued in this offering.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus, particularly those under "Risk Factors."

Overview

We are a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single or bifunctional action. Known as F_HAB™ (Fully Human Albumin Binding), the technology utilizes a fully human single-chain variable fragment (scFv) that binds to and "hitchhikes" on serum albumin for transport to target tissues. We designed the construct to improve drug accumulation in solid tumors, as well as to extend the duration of activity in the body. F_HAB development candidates can be produced in mammalian cell culture, which enables glycosylation of the interleukins, thereby reducing the risk of immunogenicity, as well as E. coli. We believe our F_HAB technology, for which we received an initial U.S. patent in June 2021 and a continuation of such patent in June 2024, is a distinguishing feature of our biopharmaceutical platform. The approach is well suited for future drug development across a range of human disease areas, including in oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

Our current internal pipeline development activities are focused on cytokines, which are a class of cell signaling molecules that serve as potent immunomodulatory agents. Working both independently and synergistically, specific cytokines have shown the ability to modulate the activation and maturation of immune cells to help fight cancer and pathogens. However, because they do not preferentially accumulate in specific tissues and are quickly eliminated from the body, the conventional approach to achieving a treatment effect with cytokine therapy typically requires the administration of high and frequent doses. This can result in the potential for systemic toxicity, which poses challenges to the therapeutic application of this class of drugs.

Our lead proprietary asset, SON-1010, is a single-chain version of human Interleukin 12 ("IL-12"), covalently linked to the F_HAB construct, for which we are pursuing clinical development in solid tumor indications, including ovarian cancer, non-small cell lung cancer and head and neck cancer. In March 2022, the FDA cleared our Investigational New Drug ("IND") application for SON-1010. This allowed us to initiate a U.S. clinical trial (SB101) in oncology patients with solid tumors during the second calendar quarter of 2022. In September 2021, we created a wholly-owned Australian subsidiary, SonnetBio Pty Ltd ("Subsidiary"), for the purpose of conducting certain clinical trials. We received approval and initiated an Australian clinical study (SB102) of SON-1010 in healthy volunteers during the third calendar quarter of 2022. Interim safety and tolerability data from the SB101 and SB102 studies were reported in April 2023.

In January 2023, we announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). The companies have entered into a Master Clinical Supply Agreement ("MCSA"), along with associated Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer ("PROC") patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). Part 1 of this 2-part study was approved in June 2023 by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. In August 2023, the FDA accepted the IND for the use of SON-1010 in ovarian cancer. The SB221 trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose ("MTD") of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose ("RP2D"). Part 2 of the study will then investigate SON-1010 in combination with atezolizumab versus the standard of care ('SOC") for PROC in a randomized comparison to show proof-of-concept ("POC").

We acquired the global development rights to our most advanced compound, SON-080, a fully human version of Interleukin 6 ("IL-6"), in April 2020 through our acquisition of the outstanding shares of Relief Therapeutics SA. We are advancing SON-080 in target indications of Chemotherapy-Induced Peripheral Neuropathy ("CIPN") and Diabetic Peripheral Neuropathy ("DPN"). We received approval to initiate an ex-U.S. Phase 1b/2a study with SON-080 in CIPN in July 2022. Enrollment of the first portion of the SB211 study in chemotherapy-induced peripheral neuropathy (CIPN) has been completed, and the Data Safety Monitoring Board completed its review of the preliminary safety data during the first calendar quarter of 2024, clearing the trial to proceed to Part 2. Pursuant to a license agreement we entered into with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, we and New Life will be jointly responsible for developing SON-080 in DPN. The objective will be to analyze the data and to consider initiating a Phase 2 study, pending the outcome of any partnering activity. In addition, in October 2024 we entered into with Alkem Laboratories Limited ("Alkem") in October 2024, for the research, development, manufacturing, marketing and commercialization of SON-080 for the treatment of DPN in India and the manufacturing, marketing and commercialization of CIPN and autonomic neuropathy in India.

SON-1210 (IL12-F_HAB-IL15), our lead bifunctional construct, combines F_HAB with single-chain human IL-12 and human Interleukin 15 ("IL-15"). This compound is being developed for solid tumor indications, including colorectal cancer. In February 2023, we announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. In August 2024, we entered into a Master Clinical Collaboration Agreement with the Sarcoma Oncology Center, to advance the development of SON-1210 in combination with chemotherapy for the treatment of metastatic pancreatic cancer. We anticipate initiating a Phase 1b/2a study in this indication during 1H 2025.

SON-1411 (IL18-F_HAB-IL12) is a bifunctional combination of human Interleukin 18 ("IL-18"), which was modified to resist interaction with the IL-18 inhibitor binding protein, and single-chain human IL-12 for solid tumor cancers. SON-1400 is a monofunctional fusion protein comprising the same IL-18 domain linked to the F_HAB. Cell line development and process development are ongoing, with early experimental drug supply suitable for formulation and analytical method development activities. SON-1411 has replaced SON-1410 as a development target.

We have completed sequence confirmation for SON-3015 (anti-IL6-F_HAB-anti-TGFβ). Early-stage bifunctional drug has been generated and is being stored for future use in in vivo mice studies. In Q4 2022, we elected to place the SON-3015 development program on hold for expense reduction purposes.

As part of the ongoing cost-cutting evaluations, all antiviral development with SON-1010 has been suspended.

We have incurred recurring operating losses and negative cash flows since inception. Our 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 our current or future product candidates. Our net losses were $4.3 million and $15.2 million for the nine months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had cash of $3.6 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct additional clinical trials for product candidates;
- continue to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approval for product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our operation as a public reporting company.

We will not generate revenue from product sales, if any, unless and until we receive licensing revenue and/or successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. We will continue to incur significant costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, including sales pursuant to our Purchase Agreement with Chardan Capital Markets, LLC ("Chardan") related to the Facility, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We 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 we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis or raise additional capital or enter into collaboration or license agreements, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate operations.

Since our inception in 2015, we have devoted substantially all of our 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 product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from sales of common stock, warrants and proceeds from the issuance of convertible debt.

Components of Results of Operations

Collaboration Revenue

Collaboration revenue is currently earned from the license arrangement entered into with New Life in May 2021, which granted New Life rights to an exclusive license (with the

right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in the Exclusive Territory. We identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the "License"); and (ii) transfer of know-how and clinical development and regulatory activities ("R&D Activities"). We determined that the License and the R&D Activities are not distinct from each other and, therefore, combined these material promises into a single performance obligation. Under this agreement, we received upfront cash payments totaling $1.0 million, which were fully allocated to the single performance obligation and are being recognized over the estimated performance period of R&D Activities.

Collaboration revenue is expected to be earned from the license agreement entered into with Alkem in October 2024. Pursuant to the terms of the Alkem Agreement, Alkem will bear the cost of certain expenses, including conducting clinical studies, preparing and filing regulatory applications and undertaking other developmental and regulatory activities for and commercializing SON-080 for DPN in India. Alkem has agreed to pay us, within twelve (12) weeks of the Effective Date of the Alkem Agreement, a $1,000,000 upfront non-refundable cash payment, of which $500,000 has been paid, as well as potential additional milestone payments to us totaling up to $1,000,000 subject to the achievement of certain development and regulatory milestones. In addition, Alkem is obligated to pay us a royalty equal to a percentage in the low double digits of net sales less Alkem's actual cost of goods sold and Alkem's sales and marketing and related expenses of SON-080 in India until the first commercial sale of a competitive Intermitted Low Dose IL-6 compound as set forth in the Alkem Agreement.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred and such costs include:

- employee-related expenses, including salaries, share-based compensation and related benefits, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and clinical research organizations;
- the cost of manufacturing drug products for use in our 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.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided by our service providers. This process involves reviewing open contracts and purchase orders, communicating with their personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of 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.

Our 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 preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under third-party license agreements. We do not allocate employee costs and costs associated with 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. We use internal resources primarily to conduct our research and discovery as well as for managing preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and therefore, we do not track costs by product candidate.

We will continue to incur research and development expenses for the foreseeable future as we attempt to advance development of our product candidates. The successful development of our product candidates is highly uncertain. At this time, we 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 our current pipeline or any future product candidates we 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 we decide to pursue;
- our ability to maintain our 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;
- our ability to establish new licensing or collaboration arrangements;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of product candidates, if approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and

- the potential impact of the widespread outbreak of any communicable disease 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 our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation, 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.

Our general and administrative expenses will increase in the future as we increase our headcount to support continued research activities and development of product candidates. We will continue to 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.

Other Income

We have participated in the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by the New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused net operating losses and unused research and development credits to sell these tax benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the state of New Jersey. Other income consists of net proceeds from the sale of New Jersey state net operating losses through the Program. We plan to sell additional net operating losses under the Program in the future, subject to program availability and state approval.

Foreign Exchange Gain (Loss)

Foreign exchange gain (loss) consists of net exchange rate changes on transactions denominated in currencies other than the U.S. dollar.

Results of Operations

Comparison of the Nine Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended June 30, 2024 and 2023:

	Nine Months Ended June 30,		
	2024	**2023**	**Change**
Collaboration revenue	$ 18,626	$ 110,550	$ (91,924)
Operating expenses:			
Research and development	4,538,363	9,972,055	(5,433,692)
General and administrative	4,156,360	5,330,967	(1,174,607)
Total operating expenses	8,694,723	15,303,022	(6,608,299)
Loss from operations	(8,676,097)	(15,192,472)	6,516,375
Other income	4,327,946	-	4,327,946
Foreign exchange gain	39,512	36,517	2,995
Net loss	$ (4,308,639)	$ (15,155,955)	$ 10,847,316

Collaboration Revenue

We recognized $18,626 of revenue related to the New Life Agreement during the nine months ended June 30, 2024, compared to $0.1 million during the nine months ended June 30, 2023. The decrease of $0.1 million was due to our completion of R&D Activities during the first quarter of fiscal 2024.

Research and Development Expenses

Research and development expenses were $4.5 million for the nine months ended June 30, 2024, compared to $10.0 million for the nine months ended June 30, 2023. The decrease of $5.4 million was primarily due to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 in the amount of $1.0 million, as well as due to cost saving initiatives, as we are managing expenses for liquidity purposes and are tightening our focus on the research and development projects we have assessed to have the greatest near-term potential. In addition to transitioning product development activities to cost advantaged locations such as India and Australia, we reduced expenditures on tertiary programs and suspended antiviral development related to SON-1010, as well as programs related to SON-080 and SON-1210 while we seek partnering opportunities.

General and Administrative Expenses

General and administrative expenses were $4.2 million for the nine months ended June 30, 2024, compared to $5.3 million for the nine months ended June 30, 2023. The decrease of $1.2 million related primarily to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 in the amount of $0.9 million, and cost saving initiatives, as we are managing expenses for liquidity purposes, and a decrease in consulting expenses related to licensing, partially offset by costs incurred in connection with the Purchase Agreement.

Other Income

Other income for the nine months ended June 30, 2024 of $4.3 million was due to net proceeds received in the second fiscal quarter of 2024 from the sale of New Jersey state net operating losses.

Comparison of the Years Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the years ended September 30, 2023 and 2022:

	Years ended September 30,		
	2023	2022	Change
Collaboration revenue	$ 147,805	$ 349,943	$ (202,138)
Operating expenses:			
Research and development	11,814,690	21,444,019	$ (9,629,329)
General and administrative	7,125,732	8,575,283	(1,449,551)
Total operating expense	18,940,422	30,019,302	(11,078,880)
Loss from operations	(18,792,617)	(29,669,359)	10,876,742
Foreign exchange loss	(40,077)	(52,482)	12,405
Net loss	$ (18,832,694)	$ (29,721,841)	$ 10,889,147

Collaboration Revenue

We recognized $0.1 million of revenue related to the New Life Agreement during the year ended September 30, 2023 compared to $0.3 million during the year ended September 30, 2022. The decrease of $0.2 million was due to a delay in timing in the performance of R&D services.

Research and Development Expenses

Research and development expenses were $11.8 million for the year ended September 30, 2023, compared to $21.4 million for the year ended September 30, 2022. The decrease of $9.6 million was primarily due to the establishment of cost savings by transitioning product development activities to cost advantaged locations such as India and Australia, by reducing expenditures on tertiary programs such as SON-3015, which has been placed on a development hold, and suspending antiviral development related to SON-1010, as well as a decrease in share-based compensation expense.

General and Administrative Expenses

General and administrative expenses were $7.1 million for the year ended September 30, 2023, compared to $8.6 million for the year ended September 30, 2022. The decrease of $1.5 million relates primarily to a decrease in share-based compensation, legal and business development expenses, as we are managing expenses for liquidity purposes and are tightening our focus on the research and development projects we have assessed to have the greatest near-term potential.

Liquidity and Capital Resources

We have funded operations to date primarily with proceeds from sales of common stock, warrants and proceeds from the issuance of convertible debt. We will likely offer additional securities for sale in response to market conditions or other circumstances, including sales to Chardan pursuant to the Facility, if we believe such a plan of financing is required to advance our business plans and is in the best interests of our stockholders. There is no certainty that equity or debt financing will be available in the future or that it will be at acceptable terms and at this time, it is not possible to predict the outcome of these matters.

We have incurred net losses of $4.3 million and $15.2 million for the nine months ended June 30, 2024 and 2023, respectively, and net losses of $18.8 million and $29.7 million for the years ended September 30, 2023 and 2022, respectively. At June 30, 2024 and at September 30, 2023, we had an accumulated deficit of $114.6 million and $110.2 million, respectively. We expect to continue to incur significant operational expenses and net losses in the upcoming 12 months and beyond. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the stage and complexity of our R&D studies and related expenditures, the receipt of additional payments on the licensing of our technology, if any, and the receipt of payments under any current or future collaborations we may enter into.

We have evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We believe our cash of $3.6 million at June 30, 2024 will fund our projected operations into November 2024. We received approval of our application to sell up to approximately $8.1 million of our New Jersey State net operating losses (NOLs) and $62,810 of our New Jersey State research and development (R&D) tax credits for proceeds of up to $0.795 million through the New Jersey Technology Business Tax Certificate Transfer Program, subject to execution of such sale. We also expect to receive a $0.7 million net cash refund from the R&D Tax Incentive Program in Australia. Substantial additional financing will be needed by us to fund our operations. These factors raise substantial doubt about our ability to continue as a going concern.

Comparison of the Nine Months Ended June 30, 2024 and 2023

The following table summarizes our sources and uses of cash for the nine months ended June 30, 2024 and 2023:

	Nine Months Ended June 30,	
	2024	2023
Net cash used in operating activities	$ (5,437,553)	$ (16,782,729)
Net cash used in investing activities	(12,000)	(273,250)
Net cash provided by financing activities	6,729,625	21,024,171
Net increase in cash	$ 1,280,072	$ 3,968,192

Operating Activities

During the nine months ended June 30, 2024, we used $5.4 million of cash in operating activities which was primarily attributable to our net loss of $4.3 million and a $2.5 million net decrease in accounts payable and accrued expenses and other current liabilities primarily due to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 and the decrease in research and development expenses; offset by a $0.9 million net decrease in prepaid expenses and other current assets and incentive tax receivable, primarily related to the collection of the incentive tax receivable for fiscal year 2023, and $0.4 million in financing costs related to the Facility that were required to be charged to general and administrative expenses.

During the nine months ended June 30, 2023, we used $16.8 million of cash in operating activities which was primarily attributable to our net loss of $15.2 million, a $0.3 million increase in prepaid expenses and other current assets primarily due to cash outflows for research and development activities, a $1.7 million net decrease in accounts payable and accrued expenses and other current liabilities, and a $0.1 million reduction in deferred income as we recognized collaboration revenue from the New Life Agreement, offset by $0.3 million in acquired in-process research and development and $0.2 million in share-based compensation expense.

Investing Activities

During the nine months ended June 30, 2024 and 2023, we used $12,000 and $0.3 million, respectively, for the purchase of acquired in-process research and development.

Financing Activities

During the nine months ended June 30, 2024, net cash provided by financing activities was $6.7 million, consisting primarily of net proceeds from the sale of common stock and pre-funded warrants in a public offering in the amount of $3.9 million and proceeds from the exercise of warrants in the amount of $3.0 million, offset by $0.2 million of financing costs paid in connection with the Facility.

During the nine months ended June 30, 2023, net cash provided by financing activities was $21.0 million, consisting of net proceeds from the sale of common stock under an at-the-market facility and through registered public offerings.

Comparison of the Years Ended September 30, 2023 and 2022

The following table summarizes our sources and uses of cash for the years ended September 30, 2023 and 2022:

	Year ended September 30,	
	2023	**2022**
Net cash used in operating activities	$ (21,341,842)	$ (27,773,528)
Net cash used in investing activities	(443,250)	(810,227)
Net cash provided by financing activities	21,006,472	4,014,567
Net decrease in cash	$ (778,620)	$ (24,569,188)

Operating Activities

During the year ended September 30, 2023, we used $21.3 million of cash in operating activities which was primarily attributable to our net loss of $18.8 million, a $0.5 million net increase in prepaid expenses and other assets primarily due to cash outflows for research and development activities and a $2.4 million net decrease in accounts payable and accrued expenses primarily due to the decrease in research and development expenses, offset by $0.3 million in acquired in-process research and development and $0.2 million in share-based compensation expense.

During the year ended September 30, 2022, we used $27.8 million of cash in operating activities which was primarily attributable to our net loss of $29.7 million. This amount was offset by $0.9 million of share-based compensation expense and $1.0 million of acquired in-process research and development, and a $0.1 million net decrease in operating assets and liabilities.

Investing Activities

During the year ended September 30, 2023, we used $0.4 million of cash in investing activities for the purchase of acquired in-process research and development.

During the year ended September 30, 2022, we used $0.8 million of cash in investing activities for the purchase of acquired in-process research and development.

Financing Activities

During the year ended September 30, 2023, net cash provided by financing activities was $21.0 million, consisting primarily of net proceeds from the sale of common stock under an at-the-market facility and through and underwritten public offering and a registered direct offering.

During the year ended September 30, 2022, net cash provided by financing activities was $4.0 million, consisting primarily of net proceeds from the sale of preferred stock and warrants and net proceeds from the sale of common stock.

Funding Requirements

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we advance preclinical activities and clinical trials of product candidates in development. In addition, we expect to continue to incur costs associated with operating as a public company. The timing and amount of our 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 our current or future product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates and programs that we develop 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 we perform more studies for our product candidates than those that we currently expect;
- our ability to obtain marketing approval for product candidates;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights covering our product candidates;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities with respect to product candidates;

- our ability to establish and maintain licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain 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 we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the success of any other business, product or technology that we acquire or in which we invest;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our 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 our business;
- market acceptance of our product candidates, to the extent any are approved for commercial sale;
- the effect of competing technological and market developments; and
- the potential impact of a widespread outbreak of any communicable disease on our clinical trials and operations.

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

October 2023 Offering

On October 26, 2023, we closed a public offering of common stock and certain warrants through Chardan and Ladenburg Thalmann & Co. Inc. as underwriters, for net proceeds of $3.9 million through the issuance and sale of 163,281 shares of our common stock and, to certain investors, pre-funded warrants to purchase 192,187 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 710,937 shares of our common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was $12.80 and the public offering price of each pre-funded warrant and accompanying common warrant was $12.7992. The common warrants were immediately exercisable at a price of $12.80 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision. In connection with the June 2024 inducement offering discussed further below, the exercise price was decreased to $9.60 per share of common stock for common warrants that remained unexercised at the time of the offer. The pre-funded warrants were immediately exercisable at any time, until exercised in full, at a price of $0.0001 per share of common stock. In addition, warrants to purchase 10,664 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of $2.00 per share and expire five years from the date of issuance.

Committed Equity Facility

On May 2, 2024, we entered into a ChEF Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement"), each with Chardan, related to a "ChEF," Chardan's committed equity facility (the "Facility"). Pursuant to the Purchase Agreement, we have the right from time to time at our option to sell to Chardan up to the lesser of (i) $25.0 million in aggregate gross purchase price of newly issued shares of our common stock and (ii) 77,771 shares of our common stock, which is equal to 19.99% of the shares of common stock outstanding immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) the average price of such shares sold to Chardan under the Facility equals or exceeds the base price set forth in the Purchase Agreement, so that the Exchange Cap limitation would not apply to such issuances and sales pursuant to the Purchase Agreement under the rules of the Nasdaq Stock Market or (ii) our stockholders approve the issuance of common stock pursuant to the Purchase Agreement in excess of the Exchange Cap. The Facility will allow us to raise primary equity on a periodic basis at our sole discretion depending on a variety of factors including, among other things, market conditions, the trading price of the common stock, and determinations by us regarding the use of proceeds of such common stock. The purchase price of the shares of common stock will be determined by reference to the Volume Weighted Average Price ("VWAP") of the common stock during the applicable purchase period, less a fixed 4% discount to such VWAP, and the total shares to be purchased on any day may not exceed 20% of the trading volume of our common stock during the applicable purchase period. The Purchase Agreement will be effective for a 36-month period ending May 16, 2027, unless earlier terminated upon the terms and conditions therein. During the three and nine months ended June 30, 2024, we sold 4,706 shares of common stock pursuant to the Purchase Agreement for net proceeds of $0.1 million.

June 2024 Inducement Offering

On June 19, 2024, we entered into inducement offer letter agreements with holders of certain existing warrants issued in October 2023 having an original exercise price of $12.80 per share to purchase up to an aggregate of 2,828,500 shares of our common stock at a reduced exercise price of $9.60 per share. The transaction closed on June 21, 2024, resulting in gross proceeds of $3.4 million and net proceeds of $2.9 million. Due to beneficial ownership limitations, 187,500 shares of common stock related to the exercise of warrants in this transaction are being held in abeyance as of June 30, 2024. Also in connection with this inducement offer, we (i) issued to holders who participated in the transaction new common stock warrants to purchase an aggregate of 703,125 shares of common stock, (ii) reduced the exercise price of existing warrants to purchase 355,000 shares of common stock for those holders who did not exercise warrants in the transaction from $12.80 per share to $9.60 per share for the remaining term of the warrants, and (iii) reduced the exercise price of certain existing warrants issued in June 2023 to purchase 28,409 shares of common stock from $118.7824 per share to $12.40 per share and extended the expiration date of these warrants from December 30, 2026 to June 21, 2029. The new common stock warrants are immediately exercisable at a price of $12.40 per share and expire five years from the date of issuance. Warrants to purchase 14,142 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants are immediately exercisable at a price of $14.88 per share and expire five years from the date of issuance.

Alkem Licensing Agreement

In October 2024, we announced the execution of the Alkem Agreement for the treatment of peripheral neuropathy (DPN) in India as well as the and the manufacturing, marketing and commercialization of SON-080 for the treatment of chemotherapy-induced peripheral neuropathy (CIPN) and autonomic neuropathy in India. Pursuant to the terms of the Alkem Agreement, Alkem will bear the cost of certain expenses, including conducting clinical studies, preparing and filing regulatory applications and undertaking other developmental and regulatory activities for commercializing SON-080 for DPN in India. Alkem has agreed to pay us, within 12 weeks of the Effective Date of the Alkem Agreement, a $1,000,000 upfront non-refundable cash payment, of which $500,000 has been paid, as well as potential additional milestone payments totaling up to $1,000,000 subject to the achievement of certain development and regulatory milestones. In addition, Alkem is obligated to pay us a royalty equal to a percentage in the low double digits of net sales less Alkem's actual cost of goods sold and Alkem's sales and marketing and related expenses of SON-080 in India until the first commercial sale of a competitive Intermitted Low Dose IL-6 compound as set forth in the Alkem Agreement.

Contractual Obligations and Commitments

The following summarizes our contractual obligations as of June 30, 2024 that will affect our future liquidity. Our estimated future contractual obligations consist of operating lease liabilities. As of June 30, 2024, we had $81,349 in short-term operating lease liabilities and $68,837 in long-term operating lease liabilities.

In addition to the operating lease, we have 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 cancellable 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-cancellable obligations to our service providers, up to the date of cancellation.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to the accrual for research and development expenses. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to the unaudited interim consolidated financial statements included elsewhere in this prospects, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of the consolidated financial statements.

Research and Development Expenses

Research and development expenses include all direct and indirect costs associated with the development of our biopharmaceutical products. These expenses include personnel costs, consulting fees, and payments to third parties for research, development and manufacturing services. These costs are charged to expense as incurred.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the related project, based on the measure of progress as defined in the contract. Factors we consider in preparing the estimates include costs incurred by the service provider, milestones achieved, and other criteria related to the efforts of our service providers. Such estimates are subject to change as additional information becomes available. Depending on the timing of payment to the third-party service providers and the progress we estimate has been made as a result of the service provided, we will record a prepaid expense or accrued liability related to these costs. Contingent development or regulatory milestone payments are recognized upon the related resolution of such contingencies. As of June 30, 2024, we did not make any material adjustments to our prior estimates of accrued research and development expenses.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to the consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

Sonnet BioTherapeutics Holdings, Inc., is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single- or bifunctional action. Known as F_HAB™ (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. We designed the F_HAB construct to improve drug accumulation in tumors, as well as to extend the duration of activity in the body. F_HAB development candidates are produced in a mammalian cell culture, which enables glycosylation and a biological structure similar to the natural cytokines *in vivo*, as well as in *E. coli.* We believe our F_HAB technology, for which we received a U.S. patent in June 2021, is a distinguishing feature of our biopharmaceutical platform that is well suited for future drug development across a range of human disease areas, including oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

Our current internal pipeline development activities are focused on cytokines, a class of cell signaling peptides that, among other important functions, serve as potent immunomodulatory agents. Working both independently and synergistically, specific cytokines have shown the ability to modulate the activation and maturation of immune cells that fight cancer and pathogens. However, cytokines on their own do not preferentially accumulate in specific tissues and are quickly eliminated from the body. The conventional approach to achieving a treatment effect with cytokine therapy typically requires the administration of high and frequent doses. This can result in a reduced treatment effect accompanied by the potential for systemic toxicity, which poses challenges to the therapeutic application of this class of drugs.

We have built an efficient R&D platform that includes a network of outsourced vendors to help remediate expenses and improve execution timelines. Most of the vendors are strategic collaborators that offer the company a preferred status with negotiated costs. The major advantages of this approach include optimized direct investment into projects with expenses that can be rapidly scaled up or down depending on the number of projects. The cost advantages of the Sonnet platform start at the vendor network selection process, with CMC being one of the most expensive components of the initial drug development step. We have chosen a strategic CMC collaborator in India and has negotiated the cost to be significantly less than the expense incurred from a similar U.S.- or Europe-based vendor. We are conducting two of our three ongoing clinical trials in Australia, which carries a substantial cost reduction relative to U.S. trials via the Australian government's R&D tax credit program. We are also coordinating the Indian and Australian execution with top R&D vendors from the U.S., England, Germany, and Switzerland, with the objective of directing the bulk of our operating expense infrastructure towards our drug development pipeline.

Pipeline

We have a pipeline of therapeutic compounds focused primarily on oncology indications of high unmet medical need.

- Our lead proprietary asset, SON-1010, is a fully human single-chain version of Interleukin 12 (IL-12), covalently linked to the F_HAB construct, for which we are pursuing clinical development in solid tumors. Sonnet has completed a non-human primate (NHP) toxicity study, conducted under current Good Laboratory Practices (cGLP), and has successfully manufactured both liquid and lyophilized forms of the drug product for clinical use. In March 2022, the FDA cleared Sonnet's Investigational New Drug (IND) application for SON-1010. This allowed us to initiate a U.S. clinical trial (SB101) in oncology patients with solid tumors during the second calendar quarter of 2022. In September 2021, we created a wholly-owned Australian subsidiary, SonnetBio Pty Ltd ("Subsidiary"), for the purpose of conducting certain clinical trials. We received approval and initiated a clinical study (SB102) of SON-1010 in Australian healthy volunteers during the third calendar quarter of 2022. Interim safety and tolerability data from the SB101 and SB102 studies were reported in April 2023 and published in February 2024. In January 2023, we announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). We have entered into a Master Clinical Trial and Supply Agreement (MCSA) with Roche, along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer (PROC) patient setting. Further, we and Roche will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). That trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose (MTD) of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose (RP2D). Part 2 of the study will then investigate SON-1010 monotherapy or its use in combination with atezolizumab with the standard of care (SOC) for PROC in a randomized comparison to show proof-of-concept (POC). As part of our ongoing cost-cutting evaluations, all antiviral development with SON-1010 has been suspended. On September 18, 2024, we announced the completion of enrollment and initiation of dosing in our Phase 1 SB101 clinical trial of SON-1010 in adult patients with advanced solid tumors. We expect to report topline data from this study in Q4 2024. SB101 is our open-label, adaptive-design dose-escalation study to assess the safety, tolerability, and PK/PD of SON-1010 administered to patients with advanced solid tumors. The study enrolled 24 subjects. Primary outcome measures for the study are to evaluate the safety and tolerability of SON-1010 and establish the maximum tolerated dose (MTD) of SON-1010.

- We acquired the global development rights to a fully human version of Interleukin 6 (IL-6), in April 2020. We refer to this candidate as SON-080, for its target indications of Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN). Our CIPN Phase 1b/2a clinical trial, SB221, has been terminated in Australia. Enrollment of the first portion of SB211 study allowed the DSMB to complete its review of the preliminary safety data during the first calendar quarter of 2024. Pursuant to a license agreement that the Company entered into with New Life Therapeutics Pte., Ltd ("New Life") of Singapore in May 2021, we and will be jointly responsible with New Life for developing SON-080 in DPN with the objective of evaluating an ex-US pilot efficacy study after analyzing the CIPN safety data. In October 2024, we entered into a license agreement with Alkem Laboratories for the development of SON-080 in DPN. The data generated from this collaboration will inform our decision about moving SON-080 forward into the next phase of DPN development in Southeast Asia,

- SON-1210 (IL12-F_HAB-IL15), our lead bifunctional compound, combines the F_HAB construct with single-chain IL-12 and fully human Interleukin 15 (IL-15). This compound is being developed for solid tumor indications, including colorectal and pancreatic cancer. In February 2023, we announced the successful completion of two IND-enabling toxicology studies with SON-1210 in NHPs. We are prepared to initiate the regulatory authorization process for SON-1210 and on August 19, 2024, we entered into a Master Clinical Collaboration Agreement with the Sarcoma Oncology Center, to advance the development of SON-1210 in combination with chemotherapy for the treatment of metastatic pancreatic cancer.

In our discovery pipeline, we are investigating:

- SON-1400 ($IL18^{BPR}$-F_HAB) and SON-1411 ($IL18^{BPR}$-F_HAB-IL12). On June 13, 2024, we announced the generation and *in vitro* characterization of two novel drug candidates, SON-1411 ($IL18^{BPR}$-F_HAB-IL12) and SON-1400 ($IL18^{BPR}$-F_HAB), each containing a modified version of recombinant human interleukin-18 ($IL\text{-}18^{BPR}$). SON-1411 is a proprietary bifunctional fusion protein consisting of $IL\text{-}18^{BPR}$ combined with single-chain wild-type IL-12, linked to Sonnet's Fully Human Albumin Binding (F_HAB®) platform, which has replaced SON-1410 as a development target. SON-1400 is a monofunctional fusion protein comprising the same $IL\text{-}18^{BPR}$ domain linked to the F_HAB. F_HAB extends the half-life and biological activity of linked molecules by binding native albumin in the serum and targets the tumor microenvironment (TME) thorough high affinity binding to glycoprotein 60 (gp60) and the Secreted Protein Acidic and Rich in Cysteine (SPARC). IL-18 can regulate both innate and adaptive immune responses through its effects on natural killer (NK) cells, monocytes, dendritic cells, T cells, and B cells. IL-18 acts synergistically with other pro-inflammatory cytokines to promote interferon-γ (IFN-γ) production by NK cells and T cells. Systemic administration of IL-18 has been shown to have anti-tumor activity in several animal models. Moreover, tumor-infiltrating lymphocytes (TILs) express more IL-18 receptors than other T cells. However, IL-18 clinical trials have shown that, although it is well tolerated, IL-18 has poor efficacy in the treatment of cancers, most likely due in large part to the high co-expression of IL-18 binding protein (IL-18BP) in the TME. In particular, IL-18BP serves as a "decoy receptor" that binds to IL-18 with higher affinity, compared with the IL-18Rc complex, thereby causing a negative feedback loop with IL-18 and inhibiting IL-18-mediated TIL activation. Thus, there exists a potential for the discovery of IL-18 variant compositions that could harness the therapeutic potential of IL-18 for the treatment of cancers. Sonnet's strategy for amino acid modifications to rIL-18 was based on a compilation of literature review, 3D X-ray crystallography structures, and computer modeling analysis. Subsequently, certain IL-18 variant sequences were synthesized, engineered into expression constructs and manufactured at small scale in either CHO cell culture or *E. coli.* Highly purified milligram quantities of SON-1411 or SON-1400 were analyzed *in vitro* for IL-18Rc or IL-18BP binding activities, respectively, using the HEK-Blue™ and Bright-Glo Luciferase™ IL-18Rc reporter assays. *In vitro* results for at least one variant of IL-18 showed equivalent binding to the IL-18Rc, compared to the wild-type IL-18 reference molecule, concomitant with no or reduced binding to IL-18BP. The known MOA of IL-18 inhibition by IL-18BP is reviving the importance of clinical applications of IL-18. IL-18BP has been shown to be elevated in cancer patients, thus nullifying the clinical applications of IL-18. SONN-1411 and SON-1400 both contain a unique IL-18 domain that does not bind the inhibitor IL-18BP but still maintains full IL-18 and IL-12 bioactivity. The clinical application of these mono or bifunctional fusion proteins could potentially expand immunotherapy applications for cancer patients.

- SON-3015 (anti-IL6- F_HAB-anti-TGFβ), a bifunctional combination of anti-IL6 and anti-Tumor Growth Factor beta (TGFβ) was being developed for tumor and bone metastases. The early-stage bifunctional drug has been generated and has been stored for future use with *in vivo* mouse studies. During Q4 2022, we elected to place the SON-3015 development program on hold for expense reduction purposes.

We face numerous challenges and uncertainties with respect to the development and commercialization of our therapeutic compounds, including our F_HAB technology. Please see "*Risk Factors*" contained elsewhere in this prospectus.

Strategy

Our goal is to rapidly advance our pipeline and leverage our therapeutic F_HAB platform to become a leader in the discovery, development, and commercialization of biologic drugs. Since our founding, we have remained focused on rapidly progressing pipeline candidates towards the clinic, while also working to establish collaborations with suitable partners. As partnership conversations evolve, we intend to prioritize our expense allocation on assets with the greatest strategic interest. To this end, we have reduced operating expenses during fiscal year 2023 and intend to negotiate a licensing deal that will help fund future pipeline expansion. As one example of a project in its early stages that was announced in October 2022, Janssen's evaluation of three of our pipeline compounds, SON-1010, SON-1210 and SON-1410, in combination with its cell therapy products remains ongoing.

F_HAB program advancement: SON-1010 has entered Phase 1b/2a clinical development to establish maximum tolerated dose (MTD) and to assess clinical benefit in platinum-resistant ovarian cancer (PROC). Regarding our first bifunctional candidate, SON-1210, two IND-enabling toxicology studies in NHPs have been successfully completed and we are prepared to initiate the regulatory authorization process, pending the outcome of any partnering activity.

Progress SON-080 into the next phase of clinical development: SON-080 is a fully human version of low dose IL-6 being studied for chemotherapy-induced peripheral

neuropathy (CIPN). IL-6 has successfully been studied in Phase 1 and Phase 2 clinical trials in cancer patients and we initiated a pilot efficacy Phase 1b/2a study in CIPN patients during the second half of 2022. Data from that study was announced in July 2024, showing safety, tolerability, and preliminary evidence of improvement in symptoms.

Manufacturing platform: Our compounds are produced using an industry standard mammalian cell (Chinese Hamster Ovary (CHO)) host cell line that allows for rapid scale-up and commercial manufacturing using state-of-the-art manufacturing processes and technologies. The mammalian cell culture system enables glycosylation and a similar biological structure to the natural cytokines *in vivo*, which reduces the chance of immunogenicity. The manufacture of cytokines for clinical applications, namely their production and purification, poses distinct technical challenges. To this end, we have developed a proprietary continuous intensive perfusion manufacturing process, including a proprietary ligand for efficient down-stream processing, as well as stable lyophilized formulations, for which we are seeking intellectual property protection for certain of these manufacturing and downstream process development steps.

Regulatory strategy: We believe that our drug candidates are significantly differentiated from existing therapies and represent potential breakthroughs in biopharmaceutical drug development. We will endeavor to seek breakthrough therapy designations with regulatory agencies, which could potentially lead to accelerated clinical development timelines.

Pipeline licensing opportunities: We are pursuing partnering opportunities with leading biopharmaceutical companies for the development and commercialization of our pipeline assets.

F_HAB technology expansion: We are exploring F_HAB technology licenses with external partners interested in expanding its therapeutic deployment, which we believe could lead to the platform's application in other areas, such as vaccines, antibody drug conjugates, and as a supplement to chimeric antigen receptor (CAR) T-cell technology *in vivo*. As soon as supportive data are available, provisional patents will be filed to secure exclusivity with F_HAB in these fields.

The F_HAB Technology

Our proprietary F_HAB technology was engineered to address several important shortcomings of existing approaches to biopharmaceutical drug development. We designed the F_HAB domain as a plug-and-play, modular construct for innovating new chemical entities that is readily reconfigured for different therapeutic payloads. As is the case with all biologic drugs, dose level and frequency of administration are critical variables that oftentimes present barriers to the development process. After injection, large molecule therapeutics, including peptides, proteins, fusion proteins, antibodies, and the like, must remain intact and be capable of reaching their designated targets inside the body, without exceeding specific toxicity thresholds. Finally, they must also be produced using commercially attractive means.

Our platform technology was designed to harness HSA as a therapeutic shuttling molecule. HSA is naturally present in the bloodstream and the predominant protein in blood plasma. Albumin is a source of energy for inflamed, hypermetabolic tissues, including tumors. Due to the active need for nutrients, cancer cells overexpress albumin-binding proteins such as the 'Secreted Protein Acidic and Rich in Cysteine' (SPARC) and gp60 (albondin glycoprotein).

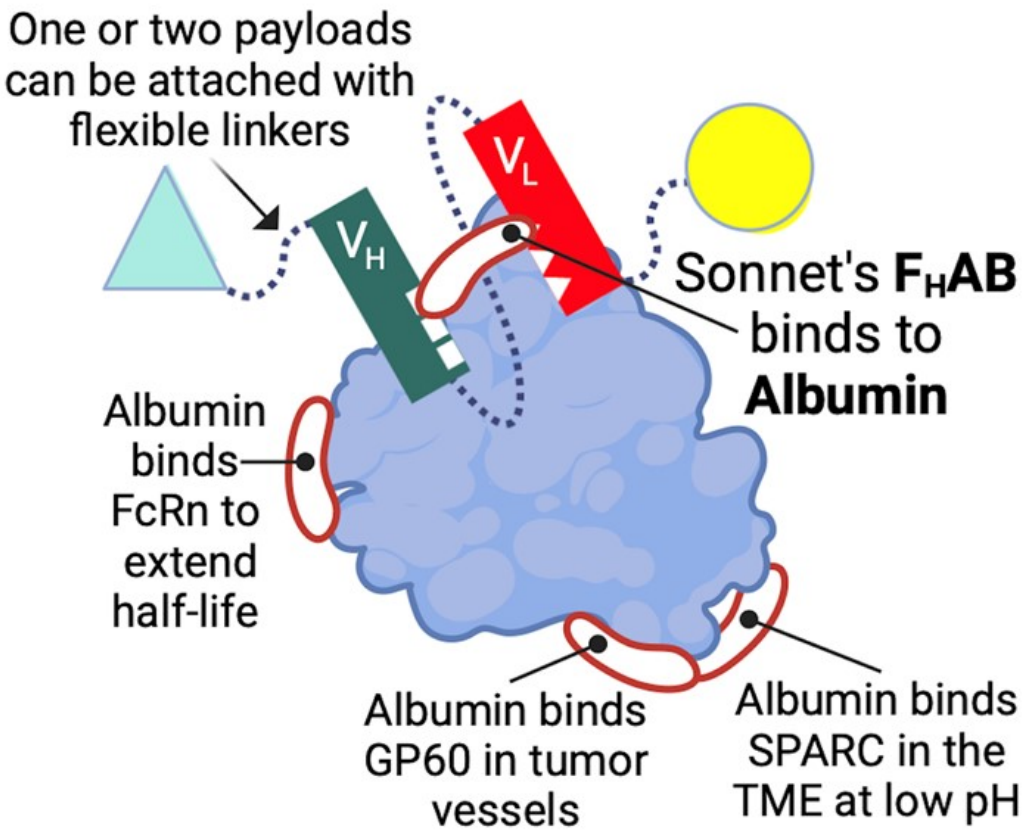
Pursuant to a Discovery Collaboration Agreement, dated July 23, 2012, and to an Amendment of Discovery Collaboration Agreement, dated May 7, 2019 (together, the "Collaboration Agreement"), XOMA (US) LLC ("XOMA") granted us a non-exclusive, non-transferrable license and/or right to use certain materials, technologies and information related to the discovery, optimization, and development of antibodies and related proteins and to develop and commercialize products thereunder (each, a "Product"). The Collaboration Agreement included a license to use a fully human bacteriophage library that was designed to generate fully human single-chain antibody variable fragments (scFv) comprising a full repertoire of human heavy and light chains for use in panning biological sequences for specific functions. Applying stringent criteria, Sonnet panned millions of scFv binders to HSA to generate Sonnet's F_HAB, which binds to HSA, a globular protein having three major functional domains. It is known that albumin domains 1 and 3 are involved in the binding to FcRn. This allowed us to select and characterize scFv binders that are specific to domain 2, a foundational aspect of Sonnet's F_HAB platform.

We are obligated to make contingent milestone payments to XOMA totaling $3.75 million on a Product-by-Product basis upon the achievement of certain development and approval milestones related to a Product. To that point, we have paid $500,000 initiation of enrollment of a Product (*i.e.,* SON-1010) in a Phase 1 Trial. Sonnet has also agreed to pay XOMA low single-digit royalties on net sales of Products sold by us. Royalties on each Product are payable on a country-by-country basis until the later of (i) twelve (12) years after the First Commercial Sale (as defined in the Collaboration Agreement), and (ii) the date of expiration of the last valid claim in the last-to-expire of the issued patents covered by the Collaboration Agreement. In addition, we have the right to reduce the rate of the royalty on a Product-by-Product basis by paying XOMA a specified amount. The Collaboration Agreement may be terminated by either party for cause and contains customary indemnification provisions.

Our F_HAB has demonstrated a high binding affinity to serum albumin across species (human, mouse and cynomolgus monkey), with little-to-no immunogenicity, and retains the benefits of neonatal FcRn-mediated recycling of albumin for extending serum half-life. Unlike monoclonal antibodies (mAbs), this binding occurs without invoking ADCC (antibody-dependent cellular cytotoxicity) or CDC (complement-dependent cytotoxicity). The F_HAB construct physically binds serum albumin (Figure 1) through an ionic, hydrophobic mechanism, which we believe offers a distinct advantage over technologies that rely on chemical, covalent binding. Once broken, a covalent bond cannot reform, whereas our F_HAB is designed with the ability to bind, unbind and rebind to albumin in dynamic equilibrium. As albumin also binds to the albumin receptors gp60 and SPARC, F_HAB leverages innate biological mechanisms for targeted delivery to and accumulation of the therapeutic payload in the tumor microenvironment.

Preclinical radiolabeling studies have validated the tumor targeting attributes of the F_HAB construct, where accumulation was demonstrated in tumors compared to the same construct without F_HAB, and was transient in liver, kidney, and other organs, as expected. Importantly, radiolabeled F_HAB also demonstrated measurable accumulation in the draining lymph nodes. These findings have important implications for therapeutic applications of any mono- (ILx-F_HAB) or bifunctional (ILx-F_HAB-ILy) molecules demonstrating enhanced tumor targeting and accumulation, as well as the potential for improved efficacy.

Another unique advantage of Sonnet's F_HAB is its linker design (Figure 1) that is used for attaching one or two large molecule therapeutic payloads for single or bifunctional activity. Our G4S (glycine, serine) peptide linkers are flexible, while being long enough to prevent steric hindrance and can assume a rod-like configuration for enhanced penetration of tight tissue matrices. In addition to maintaining distance between the therapeutic functional domains, Sonnet linkers are fully human and non-immunogenic across the linker structure, including at the payload binding region. In bifunctional constructs, the orientation of the therapeutic payloads can be manipulated to improve potential treatment effects.



As a final key design component, F_HAB is produced in mammalian cell culture, specifically Chinese Hamster Ovary (CHO) cells, which enables glycosylation for reducing or potentially eliminating immunogenicity. Using CHO, we have created several different genetic fusion constructs with various low molecular weight therapeutic proteins (e.g., recombinant cytokines such as IL-12, IL-15, IL-18, anti-IL-6, and anti-TGFβ). Recombinant therapeutic proteins, including cytokines, have shown great therapeutic potential, but can lack tissue specificity, which can lead to toxicity. Due to their small size (< 50 kDa), cytokines also suffer from a shorter circulation half-life (minutes-to-hours versus 21 days for albumin) compared to monoclonal antibodies. In mouse and NHP models, F_HAB-derived compounds have demonstrated substantially greater serum half-lives, improved tissue accumulation, and have marked tumor reduction activity when compared to their respective naked recombinant cytokines.

In summary, our F_HAB technology underpins a modular, versatile scaffold that can be customized to yield a broad array of multi-targeted therapeutic candidates. Relative to existing albumin binding technologies, F_HAB is differentiated by possessing a linear, rod-like shape designed for better target tissue penetration, a fully human design to reduce immunogenicity, mammalian glycosylation, and FcRn binding for longer serum half-life. Importantly, F_HAB-derived therapeutics have the potential for targeted delivery to tumor and lymphatic tissue, reduced toxicity, and wider therapeutic windows, with the added benefit of utilizing a tailored single- or bifunctional mechanism of action.

Expanded Applications of the F_HAB Technology:

Immunotherapy: We believe that our F_HAB platform can innovate biologic drugs that target specific tissues while also increasing therapeutic half-life. As the F_HAB construct is designed to enable the simultaneous deployment of two synergistic immunotherapy compounds, we envision a path to previously untapped immunotherapeutic advancements.

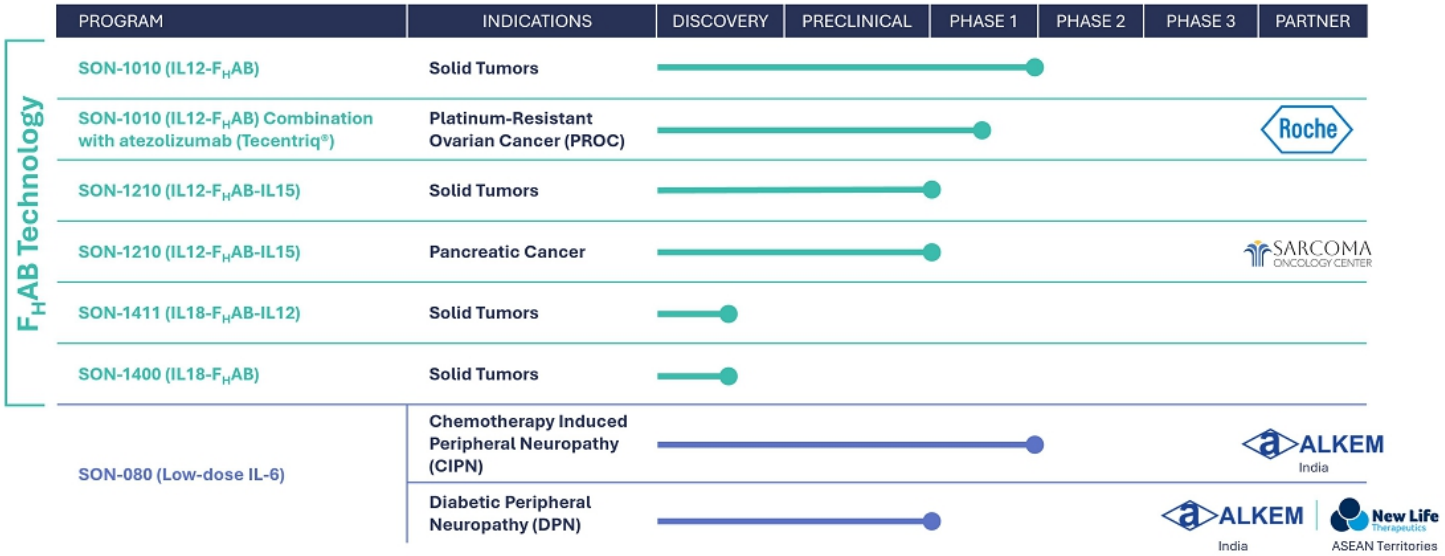
Drug Conjugation: With the F_HAB technology, various drug compounds can be linked to the F_HAB scaffold in combinations that extend beyond our first-wave pipeline of cytokines, which presents opportunities for development across myriad disease areas.

Vaccines: Vaccine developers are seeking to improve vaccine efficiency by conjugating vaccines to natural carriers, such as albumin. We believe the F_HAB platform, with its modular scaffold structure, could be an efficient vehicle for delivering vaccines to lymph nodes, improving penetration and presentation, and extending half-life.

CAR T-cell Therapy: CAR T-cell therapy involves genetically modifying a patient's own T cells to recognize cancer cells for more effectively targeting and killing tumors. We believe targeted Sonnet constructs utilizing interleukins could be systemically co-administered to enhance CAR T-cell efficacy.

Pipeline Overview

The following table summarizes information about pipeline programs where we have disclosed specific target indications:



SON-1010

IL-12 is a circulating cytokine that has been shown to exert multiple effects on innate and adaptive immunity. These immune functions are critical in attacking cancer cells and pathogens. IL-12 is a heterodimeric cytokine produced by dendritic cells, monocytes, and macrophages, also known as antigen presenting cells (APCs). IL-12 has been shown to induce interferon gamma (IFN-ɣ) secretion by T cells and natural killer (NK) cells, promote the expansion and survival of activated T and NK cells, supplement the cytolytic activity of cytotoxic T cells, support the differentiation of Th1 helper-effector cells and enhance antibody dependent cellular cytotoxicity (ADCC). IL-12 has also been shown to stimulate *in vitro* antitumor activity of lymphocytes from patients with cancer and*in vivo* anti-tumor activity in murine tumor models of melanoma, colon carcinoma, mammary carcinoma, and sarcoma.

Preclinical Studies in Mice

Initially, the murine version of SON-1010 (mIL12-F_HAB) demonstrated a larger reduction of tumor growth preclinically compared to recombinant mIL-12 without F_HAB (naked/standalone IL-12) in a mouse model of melanoma. Figure 2, from this mouse melanoma study, illustrates a 30-to-50-fold increase in tumor reduction with mIL12-F_HAB compared to standalone mIL-12.

Furthermore, in the same model, mIL12-F_HAB accumulated in tumors in higher concentrations and remained in the serum, spleen, and tumor significantly longer than mIL-12 without F_HAB, potentially enabling less frequent administration and at lower doses.

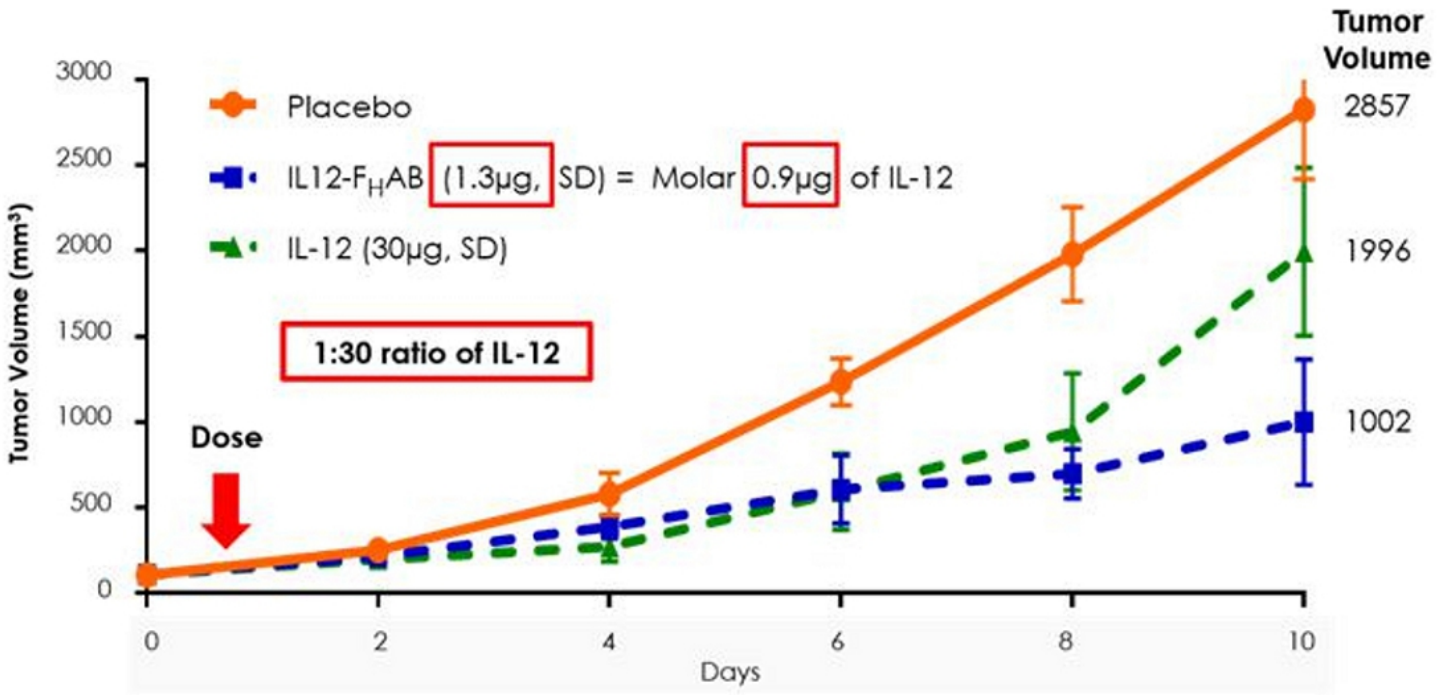


Figure 2: The molar equivalent for IL-12 (0.9µg) is IL12-F_HAB (1.3 µg) and they have similar bioactivity in vitro; however, in vivo, IL12- F_HAB is approximately 30-fold more potent than IL-12 (at day 10, 1.3µg IL12-F_HAB > IL-12 30µg).

In another preclinical study using the B16F10 tumor model, mIL12-F_HAB demonstrated an improved dose response versus recombinant murine IL-12, along with increased survival duration (Figure 3 and Figure 4). Results from this study suggest that mIL12-F_HAB may have a greater effect on reducing tumor volume and extending survival versus standalone mIL-12.

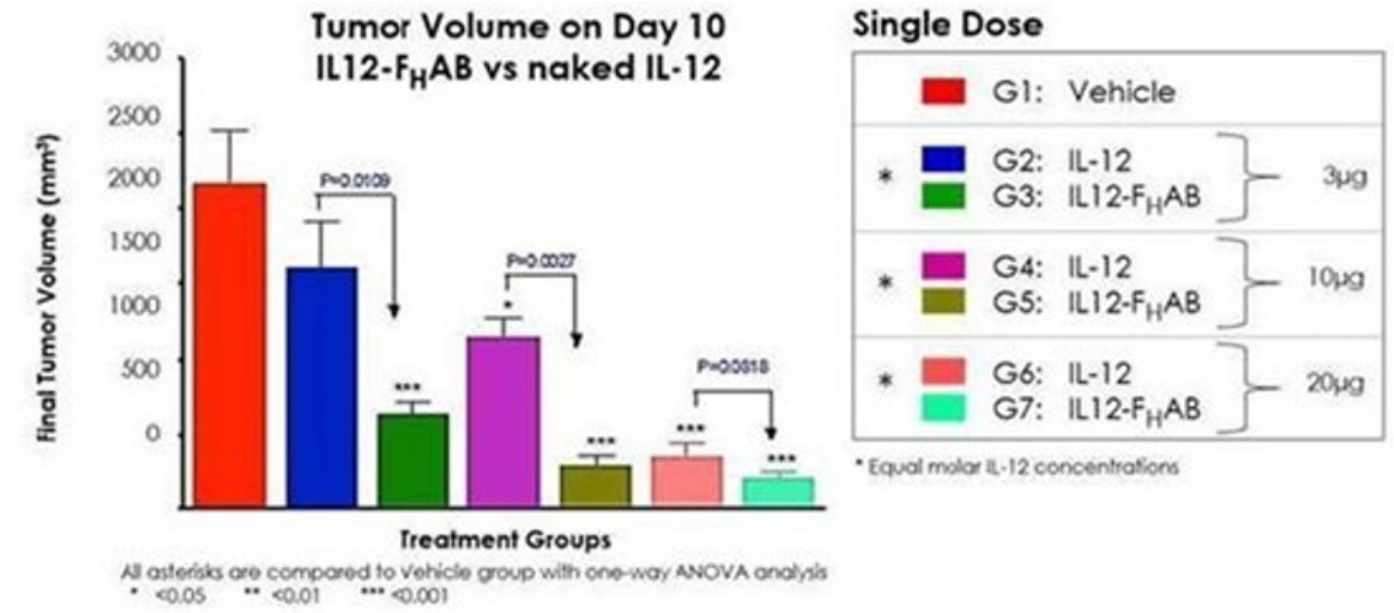


Figure 3: Analysis of tumor volumes shows dose-dependent decreases in tumors in both m*IL-12 and* m*IL12-F$_H$AB-treated mice, as compared to vehicle control. IL12-F$_H$AB-treated mice showed statistically significant decreases in tumor volumes when analyzed against equimolar-dosed,* m*IL-12-treated mice. Results suggest IL-12 anti-tumor activity is potentially enhanced with the extension of serum half-life by F$_H$AB linkage.*

In Figure 4, a Kaplan-Meier analysis was performed to compare survival between animals treated with either mIL12-F$_H$AB or mIL-12. These data illustrate a correlation between the decrease in tumor growth (Figure 3) and an increase in survival duration (Figure 4). In this study, the slower growth of tumors in animals treated with mIL12-F$_H$AB correlated with a longer survival time, as compared to more rapid tumor growth observed with naked mIL-12 treatment. Survivability at the lowest doses of mIL12-F$_H$AB (3µg) was equivalent to the highest dose of mIL-12 (30µg). All doses of mIL12-F$_H$AB showed a 50% survival increase over vehicle at 14 and 17.5 days.

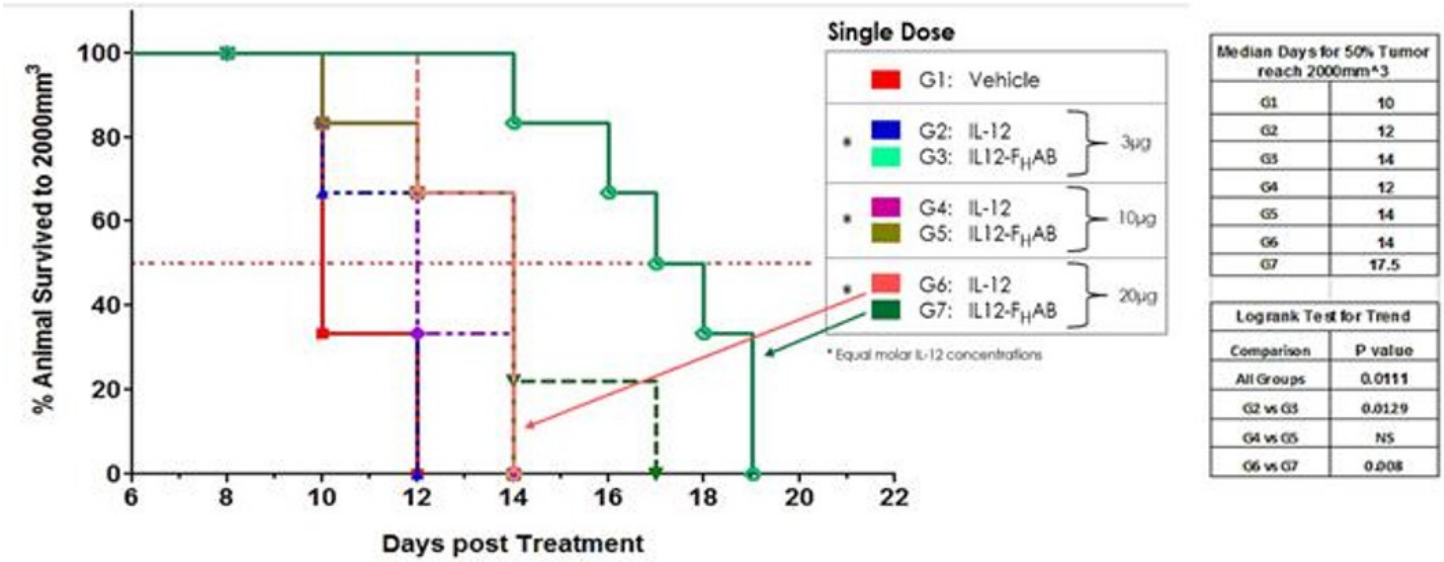


Figure 4: Kaplan-Meier evaluation of mouse B16F tumor survivability shows an increase in survival with IL12- F$_H$AB treatment. Doses of 10µg and 20µg of standalone mIL-12 exhibited 50% survival at 2 and 4 days over vehicle control (10 days). All doses of IL12- F$_H$AB showed 50% survival over vehicle at 14 and 17.5 days. Survivability at the lowest doses of IL12- F$_H$AB were equivalent to highest dose standalone IL-12

Nonhuman Primate Studies of SON-1010

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, cynomolgus monkey and human. The results show 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 completed. This work informed our decision about dosing in a nonhuman primate (NHP) study.

In February 2021, we announced the successful completion of a NHP non-GLP repeat-dose toxicology study of SON-1010, the data from which were used to inform the design of the cGLP toxicity study in preparation for IND submission. The objectives of the non-GLP study were to evaluate the toxicity of SON-1010 in a repeat dose regimen at several dose levels and to gather critical data for the design of further IND-enabling safety and toxicity studies. The study included both intravenous (IV) and SC routes of administration with a total of two injections given 14 days apart. The highest dosage rate utilized in this study was greater than 50 times the anticipated clinical level of exposure to patients. Study results included:

- Repeat dosing by IV and SC routes of administration was tolerated at both dose levels examined. As is typically observed with IL-12 administration, the white blood cell count dropped, and liver enzymes (ALT and AST) were elevated. These were transient effects that returned to baseline within 7 days following the second dose.

- SON-1010-related changes in the physiological observations, body weight, pathology, cytokines and immunophenotyping were seen, all of which were consistent with those on-target effects previously observed in single dose studies.
- A significant increase in IFN-γ levels, a key pleiotropic cytokine associated with anti-tumor activity, was observed following the initial dose of SON-1010 with lower IFN-γ levels observed following the second dose. This trend follows the published data from other studies of IL-12 in both humans and NHPs. Signs of cytokine imbalance, or uncontrolled increase of pro-inflammatory cytokines, including TNF-α, IL-1β, and IL-6 were notably absent from all dose levels tested in the study.
- Pharmacokinetic analysis indicated a mean serum half-life of approximately 40 hours in animals administered SON-1010 via SC injection. This is consistent with data from the previously conducted dose escalation phase of the study, which demonstrates a substantial improvement in half-life compared to the 13-19-hour half-life of naked, recombinant human IL-12.
- These results build on those from the work with the B16F10 mouse model of melanoma, where the mouse version of SON-1010 showed a 20-fold reduction in the dosage required to achieve a similar therapeutic effect compared to mouse IL-12. Taken together, we believe the observed extended half-life, improved therapeutic window and reduced dosing requirement, made possible by Sonnet's FHAB technology, represent key advantages of SON-1010 as a potential immune oncology therapeutic.

In May 2021, we announced the successful completion of a cGLP repeat-dose study of SON-1010 in NHPs. The objectives of the study were to evaluate the toxicity of SON-1010 in NHP using a subcutaneous (SC), repeat-dose regimen at three different dose levels versus untreated controls and to evaluate the potential reversibility of any adverse findings. Study results included:

- The No Observed Adverse Event Level (NOAEL) following repeated administration in NHP was more than 50 times the anticipated equivalent human clinical dose with no evidence of cytokine release syndrome.
- Pharmacokinetic (PK) analysis of serum samples confirmed an enhanced profile of IL12-F_HAB over recombinant human IL-12, with a half-life around 40 hours in NHP.
- A significant increase in IFN-γ, a key pleiotropic cytokine associated with anti-tumor mechanisms, was observed following dosing with IL12-F_HAB.
- SON-1010 related changes in clinical observations, body weight, clinical pathology, cytokines, and immunophenotyping were seen, all of which were consistent with on-target effects previously observed in nonhuman primates.
- By Day 38, all study subjects recovered to baseline (pre-study) laboratory values.
- Repeat dosing administration was tolerated at all dose levels examined.

Biodistribution Studies

In September 2023, we announced the completion of two independent *in vivo* proof-of-concept (POC) studies to show the biodistribution of interleukin-F_HAB molecules to the tumor microenvironment (TME), using labs with expertise in radiolabeling biologics and *in vivo* biodistribution analysis. The labs employed different radiolabeling methodologies (^{99m}Tc or ^{89}Zr) for mIL-12 and mIL12-F_HAB, either with or without a polyhistidine tag (His-Tag). The two studies were completed using the B16F10 mouse melanoma model to measure the accumulation of radiolabeled product and tumor volume inhibition over various time points. Both studies indicated that mIL12-F_HAB had significantly higher tumor accumulation, 2.5-4.7 times higher on average at the longer time points, and increased retention when compared to mIL-12. Accumulation was demonstrated in tumors compared to normal mice, and was transient in liver, kidney, and other organs, as expected. Importantly, radiolabeled mIL12-F_HAB also demonstrated measurable accumulation in the draining lymph nodes. Overall, these findings have important implications for therapeutic applications of any mono- (ILx-F_HAB) or bi-functional (ILx-F_HAB-ILy) molecules demonstrating enhanced tumor targeting and accumulation, as well as the potential for improved efficacy that could lead to a variety of drug candidates.

Manufacturing Development

Manufacturing work on the master cell bank expressing SON-1010, formulation development, and process development activities have all been completed, in addition to drug product presentation (liquid or lyophilized). Multiple cGMP drug product lots have been successfully manufactured and provide inventory for ongoing clinical trials.

SON-1010 in the Clinic

We initiated the first-in-human (FIH), Phase 1 trial (SB101) to assess the maximum tolerated dose (MTD) for adult patients with advanced solid tumors and platinum-resistant ovarian cancer (PROC) in April 2022 and we presented initial data from the study at AACR in April 2023. More patients with PROC will be enrolled in the expansion portion of the study to confirm a recommended Phase 2 dose (RP2D). The very first patient dosed, with an aggressive endometrial sarcoma, had substantial tumor shrinkage with complete resolution of her ascites at one point, and was clinically and radiographically stable for nearly two years. Dosing in the first 3 cohorts was initially performed every 4 weeks but was subsequently done every 3 weeks in the latter cohorts to enhance safety at higher doses. On September 18, 2024, we announced the completion of dose-escalation enrollment in our Phase 1 SB101 clinical trial of SON-1010 in adult patients with advanced solid tumors. We expect to report topline safety data from this study in Q4 2024 and efficacy data in the first half of 2025.

We initiated a single-ascending dose (SAD) Phase 1 clinical study (SB102) in Australian healthy volunteers in July 2022 to carefully study the PK and PD in preparation for potential combination studies. Data from the SB102 study were reported during the calendar first quarter of 2023 and were published in February 2024. Typical dose-related increases were seen with SON-1010 in the serum using a validated electrochemi-luminescence assay (Meso Scale Diagnostics, LLC (MSD)) after SC administration. Drug levels peaked at about 11 hours with a geometric mean maximum concentration (C_{max}) of 29, 68, and 125 pg/mL for the 50, 100, and 150 ng/kg dose groups, respectively (Figure 5). The mean elimination half-life ($T_{½}$) after the 150 ng/kg dose of SON-1010 was 112 hours, compared to 12 hours for rhIL-12 given SC.

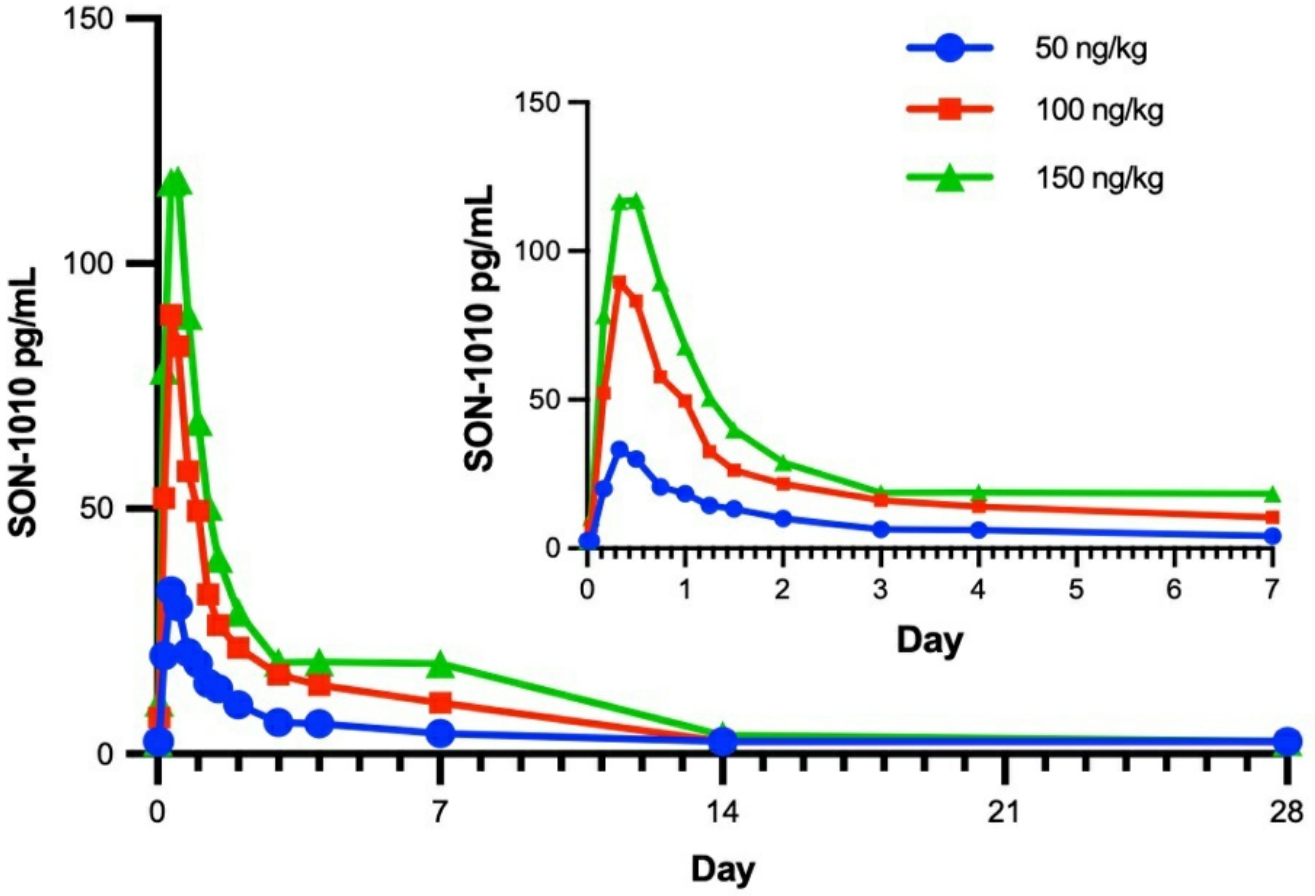


Figure 5: SON-1010 levels were assessed frequently after dosing, then followed on the days indicated for the rest of the SB102 study. The inset shows the same data in more detail for the first week.

Among the cytokine PD responses, the observed increases in IFN-ɣ were most pronounced and were dose-related, controlled, and prolonged. SON-1010 induced IFN-ɣ in all active-drug subjects, which peaked at 24 to 48 hours then returned to baseline after 2 weeks (Figure 6). The IFN-ɣ geomean C_{max} was 398, 384, and 666 pg/mL after 50, 100, or 150 ng/kg of SON-1010 respectively, while the $AUC_{0\text{-}48h}$ was 6050, 10200, and 14600 h*pg/mL. Linear regression was used to predict the IFN-ɣ C_{max} at higher doses, which remains well within the range of safety. Low amounts of IL-10 were induced in a dose-dependent manner, which could also have been in response to the increase in IFN-ɣ. There were small transient increases in IL-6, IL-8, and TNF-α after dosing but no consistent pattern was seen with IL-1β, IL-2, or IL-4, and there was no evidence of cytokine release syndrome (CRS). Safety was consistent with what has been reported previously; adverse events have generally been mild/moderate, transient in nature, and have all been tolerable.

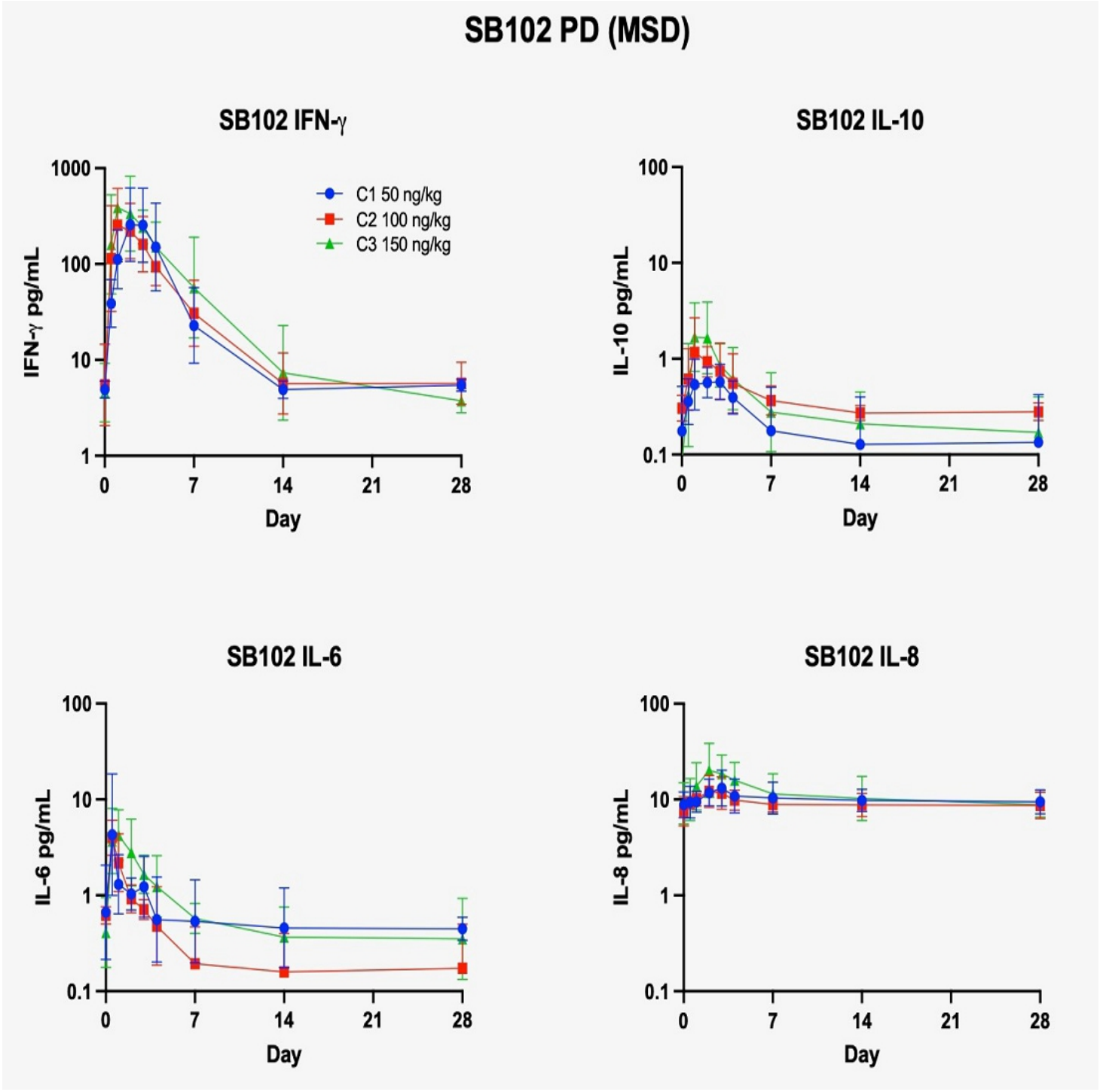


Figure 6: Cytokine levels were assessed frequently after dosing for PD, then followed on the days indicated for the rest of the SB102 study.

The geomean half-life ($T_{½}$) of SON-1010 was 113 hours in SB101, compared to 12 hours for recombinant hIL-12 given SC that has been observed in prior studies. Comparison of the PK curves between our two studies suggests that SON-1010 may be targeting tumors, as the F_HAB was designed to do. As with the healthy volunteers, cytokine analysis following each dose in the cancer patients revealed a similar controlled and prolonged induction of IFN-γ that peaked at 24 to 48 hours and returned to baseline after 2 to 4 weeks. A small increase in IL-10 was observed with each dose, as expected in response to IFN-γ. There was either minimal or no signal for IL-1β, IL-6, IL-8, or TNF-α and no indication of any potential for cytokine release syndrome (CRS) at these doses.

A Phase 1b/2a trial (SB221) of SON-1010 in combination with atezolizumab is in progress. This trial is a multicenter, dose-escalation, and randomized proof-of-concept study being conducted in the US and Australia that targets platinum-resistant ovarian cancer (PROC). The goal is to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered subcutaneously (SC), either alone or in combination with atezolizumab given intravenously (IV). SON-1010 has been safe and tolerable at all doses tested to date. Adverse events have generally been mild/moderate and transient in nature, with no study discontinuations for safety reasons. In addition, adverse effects have been less numerous and less intense with subsequent doses. Safety in both of the active cancer trials has been reviewed by their respective Safety Review Committees at each step during dose escalation. Both trials use a 'desensitizing' first dose to take advantage of the known tachyphylaxis with rhIL-12, which minimizes toxicity and allows higher maintenance doses. No dose-limiting toxicities or related serious adverse events have occurred to date. The safety and toxicity profile that has developed is typical for a Phase 1 oncology trial, with the majority of adverse events (AEs) being reported as mild. All have been transient, with no evidence of cytokine release syndrome. Of the 25 cancer patients dosed to date and evaluable for follow-up at the latest cutoff, 15 (60%) had stable disease at their first follow-up scan, 8 of whom were progressing at study entry. At four months follow-up, 8 of 23 evaluable patients remained stable at the second CT scan, suggesting clinical benefit of SON-1010 in 35% of the patients.

SON-080 for Chemotherapy Induced Peripheral Neuropathy

Through our pipeline expansion efforts, we have identified IL-6 as a cytokine with important biological properties when delivered as a standalone molecule. Our lead clinical stage asset, SON-080, is the native human version of IL-6 that is also manufactured in Chinese Hamster Ovary (CHO) cells. A previous version of recombinant IL-6 has been studied in Phase 1 and Phase 2 clinical trials in cancer patients with thrombocytopenia and in healthy volunteers. Sonnet's comparable version will advance to the next stage of

development in chemotherapy-induced peripheral neuropathy (CIPN), a common side effect of treatment with antineoplastic agents in cancer. CIPN is a debilitating condition that manifests itself as pain, numbness and tingling in the extremities. It has been reported in as many as 70% of patients undergoing specific cancer regimens and is a leading cause of patients prematurely aborting chemotherapy. In animal experiments designed to replicate the clinical symptoms of CIPN, recombinant IL-6 presented disease-modifying characteristics, including the potential to repair damaged nerves.

Based on the preclinical work, we believe that SON-080 can potentially regenerate damaged nerves, thereby addressing not only the pain-related symptoms, but also the profound discomfort and motor disability CIPN patients often experience. In the nervous system, IL-6 has exhibited neurotrophic-like properties, inducing anti-apoptotic gene expression, protecting neurons from toxic injuries, and promoting nerve regeneration and remyelination. IL-6 has demonstrated the potential to elicit nerve regrowth and to re-establish both normal nerve function (Figure 7) and sensations (Figure 6) in various preclinical models of CIPN induced by cisplatin, taxol, or vincristine. Activity from treatment with SON-080 was also observed in preclinical models of type 2 diabetic neuropathy, outlining the potential for benefit in DPN, and other diseases affecting the nervous system or other organs. This broad activity suggests that the SON-080 mechanism of action might not be restricted to a given class of chemotherapeutic drugs and could elicit a universal neuroprotective-neurorestorative response. Additionally, preclinical data point to the potential of SON-080 to elicit both preventive and curative activity in neuropathies (Figure 8). This introduces the possibility of treating cancer survivors who still suffer from neuropathies, a population representing between 10% and 60% of the 14 million cancer survivors in the US.

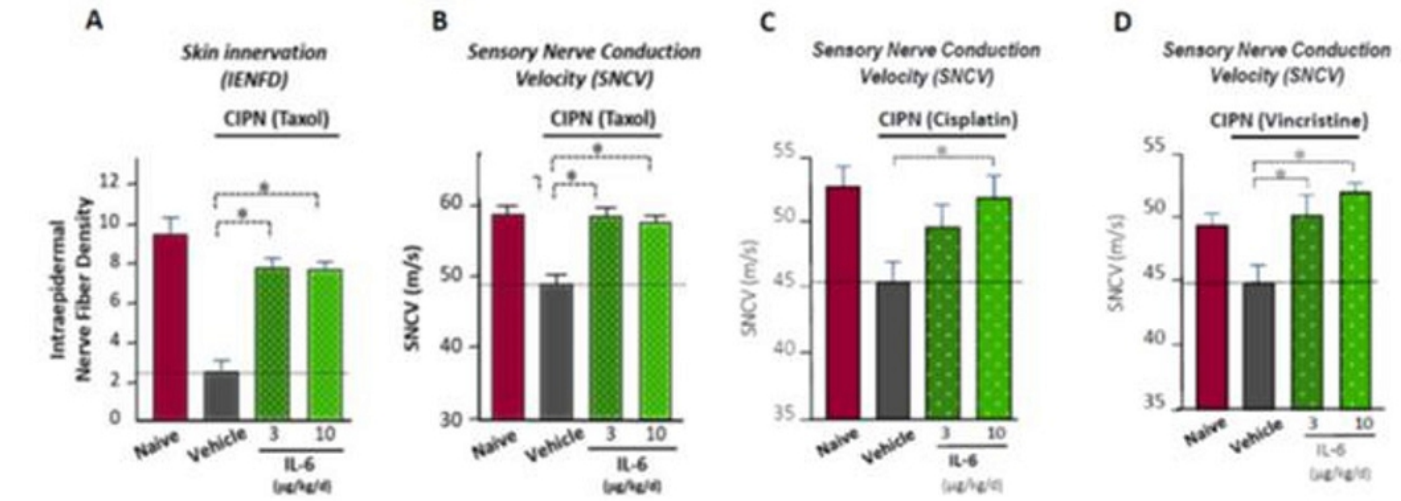


Figure 7: *Activity of IL-6 on neuropathy induced by taxol or cisplatin in rats measured at the histological (IENFD) or physiological (SNCV) levels.*

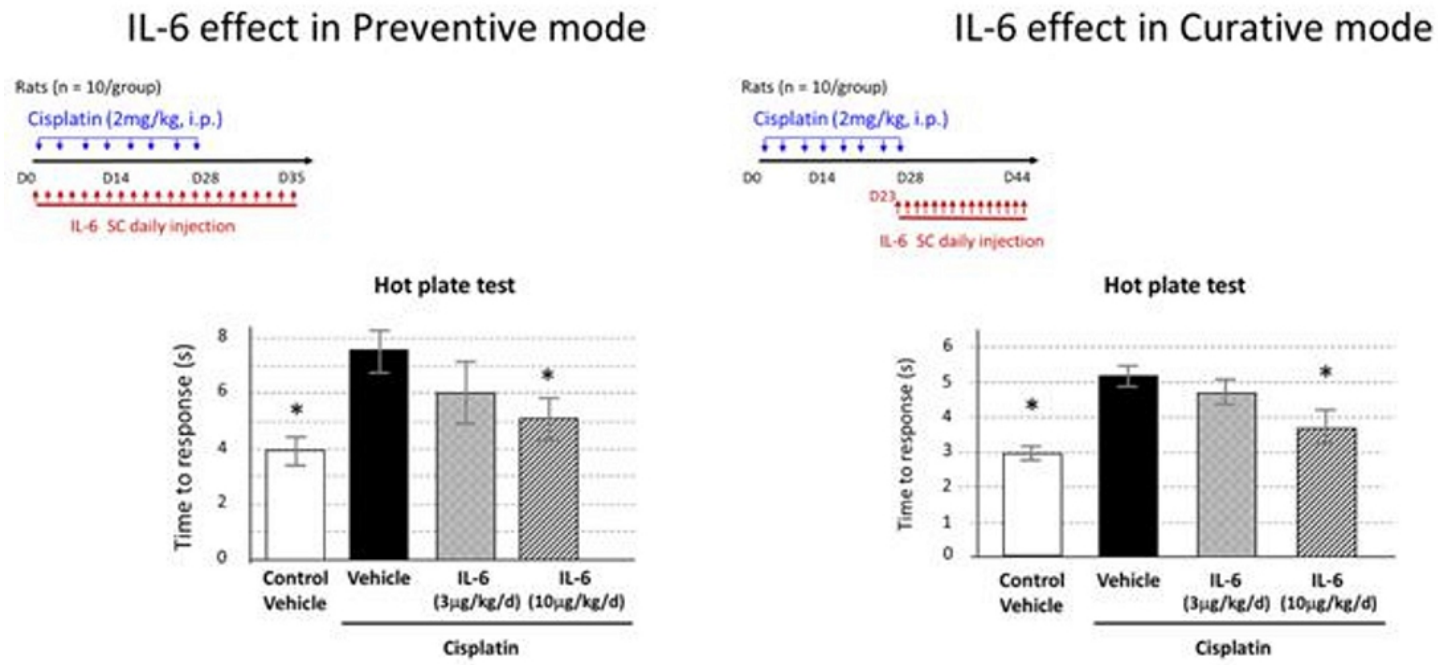


Figure 8: Data show preventive and curative activity potentiating restoration of normal sensitivity (here, using a behavioral response to hot stimulus in cisplatin-induced peripheral neuropathy).

IL-6 has been studied in Phase 1 and Phase 2 studies in over 200 cancer patients with chemotherapy-induced thrombocytopenia. Trial enrollees received SC doses ranging from 0.25 to 32 µg/kg, either daily or thrice weekly. In these trials, where solid tumor cancers were present in more than 75% of the patients treated, the cumulative doses of IL-6 averaged in the 8000 µg range (122 - 54880 µg), and the mean duration of treatment equaled 28 days. One of the trials covered six chemotherapy cycles, with an IL-6 treatment period extending to 203 days. An exacerbation of either cancer or neuropathy was not observed in any of these trials.

The MTD of SON-080 was determined in four studies by means of cohort dose escalations of sequential IL-6 dose groups utilizing established common toxicity criteria. When

administered daily, the MTD following daily SC injection was determined to be between 3 and 8 µg/kg; when given 3 times per week, the MTD was estimated to be > 10 µg/kg. The most clinically relevant toxicities that defined the treatment-limiting dose in these studies were flu-like symptoms and neurocortical toxicity, manifested by somnolence, restlessness, confusion, hallucination, and disorientation. We anticipate using a dose of SON-080 that is 50-fold less than the prior IL-6 MTD and expect a more benign adverse event profile going forward.

These data form the basis for our clinical trials in CIPN, where dosing is expected to be significantly below MTD, as supported by the preclinical studies. For comparison, our target dose will provide a cumulative dose that is 25 times below the mean cumulative dose reached for a similar period of dosing. We also believe that SON-080 has significant potential for treating other neuropathies, including DPN, as well as other diseases of the nervous system, and we are currently evaluating forward development paths for these opportunities. Sonnet initiated an ex-US Phase 1b/2a pilot-scale efficacy study with SON-080 in CIPN in July 2022. The Data Safety Monitoring Board (DSMB) reviewed the initial safety findings after enrollment was completed in Part 1. Data from that study was announced in July 2024, showing safety, tolerability and preliminary evidence of improvement in symptoms.

SON-080 for Diabetic Peripheral Neuropathy

In addition to our CIPN program with SON-080, our DPN program may, subject to data collected from our planned CIPN studies with SON-080, explore the clinical utility of IL-6 in diabetic peripheral neuropathy (DPN). DPN is currently diagnosed in 50%-80% of the diabetic patient population. According to World Health Organization (WHO) projections, the prevalence of diabetes is estimated to exceed 350 million people in 2030. Neuropathy is progressive and develops over the continuum of diabetes. The condition involves intractable pain with no obvious origin, as well as non-pain-related symptoms such as loss of balance, lack of sensation, and autonomic dysfunctions, among others. These deficits impair quality of life and lead to a reduction of life expectancy. Diabetic foot ulcers are a major cost associated with diabetic medical care and are also directly linked to the development of DPN.

Notwithstanding the seriousness of the condition, current treatments only address the pain component of DPN, leaving disease progression and non-pain-related symptoms unaddressed. Furthermore, the few drugs currently used to reduce pain (i.e. Cymbalta, Lyrica, cannabinoids, opioids) are only partially efficacious and are associated with major side effects, which typically delays their introduction into a patient's care. For these reasons, DPN remains a substantial unmet medical need with high commercial market potential.

Exercise has long been recognized by WHO and caregivers as an effective means of treating and potentially preventing diabetes and several pilot studies have provided evidence to support its role in improving DPN. However, a majority of diabetic patients are physically unable to perform exercise. Regular exercise is known to improve diabetes-associated markers such as HbA1c and glucose homeostasis, to ameliorate heart rate variability and to stimulate recovery of both nerve function and blood flow. Recent evidence demonstrates that IL-6 is released during exercise and mediates some of the beneficial effects of physical activity. Sonnet has completed preclinical work in animal models of DPN in which exogenous administration of IL-6 exhibited restorative activity in epidermal nerve density, nerve function, blood flow, and reactions to painful or disturbing stimuli. In this context, SON-080 may become a future pivotal disease-modifying therapy for the treatment of DPN.

In vitro data on oligodendrocytes or organotypic cultures have shown that IL-6 potentially induces myelin gene expression by Schwann cells or oligodendrocytes (Figure 9).

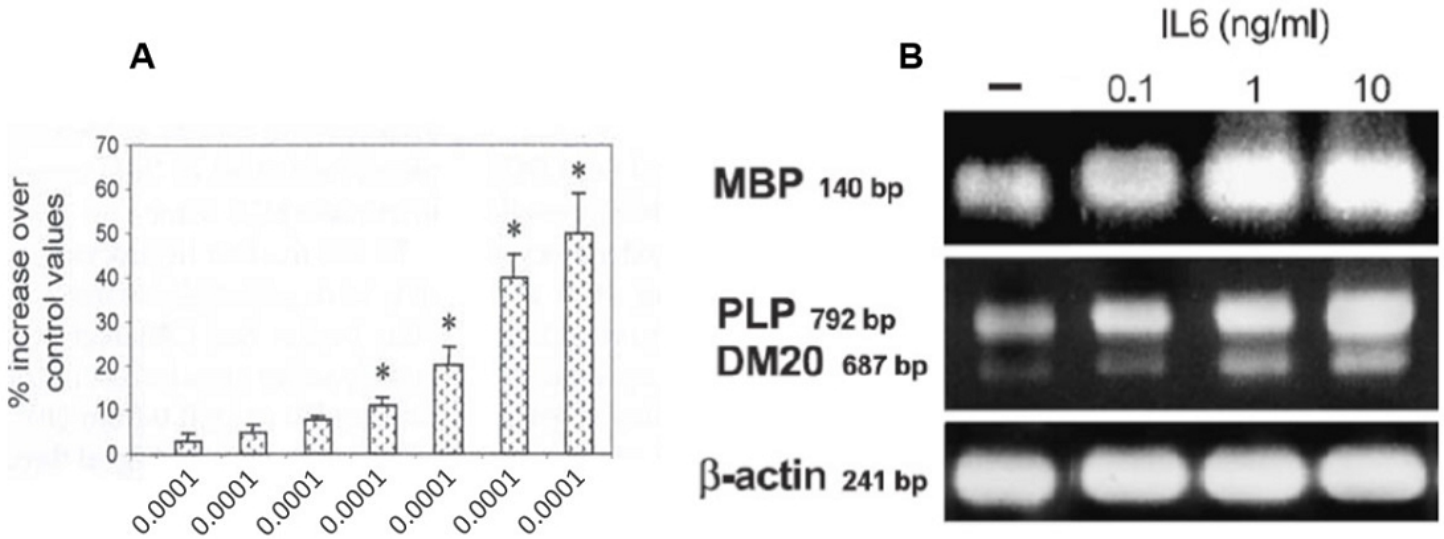


Figure 9: Illustration of survival (A) and differentiation of oligodendrocytes as assessed by myelin basic protein (MBP), proteolipid protein (PLP) and its spliced variant expression (B).

Valerio et al, Mol Cell Neurosci 21 (2002) 602-615.
Pizzi et al, Mol Cell Neurosci 25 (2004) 301-311.

The neuroprotective activity of IL-6 has been evaluated in various paradigms, including excitotoxicity. As well as protecting neurons, IL-6 potentially promotes axonal regeneration and restoration of functional synapses (Figure 10).

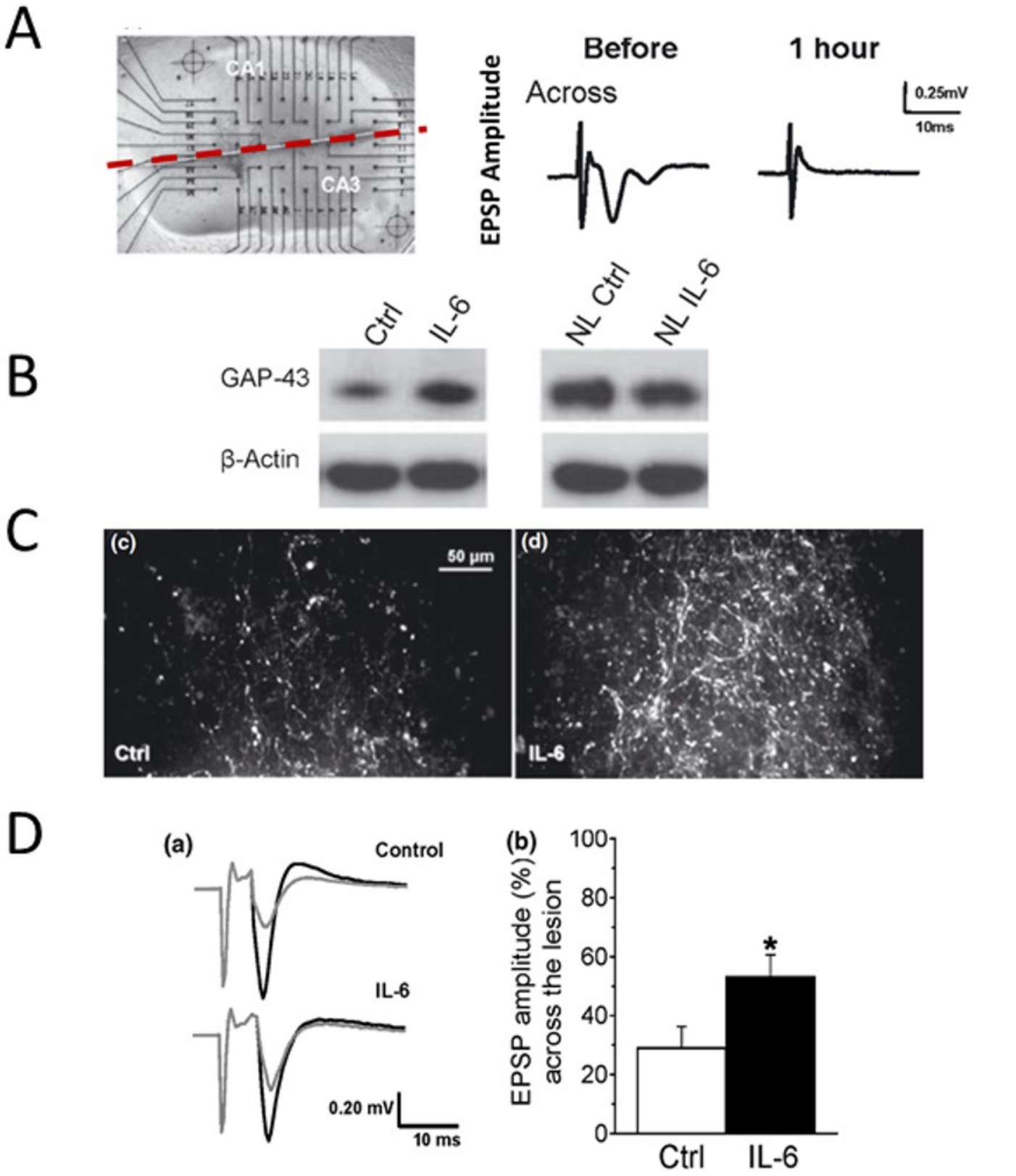


Figure 1011: Axonal regeneration activity in hemi-sectioned slices of the hippocampus (A), with increased expression of growth-associated protein 43 (GAP43) in injured slices but not in normal slices (NL) (B). Axonal regeneration activity across the lesion (C) and functional recovery (D) of suppressed (A) excitatory postsynaptic potential (EPSP).Hakkoum et al, J Neurochem 100 (2007) 747-757.

The activity of IL-6 in preclinical models of DPN has been evaluated by three independent laboratories. This work has shown that IL-6 exhibits positive activity in neuropathy in a dose-dependent manner and may also help restore normal physiological parameters after neuropathy is well established (i.e. four weeks after the induction of diabetes and consequential neuropathy). The beneficial activity is observed on motor (Figure 11A) and sensory (Figure 11B) nerve function (conduction velocity), and behaviorally by measuring thermal (Figure 11C) and tactile (Figure 11D) perceptions. In addition to the direct effects on myelin and axons previously observed *in vitro*, IL-6 has also been observed to have activity in restoring microvascular blood flow in the nerve *in vivo* (Figure 11E), which is a major driver of diabetic neuropathies. Histological analyses of nerves in animals receiving preventive treatment with IL-6 during the development of neuropathy suggest that IL-6 exhibits protective activity on myelin and may play a role in preserving nerve fiber integrity, as well as nerve conduction velocity and the perception of sensations.

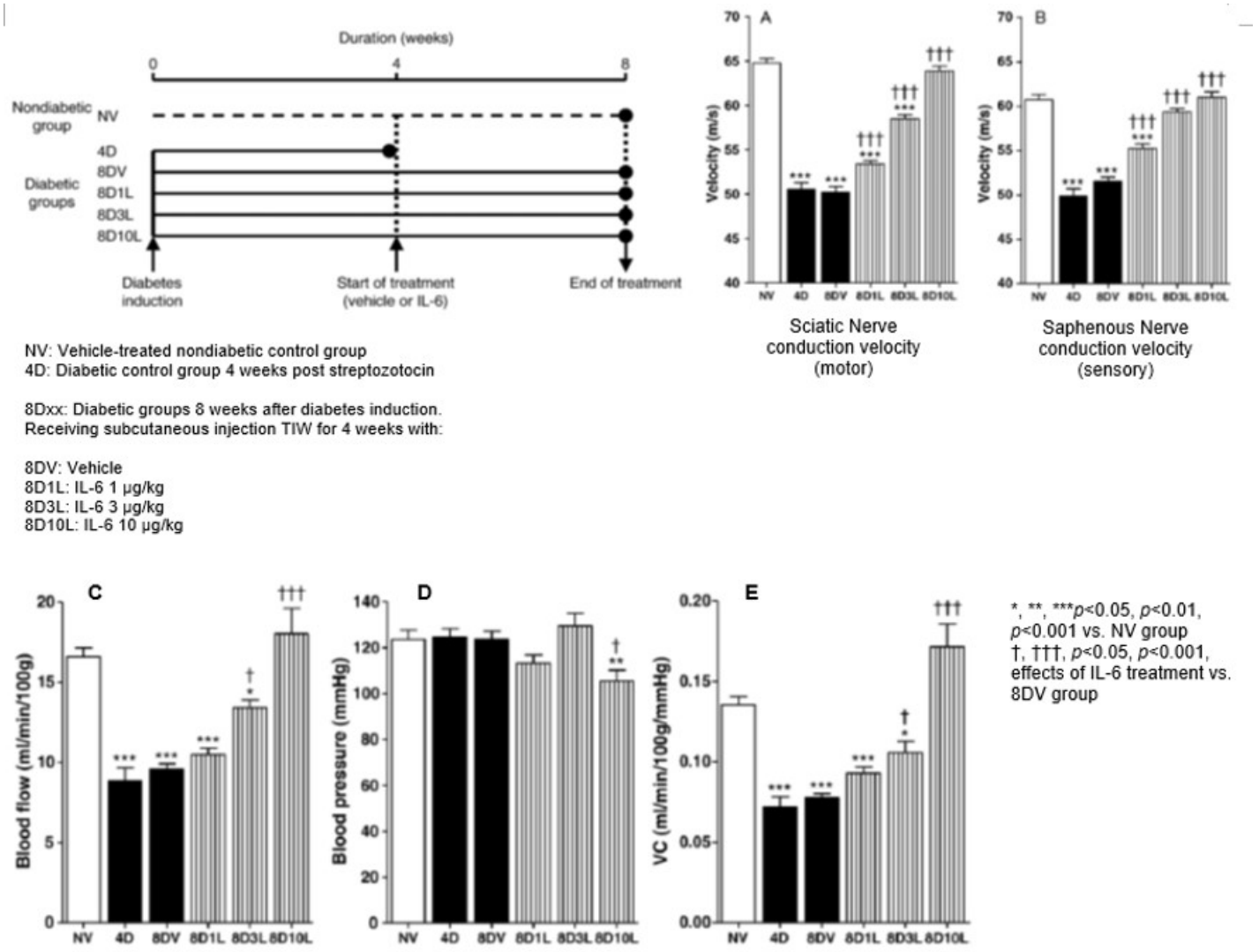


Figure 11: Curative treatment with IL-6 in rats with established diabetic neuropathy induced by streptozotocin.Cameron et al, Exp Neurol 207 (2007) 23-29.

Beyond the oncology indication, 15 pilot studies totaling 167 subjects, including 27 patients with type 2 diabetes, were conducted by independent academic groups not affiliated with Sonnet to evaluate the role of IL-6 in exercise and metabolism. The peer-reviewed results suggest that low dose IL-6 mimics several beneficial aspects of exercise, including expression of anti-inflammatory molecules, increased lipid metabolism, decreased insulin secretion, and activation of the STAT3 signaling pathway in muscle.

We believe these data provide strong support for the clinical development of IL-6 in DPN. Through its mechanism of action and potential disease modifying activity, low dose IL-6 may offer a therapeutic solution for neuropathic symptoms, as well as for cardiac autonomic neuropathies (CAN), in diabetic patients. We intend to use data collected from our CIPN studies with SON-080 to inform our decision about potential next development steps for SON-080 in DPN. Pursuant to the license agreement the Company entered with New Life of Singapore in May 2021, we and New Life will be jointly responsible for developing SON-080 in DPN, with the objective of initiating an ex-US pilot efficacy study with the objective of leveraging the ex-US Phase 1b/2a study conducted by Alkem.

SON-080: Alkem Agreement

In October 2024, we announced the execution of a license agreement with Alkem Laboratories Limited, described in detail below (the "Alkem Agreement") for the treatment of DPN in India as well as the and the manufacturing, marketing and commercialization of SON-080 for the treatment of CIPN and autonomic neuropathy in India. Pursuant to the terms of the Alkem Agreement, Alkem will bear the cost of certain expenses, including conducting clinical studies, preparing and filing regulatory applications and undertaking other developmental and regulatory activities for commercializing SON-080 for DPN in India. Alkem has agreed to pay us, within 12 weeks of the Effective Date of the Alkem Agreement, a $1,000,000 upfront non-refundable cash payment, of which $500,000 has been paid, as well as potential additional milestone payments totaling up to $1,000,000 subject to the achievement of certain development and regulatory milestones. In addition, Alkem is obligated to pay us a royalty equal to a percentage in the low double digits of net sales less Alkem's actual cost of goods sold and Alkem's sales and marketing and related expenses of SON-080 in India until the first commercial sale of a competitive Intermitted Low Dose IL-6 compound as set forth in the Alkem Agreement.

SON-080: New Life Therapeutics Agreement

In May 2021, we announced the execution of a license agreement, described in detail below (the "New Life Agreement") which resulted in the out-license of our IL-6 (SON-080) asset for DPN to New Life of Singapore. The licensed territory includes the 10 ASEAN countries of Singapore, Malaysia, Indonesia, Thailand, The Philippines, Cambodia, Brunei, Vietnam, Myanmar, and Lao PDR. In June and July of 2021, we amended the New Life Agreement to make Sonnet BioTherapeutics, CH, SA (rather than Sonnet BioTherapeutics, Inc.) the party to the New Life Agreement (First Amendment) and we also made Sonnet BioTherapeutics, Inc. the Guarantor of performance under the New Life Agreement (Second Amendment), respectively. In addition to the initial $500,000 received by Sonnet upon signing of the LOI in August 2020, an additional $500,000 non-refundable upfront payment was received by Sonnet upon execution of the New Life Agreement. According to the terms of the New Life Agreement, we could receive a $1 million deferred license fee within 30 days of the achievement of an early commercial sales milestone, a total of up to $19 million in milestone payments and a tiered royalty ranging from 12% to 30% on commercial sales. In October 2024, we entered into a license agreement with Alkem Laboratories for the development of SON-080 in DPN. The

data generated from this collaboration will inform our decision about moving SON-080 forward into the next phase of DPN development in Southeast Asia.

SON-1210

SON-1210, our lead bifunctional construct, combines IL-12 and IL-15 conjugated to F_HAB. These cytokines were selected based on synergistic biologic activity. IL-15 acts through its specific receptor, IL15Rα, which is expressed on antigen-presenting dendritic cells (APC), monocytes, and macrophages. In addition to the potential antitumor properties of IL-12 described above, we believe IL-15 can potentially add the following complementary activity:

- Induce differentiation and proliferation of T, natural killer (NK) , and B cells
- Enhance cytolytic activity of CD8+ T cells
- Induce long-lasting CD8+ memory T cells enhancing immune surveillance against cancer for month/years
- Stimulate differentiation and immunoglobulin synthesis by B cells
- Induce maturation of dendritic cells
- Up regulate IL-12β1 receptor expression

We have conducted a number of preclinical studies with the murine version of SON-1210 (mIL12-F_HAB-hIL15). Mice injected once with the doses indicated had suppressed tumor growth in the B16F10 melanoma model compared to controls (Figure 12). The combination of IL-12 and IL-15 in *cis* with F_HAB displayed synergistic activity beyond the tumor inhibition seen with mIL12-F_HAB (Figure 13). Overall, the reciprocal biologic activity of IL-12 and IL-15 suggests that:

- IL-12: Increases IL15Rα receptor, IFN-ɣ, NK/T cells, TH1 (tumor killing), and decreases Treg
- IL-15: Increases IL12β 1 receptor, NK cells, CD8 memory and decreases apoptosis

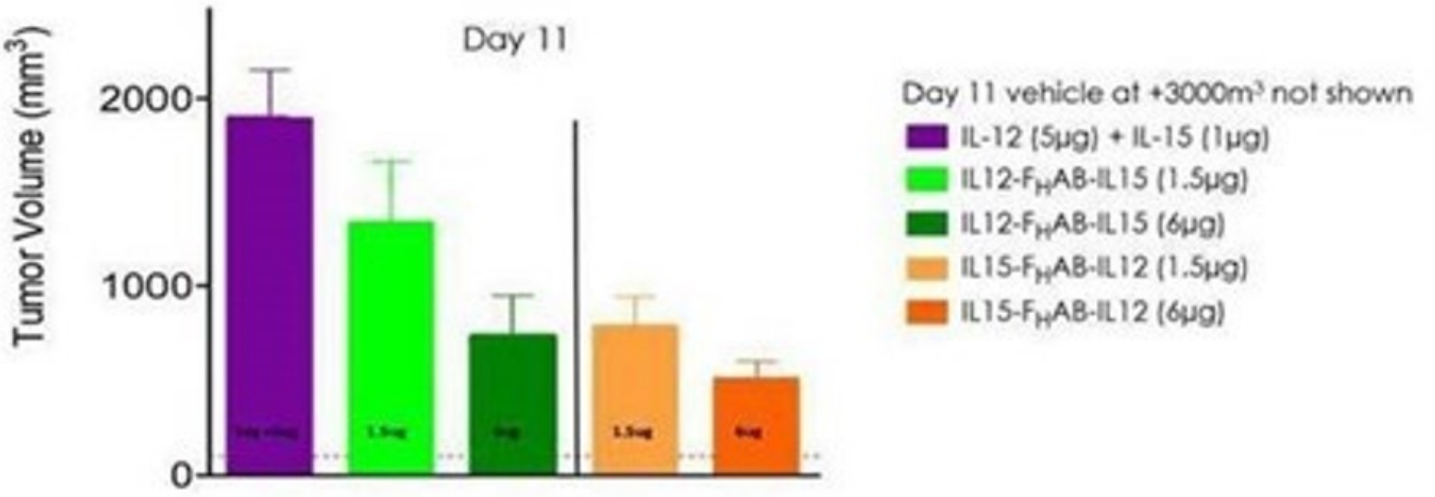


Figure 12: These data *show* an enhanced reduction in tumor growth with*mIL12-FHAB-hIL15* compared to concomitantly administered, naked*m*IL-12 and *h*IL-15 in a mouse model of melanoma.

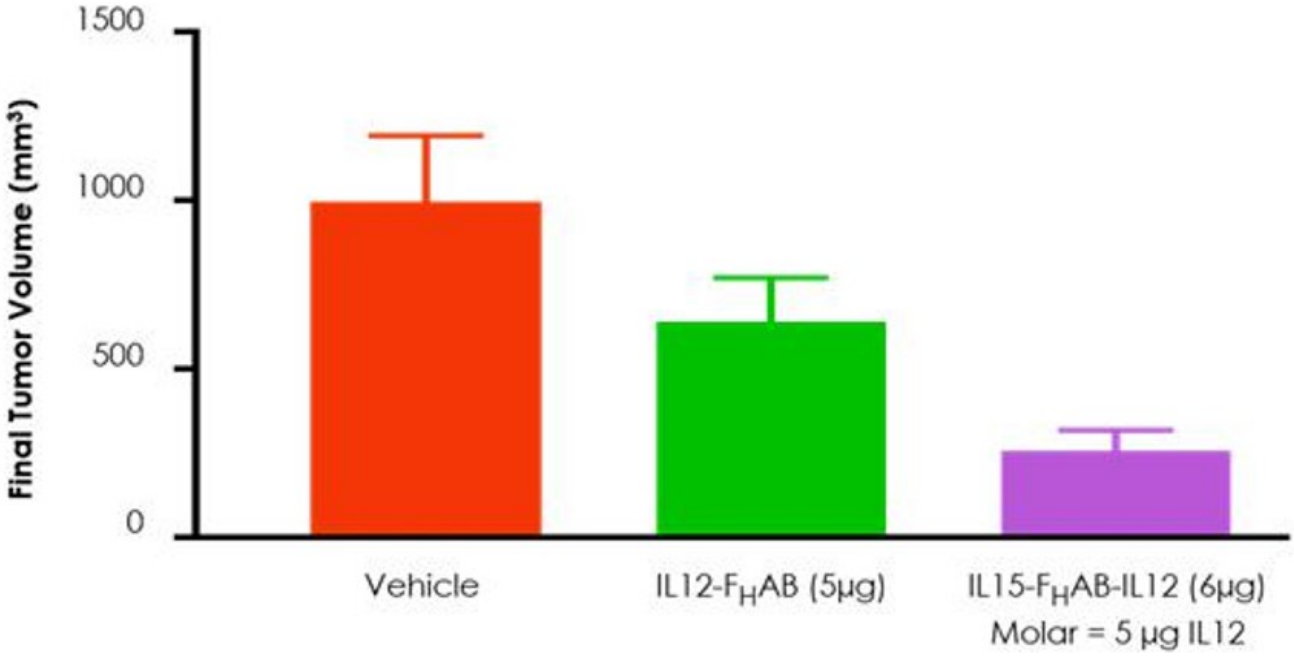


*Figure 13: The combination of IL-12 and IL-15 in*cis *with F_HAB displayed synergistic activity, leading to improved tumor volume reduction versus IL12-F_HAB alone in a mouse model of melanoma.*

In February 2023, we announced the successful completion of two IND-enabling toxicology studies with SON-1210 in NHPs. A NHP non-GLP dose escalation study of SON-1210 was completed in September 2022, and a GLP repeat dose NHP study was completed in the fourth calendar quarter of 2022. cGMP manufacturing for bulk drug is complete, and a lyophilized formulation of drug product was manufactured in early 2023, to support the FIH clinical study. The initial tox material supported the non-GLP study, while the GLP study was being performed on the same lot of GMP drug as intended for the Phase 1 clinical study. The preclinical data for these studies were published in December 2023. The regulatory authorization process for SON-1210 is scheduled to commence pending the outcome of any partnering activity.

SON-1210: Sarcoma Oncology Center Agreement

On August 19, 2024, we announced that we had entered into a Master Clinical Collaboration Agreement (the "Sarcoma Agreement") with the Sarcoma Oncology Center, to advance the development of SON-1210 , our bifunctional IL12-F_HAB-IL15 asset. Preclinical data published on December 20, 2023 demonstrated the potential of SON-1210 for solid tumor immunotherapy. An Innovative Immuno-Oncology Consortium ("IIOC") led by oncology experts funded by the Sarcoma Oncology Center will conduct an investigator-initiated Phase 1b/2a study of SON-1210 in pancreatic cancer. Under the terms of the Sarcoma Agreement, the IIOC, in collaboration with us, will prepare a protocol and conduct an investigator-initiated Phase 1b/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents for the specific treatment of metastatic pancreatic cancer. We will provide the study drug, SON-1210, and support operational services for the planned Phase 1b/2a study.

Discovery Assets: SON-1410 (IL18-F_HAB-IL12) and SON-3015 (Anti-IL6-F_HAB-Anti-TGFβ)

In August 2021, we announced the selection of a novel development candidate after completing comparative studies in a mouse melanoma model. The candidate represents Sonnet's second bifunctional compound integrating IL-12 and IL18 with the company's F_HAB platform. The target indications for SON-1410 will be melanoma and renal cancers.

IL18-F_HAB-IL12 showed statistically significant tumor size reduction in a mouse melanoma study compared with the placebo, as well as a dose response. The data demonstrated:

Compound	Day 0, Single Dose Tumor @ 100 mm^3	Day 8 Tumor Volume (mm^3 +/- SEM), N=8	Day 8 Percentage Tumor Shrinkage
Placebo	NA	1747 +/- 301	-
IL18-F_HAB-IL12	1 µg	918 +/- 130	47%
IL18-F_HAB-IL12	5 µg	619 +/- 141	65%

A separate mouse study was also performed comparing the selected version of IL18-F_HAB-IL12 with two other candidates, GMCSF-F_HAB-IL18 and GMCSF-F_HAB-IL12. The comparison data indicated significantly greater reduction in tumor volume, along with higher IFN-γ levels and immune cell responses (NK, NKT, Th1, and cytotoxic CD8 T cells) using IL18-F_HAB-IL12, compared with GMCSF-F_HAB-IL12 or GMCSF-F_HAB-IL18. Preclinical development continues for SON-1410 (IL18-F_HAB-IL12), where cell line development for GMP application is underway. After some delays in 2023, process development activities will continue into 2024, with the potential to generate a drug suitable for GLP non-clinical studies in NHP's, and subsequent human studies.

TGF-β/IL-6 biology is a strong predictor of overall survival in cancer, and combined targeting to suppress IL-6 and TGFβ signaling using SON-3015 may represent a promising strategy for treating tumor and bone metastases. TGFβ is released from degraded bone, and enhances IL-6 production, contributing to the vicious circle of bone metastasis. High FcRn expression in the bone environment would result in accumulation in the bone of the dual construct anti-IL6-F_HAB-anti-TGFβ, thereby potentially inhibiting or blocking bone metastases. Sonnet has elected to place the SON-3015 development program on hold for expense reduction purposes.

We face numerous challenges and uncertainties with respect to the development and commercialization of our therapeutic compounds, including our F_HAB technology. Please see "*Risk Factors*" contained elsewhere in this prospectus.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Any product candidates that we successfully develop and commercialize will compete with new immunotherapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology treatments. There are many other companies that have commercialized and/or are developing immuno-oncology treatments for cancer including large pharmaceutical and biotechnology companies, such as Amgen, AstraZeneca/MedImmune, Bristol-Myers Squibb, Merck, Novartis, Pfizer and Roche/Genentech.

We face significant competition from pharmaceutical and biotechnology companies that target the use of specific cytokines or other large molecules as immunomodulating therapies in the cancer setting. These generally include, single- or bi-specific antibodies, fusion proteins, antibody drug conjugates and targeted vaccines.

With respect to our lead product candidate, SON-080, we are aware of other companies developing products to treat CIPN, including but not limited to Kyorin Pharmaceuticals and Trevana; however, we believe we are the only company studying the use of a disease-modifying cytokine for the indication.

With respect to our first F_HAB-derived candidate, SON-1010, we are aware of other competing IL-12 programs, which include, but are not limited to those being developed by Xilio Therapeutics, Werewolf Therapeutics, Dragonfly Therapeutics, Krystal Biotech and Precigen. We believe that our F_HAB integrated IL-12 is tumor-targeted with an enhanced PK profile that differentiates it from the competition.

With respect to our earlier stage pipeline F_HAB product candidates SON-1210, SON-2014 and SON-3105, we are not aware of any other competing companies working on these specific bifunctional programs.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and

acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory 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 or our collaborators are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Manufacturing

We rely on contract development and manufacturing organizations, or CDMOs, to produce our drug candidates in accordance with the FDA's current Good Manufacturing Practices, or cGMP, regulations for use in our clinical trials. The manufacture of biopharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. Our pipeline molecules are manufactured using the standard industrial Chinese Hamster Ovary (CHO) platform with common bio-chemical engineering from readily available raw materials.

To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, one of the CDMOs with whom we currently work has increased their scale of production, and is building a cGMP manufacturing site in the United States, available by mid-2025. The landscape for CDMOs is strong and there are multiple potential sources for contract manufacturing. We have not yet engaged alternate suppliers since our current CDMO is able to scale production and continues to successfully manufacture Sonnet's pipeline. Our relationships with CDMOs are managed by internal personnel with extensive experience in pharmaceutical development and manufacturing.

License and Other Commercial Arrangements

Janssen Pharmaceuticals (Johnson & Johnson)

In October 2022, we announced a collaboration agreement with Janssen Biotech, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, where*in vitro* and *in vivo efficacy* of SON-1010 (IL12-F_HAB), SON-1210 (IL12-F_HAB-IL15) and SON-1410 (IL18-F_HAB-IL12) will be evaluated in combination with certain Janssen proprietary cell therapy assets. The agreement was facilitated by Johnson & Johnson Innovation. Under the terms of the agreement, we will supply the three referenced compounds for use in head-to-head *in* vitro and *in vivo* efficacy studies. If successful and subject to provisions of the agreement, Janssen could exercise its option and Sonnet could then seek a license and/or an expanded collaboration.

Alkem Laboratories Limited

On October 8, 2024, we entered into a License Agreement (the "Alkem Agreement") with Alkem Laboratories Limited, a company organized under the laws of India ("Alkem"). Pursuant to the Alkem Agreement, we granted Alkem an exclusive license (with the right to sublicense) to research, develop, manufacture, import, export, market, use and commercialize pharmaceutical products containing our IL-6 (SON-080) asset (or any derivatives, fragments or conjugates thereof) (the "Compounds") (such products, the **"**Products") for the treatment of diabetic peripheral neuropathy (DPN) (the "DPN Field") and to manufacture, import, export, market, use and commercialize Products for the treatment of chemotherapy-induced peripheral neuropathy (CIPN) and autonomic neuropathy (together with the DPN Field, collectively, the "Fields") in India (the "Exclusive Territory"). Except as provided for in the Alkem Agreement, we agreed not to develop, use, sell, offer or otherwise commercialize any Compounds or Products for use in the DPN Field in the Exclusive Territory during the term of the Alkem Agreement. We retain all rights to manufacture Compounds and Products anywhere in the world. We shall enter into a follow-on supply agreement with Alkem pursuant to which we shall manufacture for Alkem Compounds and Products for development and commercialization thereof in accordance with the Alkem Agreement on terms to be negotiated by the parties. Pursuant to the terms of the Alkem Agreement, Alkem will bear the cost of, and be responsible for, among other things, conducting clinical studies and additional non-clinical studies (if any, subject to both parties' approval), preparing and filing applications for regulatory approval and undertaking other developmental and regulatory activities for commercializing Products in the DPN Field in the Exclusive Territory. Alkem will own and maintain all regulatory filings and approvals for Products in the Exclusive Territory. Upon payment of a Clinical Data Access Fee (as defined in the Alkem Agreement), we will have rights to access and use the data generated by the clinical trials conducted in connection with the Alkem Agreement.

In consideration of the license and other rights granted by us, Alkem agreed to pay us, within 12 weeks of the effective date of the License Agreement, a $1,000,000 upfront non-refundable cash payment, of which $500,000 has been paid, as well as potential additional milestone payments totaling up to $1,000,000 subject to the achievement of certain development and regulatory milestones. In addition, during the Royalty Term (as defined below), Alkem is obligated to pay us a royalty equal to a percentage in the low double digits of net sales less Alkem's actual cost of goods sold and Alkem's sales and marketing and related expenses of Products in the Exclusive Territory. The "Royalty Term" means, on a Product-by-Product basis in the Exclusive Territory, the period commencing on the date of the First Commercial Sale (as defined in the License Agreement) of such Product in the Exclusive Territory and continuing until Alkem ceases Commercialization (as defined in the Alkem Agreement) of such Product in the DPN Field. The Royalty Term shall expire upon the first commercial sale of a competitive Intermittent Low-Dose IL6 compound as set forth in the Alkem Agreement.

We retain the sole responsibility to pay our third party licensors to the extent such obligations are applicable to the rights granted to Alkem with respect to the Products and shall remain liable for all obligations under the license related to the Compounds and Products between us and ARES Trading SA. The Alkem Agreement will remain in effect in perpetuity until terminated as a result of breach, bankruptcy or upon 90 days prior written notice, in each case as set forth in the Alkem Agreement. Pursuant to the Alkem Agreement, the parties agreed to form a joint development committee to provide strategic oversight of the parties' collaboration activities under the Alkem Agreement, including to coordinate the development of Products in the Exclusive Territory. The Alkem Agreement also contains customary representations, warranties and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

Sarcoma Oncology Center

On August 19, 2024, we announced that we had entered into a Master Clinical Collaboration Agreement (the "Sarcoma Agreement") with the Sarcoma Oncology Center, to advance the development of SON-1210, our bifunctional IL12-F_HAB-IL15 asset. Preclinical data published on December 20, 2023 has demonstrated the potential of SON-1210 for solid tumor immunotherapy. An Innovative Immuno-Oncology Consortium ("IIOC") led by oncology experts funded by the Sarcoma Oncology Center will conduct an investigator-initiated Phase 1b/2a study of SON-1210 in pancreatic cancer, an indication with significant unmet medical need. Under the terms of the Sarcoma Agreement, the IIOC, led by Dr. Sant Chawla, Director of the Sarcoma Oncology Center, in collaboration with us, will prepare a protocol and conduct an investigator-initiated Phase 1b/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to the combination of liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin ("NALIRIFOX®") for the specific treatment of metastatic pancreatic cancer. NALIRIFOX® is the U.S. FDA regimen approved for the treatment of metastatic pancreatic cancer in the front-line setting. We will provide the study drug, SON-1210, and support operational services for the planned Phase 1b/2a study.

Roche

In January 2023, we announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). Wes have entered into a Master Clinical Trial and Supply Agreement ("MCSA") with Roche, along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer ("PROC") patient setting. Further, we and Roche will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221).

New Life

In May 2021, we entered into a License Agreement (the "New Life Agreement") with New Life Therapeutics PTE, LTD ("New Life"). Under the New Life Agreement, the Company granted New Life an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in Malaysia, Singapore, Indonesia, Thailand, Philippines, Vietnam, Brunei, Myanmar, Lao PDR and Cambodia (the "Exclusive Territory"). New Life had the option exercise an option to expand (1) the field of the exclusive license to include the prevention, treatment or palliation of chemotherapy-induced peripheral neuropathy in humans (the "CIPN Field"), which option is non-exclusive and expired on December 31, 2021; and/or (2) the territorial scope of the license to include the People's Republic of China, Hong Kong and/or India, which option is exclusive and expired on December 31, 2021. In June and July of 2021, we amended the New Life Agreement to make Sonnet BioTherapeutics CH SA (rather than Sonnet BioTherapeutics, Inc.) the party to the New Life Agreement (First Amendment) and we also made Sonnet BioTherapeutics, Inc. the Guarantor of performance under the New Life Agreement (Second Amendment), respectively.

We will retain all rights to manufacture Compounds and Products anywhere in the world. The Company and New Life shall enter into a follow-on supply agreement pursuant to which the Company shall supply to New Life Products for development and commercialization thereof in the DPN Field (and the CIPN Field, if applicable) in the Exclusive Territory on terms to be negotiated by the parties. The Company will also assist in transferring certain preclinical and clinical development know-how that is instrumental in New Life's ability to benefit from the license.

New Life will bear the cost of, and be responsible for, among other things, conducting clinical studies and additional non-clinical studies and other developmental and regulatory activities for commercializing Products in the DPN Field (and the CIPN Field, if applicable) in the Exclusive Territory.

New Life paid us a $0.5 million non-refundable upfront cash payment in August 2020 upon executing a letter of intent to negotiate a license agreement and a $0.5 million non-refundable upfront cash payment in June 2021 in connection with the execution of the New Life Agreement. New Life is also obligated to pay a non-refundable deferred license fee of an additional $1.0 million at the time of the satisfaction of certain milestones, as well as potential additional milestone payments to the Company of up to $19.0 million subject to the achievement of certain development and commercialization milestones. In addition, during the Royalty Term (as defined below), New Life is obligated to pay the Company tiered double digit royalties ranging from 12% to 30% based on annual net sales of Products in the Exclusive Territory. The "Royalty Term" means, on a Product-by-Product and a country-by-country basis in the Exclusive Territory, the period commencing on the date of the first commercial sale (subject to certain conditions) of such Product in such country in the Exclusive Territory and continuing until New Life ceases commercialization of such Product in the DPN Field (or CIPN Field, if applicable).

The New Life Agreement will remain in effect on a Product-by-Product, country-by-country basis and will expire upon the expiration of the Royalty Term for the last-to-expire Product in the last-to-expire country, subject to (i) each party's early termination rights including for material breach or insolvency or bankruptcy of the other party and (ii) the Company's Buy Back Right and New Life's Give Back Right (as defined below).

In addition, New Life granted to the Company an exclusive option to buy back the rights granted by us to New Life and we granted New Life the right to give back the rights with respect to Products in the DPN Field and/or the CIPN Field (if applicable) in one or more countries in the Exclusive Territory on terms to be agreed upon, which options will expire upon the initiation of a Phase III Trial for the applicable Product.

XOMA

We (as successor-in-interest to Oncobiologics, Inc. ("Oncobiologics"), after Oncobiologics spun-off certain assets into Sonnet and concurrently distributed all of its shares in Sonnet on a pro rata basis to Oncobiologics's stockholders on April 6, 2015) and XOMA (US) LLC ("XOMA") are party to a Discovery Collaboration Agreement, dated July 23, 2012 and an Amendment of Discovery Collaboration Agreement, dated May 7, 2019 (together, the "Collaboration Agreement") pursuant to which XOMA granted us a non-exclusive, non-transferrable license and/or right to use certain materials, technologies and related information related to discovery, optimization and development of antibodies and related proteins and to develop and commercialize products thereunder (each, a "Product"). Sonnet is obligated to make contingent milestone payments to XOMA totaling $3.75 million on a Product-by-Product basis upon the achievement of certain development and approval milestones related to a Product. To that point, we have paid $500,000 for initiation of enrollment of a Product (*i.e.,* SON-1010) in a Phase 1 Trial. Sonnet has also agreed to pay XOMA low single-digit royalties on net sales of Products sold by Sonnet. Royalties on each Product are payable on a country-by-country basis until the later of (i) a specified period of time after the First Commercial Sale (as defined in the Collaboration Agreement), and (ii) the date of expiration of the last valid claim in the last-to-expire of the issued patents covered by the Collaboration Agreement. In addition, we have the right to reduce the rate of the royalty on a Product-by-Product basis by paying XOMA a specified amount. The Collaboration Agreement may be terminated by either party for cause and contains customary indemnification provisions.

ARES

On August 28, 2015, Relief, now one of our wholly owned subsidiaries, signed a License Agreement (the "ARES License Agreement") with Ares Trading, a wholly owned subsidiary of Merck KGaA ("ARES"). Under the terms of the ARES License Agreement, ARES has granted us a sublicensable, exclusive, worldwide, royalty-bearing license on proprietary patents to research, develop, use and commercialize products (each, a "Product") using atexakin alfa ("Atexakin"), a low dose formulation of human IL-6 in peripheral neuropathies and vascular complications. Three patents are included in the ARES License Agreement that protect the use of Atexakin to treat i) diabetic neuropathy, ii) chemotherapy-induced peripheral neuropathy and iii) vascular complications.

Pursuant to the ARES License Agreement, we will pay ARES high single-digit royalties on net sales of Products sold by us. Royalties are payable on a Product-by-Product and country-by-country basis until the later of (i) a specified period of time after the First Commercial Sale (as defined in the ARES License Agreement) in such country, and (ii) the last date on which such product is covered by a valid claim in such country. If a Product is not covered by a valid claim in a country or such valid claim has expired or been invalidated before the twelfth (12th) anniversary of the date of the First Commercial Sale of such Product in such country, then the royalty rate will be reduced by fifty percent (50%). We will also pay ARES a sublicensing fee that is a percentage of the proceeds received from a sublicensing event ("Sublicensing Receipts") using a sliding scale (which percentage decreases at later stages of clinical development at which the sublicensing event occurs) that starts in the low double digits and decreases to the high single digits. The ARES License Agreement may be terminated by us for convenience at any time or by either party upon a breach by the other party. The Ares License agreement contains customary indemnification provisions.

The Ares License Agreement was amended effective November 1, 2021, in order to clarify the application of some of the terms and conditions contained therein related to sublicensing. In particular:

- We are now authorized to grant sublicenses to third parties without the prior written consent of ARES, providing that the financial condition of any such sublicenses reflects fair market value as determined by us in good faith.
- Because the initial conditions by which Sonnet would remunerate ARES out of Sublicensing Receipts were unclear, the ARES License Agreement was clarified such that we will now have to pay ARES a percentage of all Sublicensing Receipts in case the relevant sublicense agreement is signed before or after completion of the first Phase 1 clinical trial (as opposed to payment only in case the relevant sublicense agreement is signed after completion of the first Phase 1 clinical trial, as was set in the original ARES License Agreement).
- It was agreed that the foregoing clarification would only apply to future sublicensing agreements, and with respect to the royalties (but not the milestone payments) that may be generated from the New Life Agreement.

Intellectual Property

With respect to our patent portfolio, we have five issued patents (two in the U.S., and one in each of Japan, New Zealand and Russia), and we have filed patent applications directed to numerous fusion proteins that include the Fully Human Albumin Binding domain (F_HAB). If granted, the resulting patents would expire on dates ranging from 2038 to 2044, subject to patent term extensions under certain circumstances. The patent application filings include:

● National filings corresponding to WO/2018/151868 - This application is directed to fully human "Albumin Binding Domain (F_HAB) Fusion Proteins," including fusion proteins with scFv's (*e.g.,* anti-TGFβ, PD-L1, TNF, IL-1, IL-6, IL-8, etc.), fusion proteins with cytokines (*e.g.,* IL-2-F_HAB, IL-12-F_HAB, IL-15-F_HAB, IL-7-F_HAB, etc.) and combinations of two cytokines, such as IL-12-F_HAB-IL-15, GM-CSF-F_HAB-IL-18, and IL-18-F_HAB-IL-12; and methods of treatments using such F_HAB fusion proteins. A patent was issued in the United States on June 8, 2021, as U.S. Patent No. 11,028,166. A patent was issued in Japan on December 23, 2022, as Japanese Patent No. 7200138. A patent was issued in Russia on December 21, 2022, as Russian Patent No. 2786444. A patent was issued in New Zealand on October 3, 2023, as New Zealand Patent No. 756674. U.S. Patent No. 11,028,166 is currently estimated to expire on March 26, 2039, while Japanese Patent No. 7200138, Russian Patent No. 2786444, and New Zealand Patent No. 756674 are estimated to expire on February 20, 2038. As of October 22, 2024, the European Patent Office sent a Communication under Rule 71(3) EPC indicating that their office intends to grant this major territory patent in those European countries selected by Sonnet. Applications are also pending in Australia, Brazil, Canada, China, Europe, Hong Kong, and India. Continuation and divisional applications are pending in the United States and Japan, respectively.

● U.S. Patent No. 11,028,166 and the PCT patent application (PCT/US2018/00085), titled "Albumin Binding Domain Fusion Proteins" originally received an application filing date of February 20, 2018, which is four days after the one-year anniversary of the filing date of U.S. provisional patent applications U.S. 62/459,975 and U.S. 62/459,981 to which both the U.S. patent and the PCT patent application claim a priority benefit. A request to restore the priority benefit to the filing date of U.S. provisional patent applications U.S. 62/459,975 and U.S. 62/459,981 was granted for the U.S. patent and PCT patent application. Subsequently, national phase patent applications were filed from the PCT patent application in Australia, Brazil, Canada, China, Europe, India, Japan, New Zealand and Russia. However, due to differences in the patent laws in these jurisdictions, the priority claims to U.S. 62/459,975 and U.S. 62/459,981 have thus far only been accepted in Australia, Europe, India, Japan, New Zealand, and Russia.

● On November 5, 2024, the USPTO granted our patent No. 12,134,635 entitled "Interleukin 18 (IL-18) Variants and Fusion Proteins Comprising Same," covering two of our novel drug candidates, SON-1411 (IL-18^{BPR}-F_HAB-IL12) and SON-1400 (IL-18^{BPR}-F_HAB), each containing a modified version of recombinant human IL-18 (IL-18^{BPR} = Binding Protein Resistant).

● On June 11, 2024, the USPTO granted our patent No. 12,006,361, titled, "Albumin Binding Domain Fusion Proteins," covering composition of matter for our product candidate SON-1210, our proprietary, bifunctional version of IL-12 and IL-15, configured using our F_HAB platform. The granted patent is a Continuation of Patent No. 11,028,166 issued in June 2021.

● US provisional application directed to anti-IL6-F_HAB fusion proteins, including anti-IL6-F_HAB, anti-IL6-F_HAB-anti-TGFβ, and anti-IL6-F_HAB-anti-IL8 fusion proteins; and methods of treatments using such fusion proteins was re-filed as US 63/245,702 on September 22, 2021. However, due in large part to scientific challenges, the supportive data was not obtained within the one-year period after filing the provisional patent, and therefore, the patent was abandoned.

● US provisional application directed to Antigen/Albumin Binding Domain Conjugates, and methods of treatments using such conjugates was re-filed as US 63/187,278 on May 11, 2021. Data in support of the provisional patent claims was not generated, and therefore, this patent was abandoned.

● US provisional application directed to Method of Treating Age-Related Frailty with Interleukin-6 was filed June 4, 2021, as Application no. 63/197,097 and converted to a PCT patent on June 3, 2022.

● US provisional application directed to Antibody-Based Drug Conjugates was filed December 7, 2021, as Application no. 63/286,996. This provisional patent was abandoned due to insufficient supportive data within the one-year timeframe.

● US provisional patent application directed to IL-12-Albumin-Binding Domain Fusion Protein Formulations and Methods of Use Thereof filed on May 27, 2022, as Application no. 63/346,368. This provisional patent was converted to a PCT application (PCT/US2023/067566) on May 26, 2023.

● US provisional patent application directed to Low Dose IL-6 Formulations and Methods of Use Thereof was filed on March 14, 2023, as Application no. 63/490,202.

● US provisional patent application directed to Low Dose IL-6 Formulations and Methods of Use Thereof filed on September 30, 2022, as Application no. 63/377,971. This provisional patent was converted to a PCT application (PCT/US2023/075593) on September 29, 2023.

● US provisional patent application directed to Methods for the Treatment of Cancer with Recombinant IL-12 Albumin Binding Domain Fusion Proteins filed on November 2, 2022, as Application no. 63/421,846. This provisional patent was converted to a PCT application (PCT/US2023/078366) on November 1, 2023.

● US provisional patent application directed to Methods of Making Recombinant IL-12/IL-15 Albumin Binding Domain Fusion Proteins was filed on April 12, 2024 as Application no. 63/633,641.

● US provisional patent application directed to Methods of Making Recombinant IL-12 Albumin Binding Domain Fusion Proteins was converted to a PCT application (PCT/US2024/19798) on March 13, 2024.

● US provisional patent application directed to Antibody-Based Drug Conjugates was filed October 21, 2024, as Application no. 63/709,765.

● US provisional patent application directed to Methods of Making Recombinant IL-12/IL-15 Albumin Binding Domain Fusion Proteins was filed on April 12, 2024 as Application no. 63/633,641.

● US provisional patent application directed to Methods of Making Recombinant IL-12 Albumin Binding Domain Fusion Proteins was converted to a PCT application (PCT/US2024/19798) on March 13, 2024.

● US provisional patent application directed to Antibody-Based Drug Conjugates was filed October 21, 2024, as Application no. 63/709,765.

With respect to our trademark portfolio, we received international registrational approval with the World Intellectual Property Office (WIPO) for the Sonnet BioTherapeutics and F_HAB marks, each having an Effective Date of September 17, 2020. Further, both marks were published by the European Union Intellectual Property Office (EUIPO), having Effective Dates of Nov. 30, 2020 and December 6, 2020, respectively. In 2021, the USPTO issued Notices of Allowance for both marks, indicating that both applications have successfully completed the opposition period and have matured to registration with the submission acceptable Statements of Use. To that end, the USPTO issued a Notice of Allowance of the Statement of Use for each of the Sonnet BioTherapeutics and F_HAB applications and the Sonnet BioTherapeutics mark already received a Certificate of Registration under Registration no. 6,790,475.

● The Switzerland Trademark Office granted protection to the Sonnet BioTherapeutics and FHAB marks on September 14, 2021, and Oct. 26, 2021, respectively, and are protected under International Trademark Registration nos. 1558330 and 1558471.

● The Canadian Intellectual Property Office granted protection to the Sonnet BioTherapeutics mark on June 8, 2022 and is protected under International Trademark Registration no. 1558330 while the FHAB mark is protected under International Trademark Registration no. 15584471, for which the 18-month opposition period began on November 16, 2022.

● In addition to Switzerland and Canada, the Sonnet BioTherapeutics mark was also granted protection in Australia, European Union, Japan, Mexico, South Korea and the United Kingdom, in each case having a Registration no. of 1558330, an Effective Registration date of Sept. 17, 2020 and a renewal date of September 17, 2030. Likewise, the FHAB mark was granted protection in Australia, China, European Union, Japan, Mexico, South Korea and the United Kingdom, in each case having a Registration no. of 1558471, a Granted Protection Date of September 17, 2020 and renewal date of Sept. 17, 2030.

● Although the Sonnet BioTherapeutics mark was initially rejected in China due to potential non-use claims directed to certain competing companies, our intellectual property law firm is quite confident that since the initial Class 42 rejection was successfully cancelled, two new trademark applications for this same mark were also registered and/or published in 2021 could also be overcome; however, we won't be able to initiate non-use cancellation filings against these marks until 2025, which is the anticipated timeframe by which these pending class 42 applications are likely to become registered in China.

Employees

As of November 1, 2024, we had 13 full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we believe our relationship with our employees is good. Additionally, we utilize independent contractors and other third parties to assist with various aspects of its business.

Government Regulation

The research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products, are extensively regulated by government authorities in the United States, at the federal, state and local level, and other countries and jurisdictions. Some jurisdictions also regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

In the United States, biological products, or biologics, are regulated under the Public Health Service Act, or PHSA, and the Federal Food, Drug, and Cosmetic Act, or FDCA, and their implementing regulations. The failure to comply with the applicable requirements at any time during the product development process may subject an applicant to delays in the conduct of a study, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, without limitation, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, product recalls, product seizures, suspension of production or distribution, injunctions, fines, investigations and civil and criminal penalties. Biological product candidates must be granted a biological license by the FDA before they may be legally marketed in the United States.

The process required by the FDA to obtain a biological license in the United States generally involves the following:

● Completion of extensive nonclinical, or preclinical, laboratory tests and preclinical animal trials and applicable requirements for the humane use of laboratory animals and formulation studies in accordance with applicable regulations, including good laboratory practices, or GLPs;

● Submission to the FDA of an investigational new drug, or IND, application prior to initiation of any human clinical trials. Permission to proceed must be received before the beginning of such trials;

● Performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with the FDA's regulation generally referred to as the good clinical practices, or GCP and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use. The FDA may also impose clinical holds on biological product candidate at any time before or during our clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA;

● Preparation and submission to the FDA of a Biologic License Application, or BLA, for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labeling;

● Review of the product by an FDA advisory committee, as determined by the FDA review division;

● Satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

● Satisfactory completion of one or more FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the BLA;

● Payment of user fees and securing FDA approval of the BLA and licensure of the new biologic product;

● Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any

post-approval studies required by the FDA.

Nonclinical Studies and Investigational New Drug Application

Each product candidate must undergo nonclinical testing before testing in humans. These tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity and must be conducted in compliance with applicable regulations. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

Submission of the IND may result in the FDA not allowing the trial to commence or on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions, it may choose to impose clinical holds on biological product candidates at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and only under terms authorized by the FDA.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted or, for trials conducted outside of the United States, by an independent ethics committee referred to above. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined. Additional studies may be required after approval.

● **Phase 1**: the biological product candidate is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients, such as cancer patients.

● **Phase 2**: the biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, preliminary evaluate the efficacy of the product for specific targeted diseases and determine dosage tolerance, optimal dosage and dosing schedule.

● **Phase 3**: Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population and geographically dispersed clinical study sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide adequate basis for product labelling.

● **Phase 4**: post-approval clinical trials, or Phase 4 clinical trials, may be conducted after initial marketing approval. They provide additional experience for the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Compliance with cGMP Requirements

Before approving a BLA, the FDA will typically inspect the facility(ies) where the product is manufactured to ensure full compliance of the manufacturing processes and facilities with cGMP requirements and consistent production with required specifications. Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities. Manufacturers may have to provide records regarding their establishments.

Review and Approval of a BLA

Results of product candidate development, nonclinical testing and clinical trials are submitted to the FDA as part of a BLA requesting a license to market the product. The BLA must contain extensive and detailed information on the manufacturing and composition of the product and proposed labeling as well as payment of a user fee. The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to accept for filing. Once the submission has been accepted for filing, the FDA begins its in-depth review. The FDA has twelve months in which to complete its initial review of a standard application (or six months for a priority review) and respond to the applicant. The FDA does not always meet its goal dates and the review process may be significantly extended by FDA requests for additional information or clarification. The review process and the goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the goal date.

On the basis of the FDA's evaluation of the application and accompanying information, the FDA may issue an approval letter, denial letter, or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under the Prescription Drug User Fee Act, or PDUFA, as either Class 1 or Class 2, based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed. The FDA issues a denial letter if it determines that the establishment or product does not meet the agency's requirements.

The FDA may also refer the application to an advisory committee for review, evaluation and non-binding recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee.

If the FDA approves a new product, the FDA may limit its approved indications for use as well as require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The FDA may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as (i) fast track designation, (ii) breakthrough therapy designation and (iii) priority review designation.

● **Fast Track Review**: The FDA may designate a product for fast track review if it is intended (alone or in combination with one or more other products) for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA.

● **Breakthrough Therapy:** A product may be designated as a breakthrough therapy and be eligible for expedited review if it is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies.

● **Priority Review**: The FDA may designate a product for priority review if such product treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. This assessment is made by the FDA on a case-by-case basis. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

Even if regulatory approval is granted, a marketed product is subject to continuing comprehensive requirements under federal, state and foreign laws and regulations, including requirements and restrictions regarding adverse event reporting, recordkeeping, marketing, and compliance with cGMP. Adverse events reported after approval of a drug can result in additional restrictions on the use of a marketed product or requirements for additional post-marketing studies or clinical trials.

Maintaining substantial compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include record-keeping requirements, reporting of adverse effects and reporting updated safety and efficacy information.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements relating to the manufacturer or promotion of an approved product may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as significant administrative, civil or criminal sanctions.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of

the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product may be designated as an orphan drug by the FDA Office of Orphan Products Development, or OOPD, based on an acceptable application. The product must then go through the review and approval process like any other product. Orphan drug designations may be revoked based on a change in the incidence of the disease.

A sponsor may request orphan drug designation of a previously unapproved product or a new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Pediatric Research

Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at the company's request or by the FDA's initiative. The FDA may determine that a Risk Evaluation and Mitigation Strategy are necessary to ensure that the benefits of a new product outweigh its risks. REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Sponsors are required to submit an initial pediatric study plan to their IND after their end-of-phase 2 meeting with the FDA

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company also must comply with numerous regulatory requirements of other countries and jurisdictions. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the Member States. Under this system, an applicant must obtain approval from the competent national authority of a European Union Member State in which the clinical trial is to be conducted or in multiple Member States if the clinical trial is to be conducted in a number of Member States. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application, or CTA, must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the Member States and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will apply in 2019 or 2020. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all Member States, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. An applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union Member States. It is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale

of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug has to be of significant benefit compared to products available for the condition. An orphan drug designation provides benefits such as fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. The market exclusivity period may however be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation.

Combination Products in the United States

Certain products, the combination products, may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. A combination product may be (i) a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (ii) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (iii) drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (iv) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect. The FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product, this determination being based on the "primary mode of action" of the combination product. Sponsors may request a jurisdiction determination by submitting a Request for Designation to the office of Combination Drug Products.

Merger with Chanticleer and Acquisition of Relief

The Company was formerly known as Chanticleer Holdings, Inc. Until March 31, 2020, the Company was in the business of owning, operating and franchising fast casual dining concepts domestically and internationally. As previously disclosed, on April 1, 2020, the Company completed its merger transaction with Sonnet BioTherapeutics, Inc. ("Sonnet"), pursuant to which Sonnet 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." Sonnet was incorporated as a New Jersey corporation on April 6, 2015.

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 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. 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 and its direct and indirect subsidiaries and the ongoing business of the Company is the Sonnet business.

In addition, in connection with and prior to the Merger, on April 1, 2020, we completed our 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 our acquisition of Relief Holding's wholly-owned subsidiary, Relief Therapeutics SA ("Relief"), in exchange for the issuance to Relief Holding of shares of Sonnet common stock that converted into an aggregate of 2,460 shares of Company common stock in the Merger.

MANAGEMENT

The following table sets forth certain information about the current directors of the Company. Directors are elected to hold office until the next annual meeting of stockholders and until their successors are elected and qualified.

Directors	Age	Year First Became Director
Pankaj Mohan, Ph.D	60	2020
Nailesh Bhatt (1)(3)	52	2020
Albert Dyrness (1)(2)(3)	61	2020
Donald Griffith	76	2020
Raghu Rao (1)(2)(3)	62	2020
Lori McNeill	52	2022

(1) Member of the Audit Committee of the Board.
(2) Member of the Compensation Committee of the Board.
(3) Member of the Nominating and Corporate Governance Committee of the Board.

Set forth below are brief biographical descriptions of the individuals currently serving as the Company's directors, based on information furnished to the Company by such individuals.

Pankaj Mohan, Ph.D.

Pankaj Mohan, Ph.D. founded Sonnet in 2015 and has since served as a member of its board of directors, and was appointed to our Board of Directors (the "Board") as Chairman at the closing of the Merger. Dr. Mohan became the Chairman of Sonnet in June 2018 and the Chief Executive Officer of Sonnet in January 2019 and was appointed President and Chief Executive Officer of the Company at the closing of the Merger. From January 2011 to June 2018, he served as the President, Chief Executive Officer and Chairman of Oncobiologics, Inc. (now Outlook Therapeutics, Inc.; Nasdaq: OTLK), a company that he founded in 2011. Previously, Dr. Mohan served as head of Business Operations and Portfolio Management of Biologics Process and Product Development at Bristol-Myers Squibb Company and as a Director of Bioprocess Engineering at Genentech, Inc. Prior to that, Dr. Mohan served as a senior manager at Eli Lilly and Company. From May 1993 to April 1996, Dr. Mohan served as Assistant Professor (Lecturer/Fellow) at the Advanced Centre for Biochemical Engineering, University College London, London, United Kingdom. Dr. Mohan received a Ph.D. in Biochemical Engineering from the School of Chemical Engineering, University of Birmingham, Birmingham, United Kingdom, a Masters in Financial Management from Middlesex University Business School, London, United Kingdom, an Executive Management Program (AMP) from Fuqua School of Business at Duke University and a Bachelor of Chemical Engineering from the Indian Institute of Technology in Roorkee, India. He is also an author of an industry reference book on bioprocess operations (McGraw Hill). The Company believes Dr. Mohan is capable of making valuable contributions to the Board due to his extensive knowledge of the biopharmaceutical industry and his prior experience as an executive officer.

Nailesh Bhatt

Nailesh Bhatt has served on Sonnet's board of directors since July 2018, and was appointed to our Board at the closing of the Merger. Since January 2018, Mr. Bhatt has been the Chief Executive Officer and a Board Member of VGYAAN Pharmaceuticals LLC, a company focused on developing and commercializing clinically critical drugs. Prior to that, in November 2001, Mr. Bhatt founded Proximare and is its Managing Director. Proximare is a strategic advisory firm focused exclusively on the pharmaceutical industry. Mr. Bhatt also serves as Board Member of Azurity Pharmaceuticals, Inc. since April 2018. In June 2015, Mr. Bhatt founded Proximare Lifesciences Fund. Mr. Bhatt pursued a Bachelor of Arts at Boston University with a major in Biology. The Company believes Mr. Bhatt can make valuable contributions to the Board due to his years of experience in the pharmaceutical industry working with start-ups to Fortune 500 companies.

Albert Dyrness

Albert Dyrness has served on Sonnet's board of directors since October 2019, and was appointed to our Board at the closing of the Merger. Mr. Dyrness is a recognized biopharmaceutical industry expert in bio-process engineering with expertise in upstream, downstream, and fill/finish processes. Since July 2019, Mr. Dyrness has been the Managing Director of ADVENT Engineering Services, Inc., a Trinity Consultants Company, which serves as its life-sciences division. In 1988, Mr. Dyrness Co-Founded ADVENT Engineering Services, Inc., an engineering consulting firm serving the energy and life sciences industries. Starting with only 4 employees in the San Francisco Bay Area, ADVENT has grown to a staff of over 130 engineers with offices in Toronto, Canada, Singapore, Raleigh, North Carolina, Portland Oregon, Boston, Massachusetts, Irvine and San Ramon, California. In 2016, Mr. Dyrness became President and Chief Technical Officer of ADVENT and, in 2017, guided the company to a merger with Trinity Consultants, a 700-person engineering consulting firm. He also served as a member of the board of directors of Oncobiologics, Inc. (now Outlook Therapeutics, Inc.; Nasdaq: OTLK) from December 2015 to September 2017. In 1986, Mr. Dyrness graduated from the Massachusetts Institute of Technology where he studied mechanical engineering and entrepreneurism. The Company believes Mr. Dyrness is capable of making valuable contributions to the Board due to his years of experience in a Nasdaq-listed public company, along with years of entrepreneurial experience, including in the biopharmaceutical industry.

Donald Griffith, CPA

Donald Griffith, CPA has served on Sonnet's board of directors since its inception in April 2015, was Chairman of the Sonnet board from April 2015 to June 2018, and was appointed to our Board at the closing of the Merger. Mr. Griffith has served as Sonnet's Financial Controller since January 1, 2019, and since the Merger serves as our Controller. Prior to being Financial Controller, he served as Sonnet's Chief Executive Officer and Chief Financial Officer from April 2015 to December 2016. Before that, Mr. Griffith was the Chief Financial Officer, Director and Secretary of Oncobiologics Inc. (now Outlook Therapeutics; Nasdaq: OTLK) from 2011 to 2018. Mr. Griffith has over 40 years' experience in finance and accounting and is the founder and Partner of Stolz & Griffith, LLC, a New Jersey accounting firm. The Company believes Mr. Griffith is capable of making valuable contributions to the Board due to his years of experience in finance as well as in the pharmaceutical industry.

Raghu Rao

Raghu Rao has served on Sonnet's board of directors since November 2019, and was appointed to our Board at the closing of the Merger. Mr. Rao is a serial entrepreneur, strategic business advisor and angel investor. Mr. Rao has founded, scaled and had successful exits with several high-technology companies. In his 33-year career, Mr. Rao has advised clients on the strategy and roll-out of high-profile projects, such as USA.gov, TSA Screening Gateway, Cancer.gov and other eGovernment initiatives. As the Vistage Princeton Chair, from July 2012 to March 2017, Mr. Rao ran three high-performing peer advisory boards for middle-market CEOs and business leaders of companies with total revenues exceeding $2 Billion. As the Chairman & President of InfoZen from August 1995 to July 2008, Mr. Rao has managed over $1 Billion in U.S. Federal Government contracts. Mr. Rao is a 20-year Charter Member of The Indus Entrepreneurs (TiE.org) and a 5-year patron of the Indiaspora. He has held board positions at several companies including Cellix BioSciences (Jan 2016 - Jan 2017), Paper Battery Company (Jan 2009 - Dec 2018), Kovid Group (Feb 2016 - Oct 2017) , WizNucleus (Jun 2010 - present) and InfoZen (Aug 1995 - Jul 2008). Mr. Rao is active in social entrepreneurship and community service. He co-founded the Hindu Jewish Coalition in December 2012 and Forum for Religious Freedom in March 2007, to preserve religious diversity worldwide. He has held non-profit board positions at the Infinity Foundation (New Jersey), Arsha Vidya Gurukulam (Pennsylvania) and the Family Services Agency (Maryland). Mr. Rao has an MBA in Finance from George Washington University (Dec 1991), an M.S. in Computer Science from Virginia Tech (Dec 1986), and a B.Tech. in Electrical Engineering from Indian Institute of Technology Madras (June 1984). The Company believes Mr. Rao is capable of making valuable contributions to the Board due to his 15 years of experience as an executive, along with 25 years of entrepreneurial experience, including in the biotech industry.

Lori McNeill

Lori McNeill has served on our Board since September 2022 and as Chairperson of our Business Advisory Committee since September 2019. Ms. McNeill is the founder and Chief Executive Officer of McNeill Consulting, LLC since 2016, a management consulting company focused on developing leaders to be more effective and ensuring that change management initiatives are seamless. Ms. McNeill has over twenty years' experience in the healthcare industry, thirteen of which were at Pfizer Inc., which included working as the Chief of Staff of Global Operations in the Integrated Health Business unit. From 2020 to 2021, Ms. McNeill was the Chief Operating Officer and Chairperson of the board of directors of Global PPE, Inc., a worldwide supplier of personal protective equipment and safety supplies focused on healthcare and government entities to fight the COVID-19 pandemic. She has been recognized by several institutions: Top 100 Global Women in Leadership - Global Council for the Promotion of International Trade, 2021; Changemakers Summit Award Winner, 2021; The State of Women in Leadership - Cover article for HR.com, 2020; and Pfizer International Innovation Excellence Award, 2011 and is currently Global Chairperson of Womenomics. The Company believes Ms. McNeill is capable of making valuable contributions to the Board due to her over 20 years of experience in the healthcare industry, including in senior leadership positions.

Executive Officers

The following table sets forth certain information about the current executive officers of the Company:

Executive Officers	Age	Position and Office
Pankaj Mohan, Ph.D.	60	President and Chief Executive Officer
Jay Cross	53	Chief Financial Officer
John K. Cini, Ph.D.	72	Chief Scientific Officer
Susan Dexter	69	Chief Technical Officer
Richard Kenney, M.D.	66	Chief Medical Officer

Set forth below are brief biographical descriptions of the individuals currently serving as the Company's executive officers, based on information furnished to the Company by such individuals.

Pankaj Mohan, Ph.D.

See description under Directors.

Jay Cross

Jay Cross joined Sonnet in May 2019 and has since served as its Chief Financial Officer and Chief Business Officer, and was appointed Chief Financial Officer of the Company at the closing of the Merger. Prior to Sonnet, Mr. Cross was a Managing Director with Chardan Capital's healthcare investment banking team from November 2015 to March 2019, where he focused on biopharmaceuticals. Prior to that, from May 2014 to June 2015, Mr. Cross served as a Director with Alere Financial Partners and from May 2011 to October 2013 as a Senior Analyst at Balyasny Asset Management. He launched his career in finance in 1999 as an associate analyst covering biotechnology on the healthcare equity research team at Hambrecht & Quist. Mr. Cross earned an M.P.H. from the Yale University School of Medicine and a B.S. in psychology from Washington & Lee University.

John K. Cini, Ph.D.

John K. Cini, Ph.D. co-founded Sonnet in 2015 and has since served as its Chief Scientific Officer, and was appointed Chief Scientific Officer of the Company at the closing of the Merger, where he oversees and directs the Company's discovery and development programs. His role includes the oversight of the selection process of cancer and immune oncology targets and proof-of-concept testing. Prior to joining Sonnet, he was Vice President of Discovery and Development Sciences at Oncobiologics, Inc. from January 2011 to April 2015. Dr. Cini has successfully advanced more than 20 novel monoclonal antibody products from discovery to IND. He is the holder of several novel product and formulation patents and applications. He has also been directly involved in several successful novel biologics through early discovery research into development and manufacturing through clinical trials and commercialization. Previous positions include Executive Director at Mederex (acquired by Bristol-Myers Squibb in 2010), lead discovery scientific roles at Johnson & Johnson (Ethicon, OrthoBioTech & Pharmaceutical Research), and Bayer. Dr. Cini's therapeutic areas of expertise in system biology include oncology, immune oncology, inflammation, osteoporosis, wound healing, surgical adhesion and cellular aging. Dr. Cini has a PhD in Biochemistry from University of North Texas.

Susan Dexter

Susan Dexter has served as a contract consultant to Sonnet in the capacity of Chief Technical Officer since May 2019 and was appointed full-time Chief Technical Officer of the Company at the closing of the Merger on April 1, 2020. Her role at Sonnet is to manage the operations for drug development from cell line development, through cGMP manufacturing of drug substance and clinical drug product, regulatory submissions to initiate human clinical trials, and supply chain for labeling/packaging and distribution to clinical depots. All activities fall under the FDA's Chemical Manufacturing and Controls for biological drugs ("CMC"). She is also responsible for drug supply and management of non-clinical animal studies in support of regulatory filings related to first-in-human studies. She came to Sonnet with more than thirty years of experience in biotechnology science, manufacturing and business development, having been directly involved in three start-up companies and multiple M&A activities. Her expertise in CMC for biologics process development ranges from cell line development to process development through commercial manufacturing. In her role as Managing Director at Latham Biopharm Group ("LBG") from September 2008 until the closing of the Merger, Ms. Dexter ran the Product Development service offering, managing the activities and disciplines related to pre- clinical toxicology studies, and CMC-related activities including IND filings, Quality oversight of cGMP activities and other related CMC supply chain activities. She came to LBG from Xcellerex, Inc., a CDMO and developer of single use technology for bioprocessing. She was Chief Business Officer at Xcellerex from April 2004 to September 2008. Prior to Xcellerex, from July 1998 to April 2004, she was VP of Business Development at The Dow Chemical Company's CDMO, an acquisition of Collaborative BioAlliance, facilitated by Ms. Dexter in 2000, and Assoc. Director of Business Development at Celltech Biologics, purchased by Lonza Biologics, a biologics CDMO. She worked at Celltech/Lonza from 1986 to July 1998. Ms. Dexter holds a double major with Honors in Immunology and Marketing from American University, Washington, D.C., and certifications from Harvard University in 'Negotiations for Lawyers' and 'Finance for Non-financial Managers'. She was also Professor Emeritus at University College, London, Department of Bioengineering, teaching a credited course lecture and workshop in "Project managing of a biologics facility", to graduate, Ph.D. and post-graduate professionals, from 1999 to 2006. She has served as a non-executive board member for Sartorius Stedim Biotech since 2015, compensation committee member since 2019, and auditing committee member since 2022. In February 2023, Susan was appointed to the board of directors for a London, UK based company Virocell, a technology developer and CDMO for manufacture of viral vectors for cell and gene therapies.

Richard Kenney, M.D.

Richard Kenney, M.D. has served as the Company's Chief Medical Officer since April 2021. Dr. Kenney has more than 20 years of experience in translational-stage development of biologics, as well as the commercialization strategy and corporate management of preclinical, clinical-stage and commercialized vaccines and immunotherapies. As President of ClinReg Biologics, he has provided strategic consulting in clinical and regulatory affairs of biologics and medical monitoring and pharmacovigilance in several capacities. As such, Dr. Kenney also serves as the CMO for Public Health Vaccines' Marburg vaccine program. He previously served as Chief Development Officer at X-VAX Technology and before that had Chief Medical Officer roles at Immune Design and Crucell Holland, where he led the clinical development and regulatory affairs groups. Dr. Kenney was a researcher/reviewer for the FDA for over six years and did post-graduate training at Duke and NIH. Dr. Kenney received a B.S. in Chemistry from George Washington University and his M.D. from Harvard Medical School.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's directors and executive, officers, and persons who are beneficial owners of more than 10% of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the SEC. These persons are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

Based solely upon the Company's review of copies of Forms 3, 4 and 5 furnished to the Company, the Company believes that all of its directors, executive officers and any other applicable stockholders timely filed all reports required by Section 16(a) of the Exchange Act during the fiscal year ended September 30, 2023, except for the following: Form 4s that were due on December 16, 2022 were filed on December 22, 2022 for Nailesh Bhatt, Albert Dyrness, Raghu Rao, Lori McNeil, Pankaj Mohan, John Cini, Jay Cross, Susan Dexter and Rick Kenney; Form 4s that were due on January 10, 2023 were filed on February 17, 2023 for Pankaj Mohan, John Cini, Susan Dexter and Rick Kenney; and a Form 4 that was due on December 13, 2022 was filed on February 17, 2023 for Donald Griffith.

Code of Business Conduct and Ethics

The Company has adopted a Code of Business Conduct and Ethics that applies to its directors, officers and employees. The purpose of the Code of Business Conduct and Ethics is to deter wrongdoing and to provide guidance to the Company's directors, officers and employees to help them recognize and deal with ethical issues, to provide mechanisms to report unethical or illegal conduct and to contribute positively to the Company's culture of honesty and accountability. The Company's Code of Business Conduct and Ethics is publicly available on the Company's website at https://www.sonnetbio.com/. If the Company makes any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver, including any implicit waiver from a provision of the Code of Business Conduct and Ethics to its directors or executive officers, the Company will disclose the nature of such amendments or waiver on its website or in a current report on Form 8-K.

Board Committees

Audit Committee

The Board has established an Audit Committee currently consisting of Messrs. Bhatt (Chairman), Dyrness and Rao. The Audit Committee's primary functions are to oversee and review: the integrity of our consolidated financial statements and other financial information furnished by us, our compliance with legal and regulatory requirements, our systems of internal accounting and financial controls, the independent auditor's engagement, qualifications, performance, compensation and independence, related party transactions, and compliance with our Code of Business Conduct and Ethics.

Each member of the Audit Committee is "independent" as that term is defined under the applicable rules of the SEC and the applicable rules of The Nasdaq Capital Market. The Board has determined that each Audit Committee member has sufficient knowledge in financial and auditing matters to serve on the Committee. The Board determined that Mr. Rao is an "audit committee financial expert," as defined under the applicable rules of the SEC and the applicable rules of The Nasdaq Capital Market. Our Board has adopted an Audit Committee Charter, which is available for viewing at https://www.sonnetbio.com/investors/corporate-governance/governance-documents.

Compensation Committee

The Compensation Committee of the Board of Directors is currently composed of the following two non-employee directors: Mr. Rao (Chairman) and Mr. Dyrness. None of these Compensation Committee members was an officer or employee of the Company during the year ended September 30, 2024. Each member of the Compensation Committee is "independent" as that term is defined under the applicable rules of the SEC and the applicable rules of The Nasdaq Capital Market.

The responsibilities of the Compensation Committee include overseeing the evaluation of our executive officers (including the Chief Executive Officer), determining the compensation of our executive officers, and overseeing the management of risks associated therewith. The Compensation Committee determines and approves the Chief Executive Officer's compensation. The Compensation Committee develops and periodically reviews compensation policies and practices applicable to executive officers, including the criteria upon which executive compensation is based, the specific relationship of corporate performance to executive compensation and the composition in terms of base salary, deferred compensation and incentive or equity-based compensation and other benefits. The Compensation Committee also administers our equity-based plans and makes recommendations to the board with respect to actions that are subject to approval of the board regarding such plans. The Compensation Committee also reviews and makes recommendations to the board with respect to the compensation of directors. The Compensation Committee monitors the risks associated with our compensation policies and practices as contemplated by Item 402(s) of Regulation S-K. Our Board has adopted a Compensation Committee Charter, which is available for viewing at https://www.sonnetbio.com/investors/corporate-governance/governance-documents.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee of the Board is currently composed of Messrs. Bhatt, Dyrness (Chairman) and Rao. None of these members was an officer or employee of the Company during the year ended September 30, 2024. Each member of the Nominating and Corporate Governance Committee is "independent" as that term is defined under the applicable rules of the SEC and the applicable rules of The Nasdaq Capital Stock Market. The Nominating and Corporate Governance Committee nominates individuals to be elected to the Board by our stockholders. The Nominating and Corporate Governance Committee of the Board assesses potential candidates to fill perceived needs on the Board for required skills, expertise, independence and other factors.

The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws and will apply the same criteria to all persons being considered. Our Board has adopted a Nominating and Corporate Governance Committee Charter, which is available for viewing at https://www.sonnetbio.com/investors/corporate-governance/governance-documents.

EXECUTIVE AND DIRECTOR COMPENSATION

Our Board has formed a Compensation Committee. The Compensation Committee is responsible for reviewing and approving management compensation, including salaries, bonuses, and equity compensation. We seek to provide competitive compensation arrangements that attract and retain key talent necessary to achieve our business objectives. At our 2022 annual meeting of stockholders, stockholders voted, on an advisory, non-binding basis, to approve the compensation paid to our Named Executive Officers (as defined below).

Summary Compensation Table

The following table shows the compensation awarded to or earned by each person serving as our principal executive officer during fiscal year 2024, our two most highly compensated executive officers who were serving as executive officers as of September 30, 2024, and up to two additional individuals for whom disclosure would have been provided but for the fact that such individuals were not serving as an executive officer as of September 30, 2024. The persons listed in the following table are referred to herein as the "Named Executive Officers."

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Pankaj Mohan, Ph.D.	2024	538,998	-	87,628	-	-	626,626
President and Chief Executive Officer(2)	2023	538,998	-	95,724	-	-	634,722
John Cini, Ph.D.	2024	397,750	-	21,907	-	-	419,657
Chief Scientific Officer	2023	397,750	-	23,931	-	20,000	441,681
Jay Cross	2024	388,725	-	16,852	-	1,228	406,805
Chief Financial Officer(3)	2023	388,725	-	15,829	-	-	404,554

(1) Represents the aggregate grant date fair value for grants made in fiscal year 2024 and 2023 computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718. This calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full.

(2) Dr. Mohan became the Chairman of Sonnet in June 2018 and the Chief Executive Officer in January 2019, and the Chairman, President and Chief Executive Officer of the Company at the closing of the Merger.

(3) Mr. Cross became the Chief Financial Officer of Sonnet in May 2019, and the Chief Financial Officer of the Company at the closing of the Merger.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

The material terms of each Named Executive Officer's employment agreement or arrangement are described below.

We entered into an employment agreement with Dr. Mohan on December 31, 2018, as amended (the "Mohan Agreement"), setting forth the terms of his employment as Chief Executive Officer. Pursuant to the employment agreement, Dr. Mohan is entitled to, among other things, (i) an annual gross base salary of $490,000, (ii) eligibility for a bonus equal to 5.4% of gross revenue received by the Company from a strategic transaction and (iii) for any year in which the bonus in the previous clause amounts to less than 50% of the base salary, an additional performance-based cash bonus to bring the aggregate cash bonus for such year to up to 50% of the base salary, as determined by the Board. The employment agreement shall terminate in accordance with its terms. Pursuant to Dr. Mohan's employment agreement, if he is terminated without "Cause" or for "Good Reason" within 2 months prior to or within 12 months following a "Change in Control", he is entitled to (i) his base salary for 18 months, (ii) a bonus equal to his performance bonus for the year in which the termination occurs, divided by 12, and then multiplied by 18, and (iii) if he timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 18 months following the termination date, (b) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date he becomes ineligible for COBRA continuation coverage. If Dr. Mohan is terminated without "Cause" or for "Good Reason" not coincident with a "Change in Control", he is entitled to (i) his base salary for 18 months, (ii) any performance bonus for the performance year in which his termination occurs, and (iii) if he timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 18 months following the termination date, (b) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date he becomes ineligible for COBRA continuation coverage.

We entered into an employment agreement with Dr. Cini on January 10, 2020, as amended (the "Cini Agreement"), setting forth the terms of his employment as Chief Scientific Officer. Pursuant to the employment agreement, Dr. Cini is entitled to, among other things, (i) an annual gross base salary of $370,000, (ii) eligibility for a bonus equal to 1.1% of gross revenue received by the Company from a strategic transaction and (iii) for any year in which the bonus in the previous clause amounts to less than 35% of the base salary, an additional performance-based cash bonus to bring the aggregate cash bonus for such year to up to 35% of the base salary, as determined by the Board. The employment agreement shall terminate in accordance with its terms. Pursuant to Dr. Cini's employment agreement, if he is terminated without "Cause" or for "Good Reason" within 2 months prior to or within 12 months following a "Change in Control", he is entitled to (i) his base salary for 12 months and (ii) if he timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 18 months following the termination date, (b) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date he becomes ineligible for COBRA continuation coverage. If Dr. Cini is terminated without "Cause" or for "Good Reason" not coincident with a "Change in Control", he is entitled to (i) his base salary for 9 months and (ii) if he timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 12 months following the termination date, (b) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date he becomes ineligible for COBRA continuation coverage.

We entered into an employment agreement with Mr. Cross on January 10, 2020 (the "Cross Agreement"), setting forth the terms of his employment as Chief Financial Officer. Pursuant to the employment agreement, Mr. Cross is entitled to, among other things, (i) an annual gross base salary of $365,000 and (ii) eligibility for a performance-based cash bonus of up to 40% of the base salary, as determined by the Board. The employment agreement shall terminate in accordance with its terms. Pursuant to Mr. Cross's employment agreement, if he is terminated without "Cause" or for "Good Reason" within 2 months prior to or within 12 months following a "Change in Control", he is entitled to (i) his base salary for 12 months, (ii) any performance bonus for the performance year in which his termination occurs, and (iii) if he timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 18 months following the termination date, (b) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date he becomes ineligible for COBRA continuation coverage. If Mr. Cross is terminated without "Cause" or for "Good Reason" not coincident with a "Change in Control", he is entitled to (i) his base salary for 9 months, (ii) any performance bonus for the performance year in which his termination occurs, and (iii) if he timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 12 months following the termination date, (b) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date he becomes ineligible for COBRA continuation coverage.

Other Agreements

On April 1, 2020, we entered into an employment agreement with Ms. Dexter (the "Dexter Agreement"), setting forth the terms of her employment as Chief Technical Officer. Pursuant to the employment agreement, Ms. Dexter is entitled to, among other things, (i) an annual gross base salary of $310,000 and (ii) eligibility for a performance-based cash bonus of up to 35% of the base salary, as determined by the Board. The employment agreement shall terminate in accordance with its terms. Pursuant to Ms. Dexter's employment agreement, if she is terminated without "Cause" or for "Good Reason" within 2 months prior to or within 12 months following a "Change in Control", she is entitled to (i) her base salary for 12 months, (ii) any performance bonus for the performance year in which her termination occurs, and (iii) if she timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 18 months following the termination date, (b) the date she becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date she becomes ineligible for COBRA continuation coverage. If Ms. Dexter is terminated without "Cause" or for "Good Reason" not coincident with a "Change in Control", she is entitled to (i) his base salary for 9 months, (ii) any performance bonus for the performance year in which her termination occurs, and (iii) if she timely continued coverage under COBRA, payment for COBRA premiums necessary to continue coverage until the earliest of (a) 18 months following the termination date, (b) the date she becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment, or (c) the date she becomes ineligible for COBRA continuation coverage.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth certain information, on an award-by-award basis, concerning unexercised options to purchase common stock, restricted shares of common stock and common stock that has not yet vested for each Named Executive Officer and outstanding as of September 30, 2024.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END - 2024

						Stock Awards			

Name	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Pankaj Mohan Ph.D.	7,554.(1)	$ 49,857
John Cini, Ph.D.	1,888(1)	$ 12,464
Jay Cross	1,452(1)	$ 9,588

(1) Scheduled to vest on January 1, 2025.

Director Compensation

Non-Employee Director Compensation Policy

In connection with the Merger, the Board approved a compensation policy for its non-employee directors. Other than reimbursement for reasonable expenses incurred in connection with attending board and committee meetings, this policy provides for the following cash compensation:

- each non-employee director is entitled to receive an annual fee from us of $35,000;
- the chair of our audit committee will receive an annual fee from us of $15,000;
- the chair of our compensation committee will receive an annual fee from us of $10,000;
- the chair of our nominating and corporate governance committee will receive an annual fee from us of $8,000; and
- each non-chairperson member of the audit committee, the compensation committee and the nominating and corporate governance committee will receive annual fees from us of $7,500, $5,000 and $4,000, respectively.

Except as set forth in the table below, the non-employee directors did not receive any cash or equity compensation during fiscal year 2024:

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Nailesh Bhatt(2)	54,000	4,328	-	-	58,328
Albert Dyrness(3)	55,500	4,328	-	-	59,828
Donald Griffith (4)	-	3,682	-	90,256	93,938
Raghu Rao(5)	116,500	4,328	-	-	120,828
Lori McNeill(6)	60,000	4,328	-	-	64,328

(1) Represents the aggregate grant date fair value for grants made in 2024 computed in accordance with FASB ASC Topic 718. This calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full.
(2) Mr. Bhatt holds an aggregate of 373 restricted stock units, as of September 30, 2024.
(3) Mr. Dyrness holds an aggregate of 373 restricted stock units, as of September 30, 2024.
(4) Mr. Griffith has served as Sonnet's Financial Controller since January 1, 2019, and since the Merger serves as our Controller. The amounts in the table above under "*All Other Compensation*" represent salary and bonus earned by Mr. Griffith for the fiscal year 2024. See the description of the employment agreement with Mr. Griffith below. Mr. Griffith holds an aggregate of 317 restricted stock units, as of September 30, 2024.
(5) Mr. Rao holds an aggregate of 373 restricted stock units, as of September 30, 2024.
(6) Ms. McNeill holds an aggregate of 373 restricted stock units, as of September 30, 2024.

Other Agreement with a Director

We entered into an employment agreement with Mr. Griffith on January 1, 2019, setting forth the terms of his employment as Financial Controller. Pursuant to the employment agreement, Mr. Griffith is entitled to, among other things, (i) an annual prorated gross base salary of $150,000 and (ii) eligibility for a target bonus equal to 25% of gross salary earned. The employment agreement has no specific term and constitutes an at-will employment.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee of the Board is currently composed of the following two non-employee directors: Mr. Rao (chairman) and Mr. Dyrness. None of these Compensation Committee members was an officer or employee of the Company during the year. No Compensation Committee interlocks between the Company and another entity existed.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information as of November 1, 2024 with respect to the beneficial ownership of common stock of the Company by the following: (i) each of the Company's current directors; (ii) each of the named executive officers; (iii) all of the current executive officers and directors as a group; and (iv) each person known by the Company to own beneficially more than five percent (5%) of the outstanding shares of the Company's common stock.

For purposes of the following table, beneficial ownership is determined in accordance with the applicable SEC rules and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as otherwise noted in the footnotes to the table, the Company believes that each person or entity named in the table has sole

voting and investment power with respect to all shares of the Company's common stock shown as beneficially owned by that person or entity (or shares such power with his or her spouse). Under the SEC's rules, shares of the Company's common stock issuable under options that are exercisable on or within 60 days after November 1, 2024 ("Presently Exercisable Options") are deemed outstanding and therefore included in the number of shares reported as beneficially owned by a person or entity named in the table and are used to compute the percentage of the common stock beneficially owned by that person or entity. These shares are not, however, deemed outstanding for computing the percentage of the common stock beneficially owned by any other person or entity.

The percentage of the common stock beneficially owned by each person or entity named in the following table is based on 682,659 shares of common stock issued and outstanding as of November 1, 2024 plus any shares issuable upon exercise of Presently Exercisable Options held by such person or entity.

Name And Address of Beneficial Owner*	Number of Shares of Common Stock Beneficially Owned Prior to this Offering	Percentage of Shares of Common Stock Beneficially Owned	
		Prior to this Offering	After this Offering
Named Executive Officers and Directors:			
Pankaj Mohan, Ph.D.	16,409(1)	2.4%	**%
Nailesh Bhatt	174	**%	**%
Albert Dyrness	164	**%	**%
Donald Griffith	58	**%	**%
Raghu Rao	5,889(2)	**%	**%
Lori McNeill	21	**%	**%
John. K. Cini, Ph.D.	228	**%	**%
Jay Cross	136	**%	**%
All current executive officers and directors as a group (10 persons)	23,373	3.4%	1.3%

* Unless otherwise indicated, the address is c/o Sonnet BioTherapeutics, Inc., 100 Overlook Center, Suite 102, Princeton, New Jersey, 08540.

** Less than 1%.

(1) Includes (i) 377 shares of common stock held by the Mohan Family Office, over which Dr. Mohan has shared power to vote and dispose with Swati Mohan, his spouse and (ii) 3 shares of common stock held individually by Pankhuri Mohan, Dr. Mohan's child, over which Dr. Mohan has shared power to vote and dispose with Pankhuri Mohan. Includes 8,593 shares of common stock currently issuable upon the exercise of warrants.

(2) Includes 3,906 shares of common stock issuable upon exercise of warrants which are exercisable within 60 days of November 1, 2024.

Equity Compensation Plan Information

The following table provides information as of June 30, 2024 regarding shares of the Company's common stock that may be issued under the Company's existing equity compensation plans, including its 2020 Omnibus Equity Incentive Plan (the "2020 Plan").

Plan Category	Equity Compensation Plan Information		
	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (1)	17,152	N/A	-
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	17,152	-	-

(1) The weighted-average exercise price does not reflect the shares that will be issued in connection with the settlement of RSUs, since RSUs have no exercise price. Other than RSUs, there were no outstanding options, warrants, or rights under our equity compensation plan as of June 30, 2024.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than compensation arrangements for named executive officers and directors, the Company describes below each transaction and series of similar transactions, since the beginning of fiscal year 2022, to which the Company was a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 or one percent of the average of the smaller reporting company's total assets at year-end for the last two completed fiscal years; and
- any of the Company's directors, nominees for director, executive officers or holders of more than 5% of the Company's common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for the Company's named executive officers and directors are described in the section entitled "Executive Compensation".

Public Offering

Pankaj Mohan, our Chairman and Chief Executive Officer, purchased 4,296 shares of common stock and 8,593 warrants to purchase 8,593 shares of common stock pursuant to an underwritten public offering by the us at $12.80 per share and accompanying two warrants. The offering closed on October 27, 2023.

Raghu Rao, a director, purchased 1,953 shares of common stock and 3,906 warrants to purchase 3,906 shares of common stock pursuant to an underwritten public offering by the us at $12.80 per share and accompanying two warrants. The offering closed on October 27, 2023.

Indemnification Agreements

The Company has entered into indemnification agreements with each of its current directors and executive officers. These agreements will require the Company to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. The Company also intends to enter into indemnification agreements with its future directors and executive officers.

Director Independence

The Company is currently managed by a six-member board of directors. The Company has determined that Messrs. Bhatt, Dyrness and Rao and Ms. McNeill are "independent" as that term is defined under the rules of The NASDAQ Stock Market.

DESCRIPTION OF CAPITAL STOCK

The following summary of the rights of our capital stock is not complete and is subject to and qualified in its entirety by reference to our Certificate of Incorporation and our Amended and Restated Bylaws ("Bylaws"), copies of which are filed as exhibits to the registration statement of which this prospectus forms a part.

Our authorized capital stock consists of 125,000,000 shares of common stock, par value $0.0001 per share, and 5,000,000 shares of preferred stock, par value $0.0001 per share, of which, as of the date of this prospectus, none of which shares have been designated.

As of close of business on November 1, 2024, 682,659 shares of common stock were issued and outstanding and no shares of preferred stock were issued and outstanding.

The additional shares of our authorized stock available for issuance may be issued at times and under circumstances so as to have a dilutive effect on earnings per share and on the equity ownership of the holders of our common stock. The ability of our board of directors to issue additional shares of stock could enhance the board's ability to negotiate on behalf of the stockholders in a takeover situation but could also be used by the board to make a change-in-control more difficult, thereby denying stockholders the potential to sell their shares at a premium and entrenching current management. The following description is a summary of the material provisions of our capital stock. You should refer to our Certificate of Incorporation and Bylaws, both of which are filed as exhibits to the registration statement of which this prospectus forms a part. The summary below is qualified by provisions of applicable law.

Common Stock

Holders of our common stock are each entitled to cast one vote for each share held of record on all matters presented to stockholders. Cumulative voting is not allowed; the holders of a majority of our outstanding shares of common stock may elect all directors. Holders of our common stock are entitled to receive such dividends as may be declared by our board out of funds legally available and, in the event of liquidation, to share pro rata in any distribution of our assets after payment of liabilities. Our directors are not obligated to declare a dividend. It is not anticipated that we will pay dividends in the foreseeable future. Holders of our do not have preemptive rights to subscribe to any additional shares we may issue in the future. There are no conversion, redemption, sinking fund or similar provisions regarding the common stock. All outstanding shares of common stock are fully paid and nonassessable.

The rights, preferences and privileges of holders of common stock are subject to the rights of the holders of any outstanding shares of preferred stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Securities Transfer Corporation. The transfer agent address is Securities Transfer Corporation, 2901 N Dallas Parkway, Suite 380, Plano, TX 75093, (469) 633-0101.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, all of which are undesignated. Our board of directors has the authority to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders. Although we have no present plans to issue any other shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal. The preferred stock may provide for an adjustment of the conversion price in the event of an issuance or deemed issuance at a price less than the applicable conversion price, subject to certain exceptions.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

- the title and stated value;
- the number of shares offered, the liquidation preference per share and the purchase price;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;

- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
- any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs.

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

Our Certificate of Incorporation and Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control. These provisions are as follows:

- they provide that special meetings of stockholders may be called by the President, the board of directors or at the request by stockholders of record owning at least thirty-three and one-third (33 1/3%) percent of the issued and outstanding voting shares of our common stock;
- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors; and
- they allow us to issue, without stockholder approval, up to 5,000,000 shares of preferred stock that could adversely affect the rights and powers of the holders of our common stock.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), an anti-takeover law. Subject to certain exceptions, the statute prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless:

- prior to such date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least eighty-five percent 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (1) by persons who are directors and also officers and (2) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least sixty-six and two-thirds percent 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, for purposes of Section 203, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns or, within three (3) years prior to the determination of interested stockholder status, owned fifteen percent (15%) or more of a corporation's outstanding voting securities.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the DGCL and subject to any limitations set forth in our Certificate of Incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Nasdaq Listing

Our common stock is traded on The Nasdaq Capital Market under the symbol "SONN."

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) 155,000 shares of our common stock, (ii) pre-funded warrants to purchase up to an aggregate of 956,111 shares of our common stock and (iii) common warrants to purchase up to an aggregate of 2,222,222 of shares of our common stock. Each share of common stock or pre-funded warrant is being sold together with a common warrant to purchase two shares of our common stock. The shares of common stock or pre-funded warrants and accompanying common warrants will be issued separately. We are also registering the shares of common stock issuable from time to time upon exercise of the pre-funded warrants and common warrants offered hereby.

Common Stock

The material terms and provisions of our common stock are described under the caption "Description of Capital Stock" in this prospectus.

Pre-Funded Warrants

The following summary of certain terms and provisions of pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price. Each pre-funded warrant offered hereby will have an initial exercise price per share equal to $0.0001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying common warrants and may be transferred separately immediately thereafter.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Purchasers of the pre-funded warrants in this offering may elect to deliver their exercise notice following the pricing of the offering and prior to the issuance of the pre-funded warrants at closing to have their pre-funded warrants exercised immediately upon issuance and receive shares of common stock underlying the pre-funded warrants upon closing of this offering. A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will round down to the next whole share.

Cashless Exercise. If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act of 1933, as amended ("Securities Act") is not then effective or available, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability. Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing. There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder. Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Common Warrants

The following summary of certain terms and provisions of common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of common warrants for a complete description of the terms and conditions of the common warrants.

Duration and Exercise Price. Each common warrant offered hereby will have an initial exercise price per share equal to $4.50. The common warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock (or pre-funded warrants) and may be transferred separately immediately thereafter. A common warrant to purchase two shares of our common stock will be issued for every share of common stock (or pre-funded warrant to purchase a share of common stock) purchased in this offering.

Exercisability. The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants. No fractional shares of common stock will be issued in connection with the exercise of a common warrant. In lieu of fractional shares, we will round down to the next whole share.

Cashless Exercise. If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

Transferability. Subject to applicable laws, a common warrant may be transferred at the option of the holder upon surrender of the common warrant to us together with the appropriate instruments of transfer.

Exchange Listing. There is no established public trading market for the common warrants, and we do not expect a market to develop. In addition, we do not intend to list the common warrants on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the common warrants will be limited.

Right as a Stockholder. Except as otherwise provided in the common warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the form of common warrant, and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction. In the event of a Change of Control (as defined in each common warrant) approved by our board of directors, the holders of the common warrants have the right to require us or a successor

entity to redeem the common warrants for cash in the amount of the Black-Scholes Value (as defined in each common warrant) of the unexercised portion of the common warrants on the date of the consummation of the Change of Control. In the event of a Change of Control which is not approved by our board of directors, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrants for the consideration paid in the Change of Control in the amount of the Black-Scholes Value of the unexercised portion of the common warrants on the date of the consummation of the Change of Control.

UNDERWRITING

We entered into an underwriting agreement with Chardan, as the underwriter (the "Underwriter") relating to this offering. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the Underwriter and the Underwriter has agreed to purchase the number of shares, pre-funded warrants and common warrants set forth opposite its name in the following table:

	Number of Shares of Common Stock	Number of Pre-Funded Warrants	Number of Common Warrants
Chardan Capital Markets, LLC	155,000	956,111	2,222,222

The Underwriter has agreed to purchase all of the shares of common stock and pre-funded warrants and accompanying common warrants offered by us, if any are purchased. The obligations of the Underwriter may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the obligations of the Underwriter is subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the Underwriter of officers' certificates and legal opinions.

The Underwriter has advised us that it proposes initially to offer the shares of common stock and pre-funded warrants and accompanying common warrants to purchase shares of common stock to the public at the public offering price set forth on the cover page of this prospectus. After the shares of common stock and pre-funded warrants and accompanying common warrants are released for sale to the public, the Underwriter may change the offering price, the concession, and other selling terms at various times.

We have agreed to indemnify the Underwriter against certain liabilities, including liabilities under the Securities Act and to contribute to payments the Underwriter may be required to make in respect thereof.

The Underwriter is offering the securities in this offering subject to prior sale, when, as and if issued to and accepted by them subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The Underwriter reserves the right to withdraw, cancel or modify orders to the public, and to reject orders in whole or in part.

Discounts, Commissions and Reimbursement

The following table provides information regarding the amount of the discounts and commissions to be paid to the Underwriter by us.

	Per Share and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Public offering price	$ 4.500	$ 4.4999	$ 4,999,904
Underwriting discounts and commissions (1)	$ 0.315	$ 0.3150	$ 349,993
Proceeds to us, before expenses	$ 4.185	$ 4.1849	$ 4,649,911

(1) We have agreed to pay the Underwriter a commission of 7.0% of the gross proceeds of this offering.

We have agreed to pay all reasonable out-of-pocket expenses of the Underwriter relating to this offering, including a maximum of $125,000 for the fees and disbursements of counsel to the Underwriter. We have also agreed to pay to the Underwriter, at the closing of this offering, a non-accountable expense allowance equal to 1% of the gross proceeds of this offering.

We estimate that our total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $0.3 million.

Lock-Up Agreements

We have agreed with the Underwriter that we will not, without the prior written consent of the Underwriter, for a period of 30 days after the date of this prospectus: (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any classes of our stocks or any securities convertible into or exercisable or exchangeable for any classes of our stocks, (ii) file or caused to be filed any registration statement with the SEC, relating to the offering of any classes of our stocks or any securities convertible into or exercisable or exchangeable for any classes of our stocks, (iii) complete any offering of debt securities, other than entering into a line of credit with a traditional bank, or (iv) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any classes of our stocks, whether any such transaction described in clause (i), (ii), (iii) or (iv) above is to be settled by delivery of any classes of our stocks or such other securities, in cash or otherwise.

Tail Period

Subject to FINRA Rule 5110(g)(5)(B), the Underwriter will be entitled to receive a cash fee equal to 7.0% of the gross proceeds received by us from any financing or capital raising transaction to the extent that such proceeds are provided to us by any investor directly introduced by the Underwriter to us in connection with this offering during the period beginning on October 23, 2024 and ending on the earlier of April 22, 2025 or six months following the closing of this offering.

Discretionary Accounts

The Underwriter does not intend to confirm sales of the shares of common stock, the pre-funded warrants and the common warrants offered hereby to any accounts over which they have discretionary authority.

Electronic Offer, Sale, and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the Underwriter. The prospectus in electronic format will be identical to the paper version of such prospectus. The Underwriter may agree to allocate a number of shares to the Underwriter and selling group members for sale to their online brokerage account

holders. Internet distributions will be allocated by the Underwriter and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us, and should not be relied upon by investors.

Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "SONN." On November 5, 2024, the last reported sale price of our common stock on The Nasdaq Capital Market was $4.21 per share. There is no established public trading market for the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the pre-funded warrants on any national securities exchange. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Stabilization

In connection with this offering, the Underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids, and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

- Over-allotment transactions involve sales by the underwriter of securities in excess of the number of securities the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriter is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriter may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriter will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriter sells more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, over-allotment transactions, syndicate covering transactions, and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the Underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be affected on the Nasdaq Stock Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, the Underwriter and selling group members may engage in passive market making transactions in our securities on the Nasdaq Stock Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Certain Relationships

The Underwriter and its affiliates have provided, or may in the future, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the Underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of our Company. The Underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Except for the services provided in connection with this offering and as described below, the Underwriter has not provided us with any investment banking or other financial services during the 180-day period preceding the date of this prospectus:

Engagement

On May 22, 2024, we issued a press release announcing that our board of directors initiated a process to explore and review a range of strategic alternatives focused on maximizing stockholder value. We engaged Chardan to act as our financial advisor for this process. With assistance from Chardan and our other advisors, we will assess a full range of strategic alternatives, including but not limited to, business development, strategic partnerships, joint ventures, acquisitions, mergers, business combinations, in-licensing, or other strategic transactions. We have not set a timetable for the conclusion of our review and have not made any decisions related to strategic alternatives at this time. We do not intend to comment further with respect to this review unless or until our board of directors have approved a definitive course of action, the review process has concluded, or we determine that other disclosure is appropriate. There can be no assurance that this evaluation will result in any definitive documentation to consummate one or more transactions, or other strategic changes or outcomes, or, that the terms of any such transactions, changes, or outcomes will be favorable. Even if we enter into a definitive agreement, we may not be successful in completing a transaction, change or outcome, or, if it completes such a transaction, change or outcome, it may not ultimately enhance value or deliver expected benefits.

ChEF Purchase Agreement

On May 2, 2024, we entered into the Purchase Agreement and the Registration Rights Agreement Registration Rights Agreement, each with Chardan related to the Facility. Pursuant to the Purchase Agreement, we have the right from time to time at our option to sell to Chardan up to $25.0 million in aggregate gross purchase price of newly issued shares of our common stock. The Facility will allow us to raise primary equity on a periodic basis at our sole discretion depending on a variety of factors including, among other things, market conditions, the trading price of our common stock, and determinations by us regarding the use of proceeds of such common stock. The Purchase Agreement will be effective for a 36-month period ending May 16, 2027, unless earlier terminated upon the terms and conditions therein. In connection with the execution of the Purchase Agreement, we agreed to pay Chardan a commitment fee in an aggregate amount of $250,000, consisting of (i) $100,000 paid by us on May 15, 2024 (the "Commencement Date"), and (ii) $150,000 payable by us prior to or on the 6-month anniversary of the Commencement Date. We also paid Chardan a documentation fee equal to $25,000 as

consideration in connection with the preparation of the Purchase Agreement.

LEGAL MATTERS

The validity of the common stock and certain other legal matters will be passed upon for us by Lowenstein Sandler LLP, New York, New York. Sullivan & Worcester LLP has acted as counsel to the Underwriter in connection with this offering.

EXPERTS

The consolidated financial statements of Sonnet BioTherapeutics Holdings, Inc. as of September 30, 2023 and 2022 and for the years then ended have been incorporated in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein and in the registration statement, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the September 30, 2023 consolidated financial statements contains an explanatory paragraph that states that Sonnet BioTherapeutics Holdings, Inc. has incurred recurring losses and negative cash flows from operations since inception and will require substantial additional financing to continue to fund its research and development activities that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You should rely only on the information contained in this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information contained in this prospectus is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or any sale of our securities.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public from commercial document retrieval services and over the Internet at the SEC's website at http://www.sec.gov.

We maintain a website at www.sonnetbio.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference into, and is not part of, this prospectus.

INDEX TO FINANCIAL STATEMENTS

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

The financial statements and accompanying notes thereto do not reflect the 1-for-8 reverse stock split that occurred on September 30, 2024.

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Balance Sheets
(unaudited)

	June 30, 2024	September 30, 2023
Assets		
Current assets:		
Cash	$ 3,554,331	$ 2,274,259
Prepaid expenses and other current assets	1,053,830	1,677,396
Incentive tax receivable	519,610	786,574
Total current assets	5,127,771	4,738,229
Property and equipment, net	23,733	33,366

Operating lease right-of-use asset	141,813	193,689
Deferred offering costs	15,000	49,988
Other assets	488,480	414,206
Total assets	$ 5,796,797	$ 5,429,478
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,879,013	$ 2,201,999
Accrued expenses and other current liabilities	1,149,492	3,230,922
Current portion of operating lease liability	81,349	73,048
Deferred income	—	18,626
Total current liabilities	3,109,854	5,524,595
Operating lease liability, net of current portion	68,837	130,863
Total liabilities	3,178,691	5,655,458
Commitments and contingencies (Note 4)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 125,000,000 shares authorized; 5,218,505 and 1,750,426 issued and outstanding at June 30, 2024 and September 30, 2023, respectively	522	175
Additional paid-in capital	117,169,976	110,017,598
Accumulated deficit	(114,552,392)	(110,243,753)
Total stockholders' equity (deficit)	2,618,106	(225,980)
Total liabilities and stockholders' equity (deficit)	$ 5,796,797	$ 5,429,478

See accompanying notes to unaudited interim consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ —	$ 36,850	$ 18,626	$ 110,550
Operating expenses:				
Research and development	1,727,033	2,409,471	4,538,363	9,972,055
General and administrative	1,801,632	1,542,689	4,156,360	5,330,967
Total operating expenses	3,528,665	3,952,160	8,694,723	15,303,022
Loss from operations	(3,528,665)	(3,915,310)	(8,676,097)	(15,192,472)
Other income	—	—	4,327,946	—
Foreign exchange gain (loss)	23,110	(31,432)	39,512	36,517
Net loss	$ (3,505,555)	$ (3,946,742)	$ (4,308,639)	$ (15,155,955)
Per share information:				
Net loss per share, basic and diluted	$ (0.70)	$ (2.95)	$ (0.96)	$ (18.98)
Weighted average shares outstanding, basic and diluted	5,037,508	1,335,872	4,481,803	798,711

See accompanying notes to unaudited interim consolidated financial statements

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

	Common stock		Additional paid-in	Accumulated	
	Shares	Amount	capital	deficit	Total
Balance at October 1, 2023	1,750,426	$ 175	$ 110,017,598	$ (110,243,753)	$ (225,980)
Sale of common stock, net of issuance costs	1,306,250	131	3,916,812	—	3,916,943
Retirement of shares in connection with reverse stock split	(1,522)	—	—	—	—
Net share settlement of warrants	14,362	1	(1)	—	—
Share-based compensation	—	—	50,005	—	50,005
Net loss	—	—	—	(1,168,509)	(1,168,509)
Balance at December 31, 2023	3,069,516	307	113,984,414	(111,412,262)	2,572,459
Issuance of common stock on vesting of restricted stock units and restricted stock awards	7,885	—	—	—	—
Exercise of warrants	35,000	4	55,996	—	56,000
Share-based compensation	—	—	60,395	—	60,395
Net income	—	—	—	365,425	365,425
Balance at March 31, 2024	3,112,401	311	114,100,805	(111,046,837)	3,054,279
Sale of common stock	37,654	4	62,015	—	62,019
Net share settlement of warrants	739,950	74	(74)	—	—
Exercise and modification of warrants, net of issuance costs	1,328,500	133	2,946,835	—	2,946,968
Share-based compensation	—	—	60,395	—	60,395
Net loss	—	—	—	(3,505,555)	(3,505,555)

Balance at June 30, 2024	5,218,505	$ 522	$ 117,169,976	$ (114,552,392)	$ 2,618,106

	Common stock		Additional paid-in	Accumulated	
	Shares	Amount	capital	deficit	Total
Balance at October 1, 2022	251,973	$ 25	$ 88,872,315	$ (91,411,059)	$ (2,538,719)
Sale of common stock, net of issuance costs	109,841	11	4,452,001	—	4,452,012
Net share settlement of warrants	137	—	—	—	—
Share-based compensation	—	—	91,617	—	91,617
Net loss	—	—	—	(5,542,142)	(5,542,142)
Balance at December 31, 2022	361,951	36	93,415,933	(96,953,201)	(3,537,232)
Sale of common stock, net of issuance costs	557,083	56	14,515,912	—	14,515,968
Net share settlement of warrants	10,521	1	(1)	—	—
Issuance of common stock on vesting of restricted stock units	2,127	—	—	—	—
Share-based compensation	—	—	56,998	—	56,998
Net loss	—	—	—	(5,667,071)	(5,667,071)
Balance at March 31, 2023	931,682	93	107,988,842	(102,620,272)	5,368,663
Sale of common stock, net of issuance costs	166,364	17	1,945,660	—	1,945,677
Net share settlement of warrants	508,834	51	(51)	—	—
Issuance of common stock on vesting of restricted stock units	35	—	—	—	—
Exercise of warrants	137,998	14	835	—	849
Share-based compensation	—	—	50,005	—	50,005
Net loss	—	—	—	(3,946,742)	(3,946,742)
Balance at June 30, 2023	1,744,913	$ 175	$ 109,985,291	$ (106,567,014)	$ 3,418,452

See accompanying notes to unaudited interim consolidated financial statements

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

	Nine Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (4,308,639)	$ (15,155,955)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	9,633	9,634
Acquired in-process research and development	12,000	282,000
Amortization of operating lease right-of-use asset	51,876	46,650
Share-based compensation	170,795	198,620
Financing costs related to ChEF Purchase Agreement	370,426	—
Non-cash financing costs	1,732	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	623,566	(218,940)
Incentive tax receivable	266,964	(31,864)
Other assets	(74,274)	(155,366)
Accounts payable	(455,038)	(1,877,222)
Accrued expenses and other current liabilities	(2,034,243)	264,872
Operating lease liability	(53,725)	(34,609)
Deferred income	(18,626)	(110,549)
Net cash used in operating activities	(5,437,553)	(16,782,729)
Cash flows from investing activities:		
Purchase of in-process research and development	(12,000)	(273,250)
Net cash used in investing activities	(12,000)	(273,250)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	3,899,157	21,024,070
Payment of deferred offering costs	(15,000)	—
Payment of financing costs related to ChEF Purchase Agreement	(157,500)	—
Proceeds from exercise and modification of warrants, net of issuance costs	3,002,968	849
Repayments of related party note	—	(748)
Net cash provided by financing activities	6,729,625	21,024,171
Net increase in cash	1,280,072	3,968,192
Cash, beginning of period	2,274,259	3,052,879
Cash, end of period	$ 3,554,331	$ 7,021,071
Supplemental disclosure of non-cash operating, investing and financing activities:		
Net settlement of warrants	$ 75	$ 1,142
ChEF Purchase Agreement financing costs in accounts payable	$ 212,926	$ —
In-process research and development in accounts payable and accrued expenses	$ —	$ 170,000
Deferred offering costs charged against proceeds from sale of common stock	$ —	$ 32,340
Issuance of common stock on vesting of restricted stock units	$ —	$ 5
Common stock issuance costs in accounts payable	$ —	$ 78,073

Sonnet BioTherapeutics Holdings, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

1. Organization and Description of Business

Description of business

Sonnet BioTherapeutics, Inc. ("Prior Sonnet") was incorporated as a New Jersey corporation on April 6, 2015. Prior Sonnet completed a merger with publicly-held Chanticleer Holdings, Inc. ("Chanticleer") on April 1, 2020. After the merger, Chanticleer changed its name to Sonnet BioTherapeutics Holdings, Inc. ("Sonnet" or the "Company"). Sonnet is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single or bifunctional 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. Sonnet designed the construct to improve drug accumulation in solid tumors, as well as to extend the duration of activity in the body. F_HAB development candidates can be produced in mammalian cell culture, which enables glycosylation of the interleukins, thereby reducing the risk of immunogenicity, as well as E. coli. Sonnet believes its F_HAB technology, for which it received a U.S. patent in June 2021, is a distinguishing feature of its biopharmaceutical platform. The approach is well suited for future drug development across a range of human disease areas, including in oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

Sonnet's lead proprietary asset, SON-1010, is a fully human version of Interleukin 12 ("IL-12"), covalently linked to the F_HAB construct, for which Sonnet is pursuing clinical development in solid tumor indications, including ovarian cancer, non-small cell lung cancer and head and neck cancer. In March 2022, the FDA cleared Sonnet's Investigational New Drug ("IND") application for SON-1010. This allowed the Company to initiate a U.S. clinical trial (SB101) in oncology patients with solid tumors during the second calendar quarter of 2022. In September 2021, the Company created a wholly-owned Australian subsidiary, SonnetBio Pty Ltd ("Subsidiary"), for the purpose of conducting certain clinical trials. Sonnet received approval and initiated an Australian clinical study (SB102) of SON-1010 in healthy volunteers during the third calendar quarter of 2022. Interim safety and tolerability data from the SB101 and SB102 studies were reported in April 2023.

In January 2023, Sonnet announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). The companies have entered into a Master Clinical Trial and Supply Agreement ("MCSA"), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer ("PROC") patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and proof-of-concept study (SB221). Part 1 of this 2-part study was approved in June 2023 by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. In August 2023, the FDA accepted the IND for SB221. The trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose ("MTD") of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose ("RP2D"). Part 2 of the study will then investigate SON-1010 in combination with atezolizumab, or the standard of care ("SOC") for PROC in a randomized comparison to show proof-of-concept ("POC").

As part of the ongoing cost-cutting efforts, all antiviral development with SON-1010 has been suspended.

The Company acquired the global development rights to its most advanced compound, SON-080, a fully human version of Interleukin 6 ("IL-6"), in April 2020 through its acquisition of the outstanding shares of Relief Therapeutics SA. Sonnet is advancing SON-080 in target indications of Chemotherapy-Induced Peripheral Neuropathy ("CIPN") and Diabetic Peripheral Neuropathy ("DPN"). Sonnet received approval to initiate an ex-U.S. Phase 1b/2a study with SON-080 in CIPN during the third quarter of 2022. The Data Safety Monitoring Board ("DSMB") overseeing the study met during the first calendar quarter of 2024 and cleared the trial to proceed to Part 2. Following the completion of the DSMB review, Sonnet announced initial safety data from the CIPN study. Pursuant to a license agreement the Company entered into with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, Sonnet and New Life will be jointly responsible for developing SON-080 in DPN. The objective will be to analyze the data and to consider initiating a Phase 2 study, pending the outcome of any partnering activity.

SON-1210 (IL12-F_HAB-IL15), Sonnet's lead bifunctional construct, combines F_HAB with single-chain human IL-12 and human Interleukin 15 ("IL-15"). This compound is being developed for solid tumor indications, including colorectal cancer. In February 2023, Sonnet announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. Sonnet is prepared to initiate the regulatory authorization process for SON-1210, pending the outcome of any partnering activity.

SON-1411 (IL18-F_HAB-IL12) is a bifunctional combination of human Interleukin 18 ("IL-18"), which was modified to resist interaction with the IL-18 inhibitor binding protein, and single-chain human IL-12 for solid tumor cancers. Cell line development and process development are ongoing, with early experimental drug supply suitable for formulation and analytical method development activities. After some delays in 2023, activities will continue through 2024 with the potential to generate a drug suitable for preclinical studies and subsequent human studies.

Sonnet has completed sequence confirmation for SON-3015 (anti-IL6-F_HAB-anti-TGFβ). Early-stage bifunctional drug has been generated and is being stored for future use in in vivo mice studies. The Company has elected to place the SON-3015 development program on hold for expense reduction purposes.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and it expects to incur losses from operations for the foreseeable future primarily due to research and development costs for its potential product candidates. The Company believes its cash of $3.6 million at June 30, 2024 will fund the Company's projected operations into November 2024. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited interim consolidated 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. However, substantial doubt about the Company's ability to continue as a going concern exists. The unaudited interim consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company plans to secure additional capital in the future through equity and/or debt financings, partnerships, collaborations, or other sources to carry out the Company's planned development activities. If additional capital is not available when required, the Company may need to delay or curtail or cease 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 product 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 technologies through research and development and conducting preclinical and clinical 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 consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates (ASUs") of the Financial Accounting Standards Board ("FASB"). In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2024 and its results of operations and cash flows for the three and nine months ended June 30, 2024 and 2023. The unaudited interim consolidated financial statements presented herein do not contain all of the required disclosures under U.S. GAAP for annual financial statements and should be read in conjunction with the annual audited consolidated financial statements and related notes of Sonnet as of and for the year ended September 30, 2023 included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2023. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

b. Consolidation

The unaudited interim consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

c. Use of estimates

The preparation of the unaudited interim consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant estimates and assumptions reflected in these unaudited interim consolidated financial statements include the accrual of research and development expenses. Estimates and assumptions are periodically reviewed in-light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from management's estimates.

d. Incentive tax receivable

Subsidiary is eligible to participate in an Australian research and development tax incentive program. As part of this program, Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by Subsidiary in Australia. The cash refund is available to eligible companies with annual aggregate revenues of less than $20.0 million (Australian) during the reimbursable period. The Company estimates the amount of cash refund it expects to receive related to the Australian research and development tax incentive program and records the incentive when it is probable (i) the Company will comply with relevant conditions of the program and (ii) the incentive will be received. As of June 30, 2024, the Company's estimate of the amount of cash refund it expects to receive for eligible spending related to the Australian research and development tax incentive program was $0.5 million. For the three months ended June 30, 2024 and 2023, $0.1 million and $0.3 million, respectively, for the expected net cash refund related to the tax incentive program was included as a reduction in research and development expenses. For the nine months ended June 30, 2024 and 2023, $0.5 million and $0.8 million, respectively, for the expected net cash refund related to the tax incentive program was included as a reduction in research and development expenses. In December 2023, the Company received $0.8 million from the Australian government related to eligible research and development expenses for the year ended September 30, 2023.

e. Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets. 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 consolidated statement of operations.

f. Collaboration revenue

Collaboration arrangements may contain multiple components, which may include (i) licenses; (ii) research and development activities; and (iii) the manufacturing and supply of certain materials. Payments pursuant to these arrangements may include non-refundable payments, upfront payments, milestone payments upon the achievement of significant regulatory and development events, sales milestones and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under a collaboration arrangement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue as the Company satisfies each performance obligation.

The Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, and assessing the recognition of variable consideration. When consideration is received prior to the Company completing its performance obligation under the terms of a contract, a contract liability is recorded as deferred income. Deferred income expected to be recognized as revenue within the twelve months following the balance sheet date is classified as a current liability. In May 2021, the Company entered into a License Agreement (the "New Life Agreement") with New Life. See Note 5 for further discussion of the New Life Agreement.

g. Research and development expense

Research and development expenses include all direct and indirect costs associated with the development of the Company's biopharmaceutical products. These expenses include personnel costs, consulting fees, and payments to third parties for research, development, and manufacturing services. These costs are charged to expense as incurred.

At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the related project, based on the measure of progress as defined in the contract. Factors the Company considers in preparing the estimates include costs incurred by the service provider, milestones achieved, and other criteria related to the efforts of its service providers. Such estimates are subject to change as additional information becomes available. Depending on the timing of payment to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company will record a prepaid expense or accrued liability relating to these costs. Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Contingent development or regulatory milestone payments are recognized upon the related resolution of such contingencies.

h. Other income

The Company has participated in the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by the New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused net operating losses and unused research and development credits to sell these tax benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the state of New Jersey. The Company received net proceeds of $4.3 million during the nine months ended June 30, 2024 from the sale of New Jersey state net operating losses through the Program, which is included in other income in the unaudited interim consolidated statements of operations. No such proceeds were received during the three months ended June 30, 2024 or during the three and nine months ended June 30, 2023.

i. Reverse stock split

On August 31, 2023, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware, which effected a 1-for-22 reverse stock split of the Company's issued and outstanding shares of common stock. As a result of the reverse stock split, every 22 shares of common stock issued and outstanding was converted into one share of common stock. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity. No fractional shares were issued in connection with the reverse stock split. Stockholders who would otherwise be entitled to a fractional share of common stock were instead entitled to receive a proportional cash payment. The reverse stock split did not change the par value or authorized number of shares of common stock. All common share and per share amounts presented in the unaudited interim consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

j. Net loss per share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period (and potential shares of common stock that are exercisable for little or no consideration). Included in basic weighted-average number of shares of common stock outstanding during the three and nine months ended June 30, 2024 are the pre-funded October 2023 warrants to purchase 797,500 shares of common stock with an exercise price of $0.0001 per share and warrants exercised through the June 2024 inducement offer for 1,500,000 shares of common stock that are being held in abeyance as of June 30, 2024 (see Note 6). Included in basic weighted-average number of shares of common stock outstanding during the nine months ended June 30, 2023 are the Series B warrants to purchase 137 shares of common stock with an exercise price of $0.0308 per share, which were net share settled in November 2022.

Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities such as common stock warrants and stock options which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted shares of common stock outstanding as they would be anti-dilutive:

	June 30,	
	2024	2023
Common stock warrants August 2021	112,429	128,500
Underwriter warrants August 2021	2,287	2,287
Chanticleer warrants	57	57
Series C warrants	18,391	36,778
Series 3 warrants	12,548	12,548
Unvested restricted stock units and awards	137,259	7,840
Common stock warrants February 2023	271,883	271,883
Underwriter warrants February 2023	15,466	44,190
Common stock private placement warrants June 2023	227,272	227,272
Placement agent warrants June 2023	6,818	6,818
Common stock warrants October 2023	2,840,000	—
Underwriter warrants October 2023	85,312	—
Placement agent warrants June 2024	113,140	—
Common stock warrants June 2024	5,625,000	—
	9,467,862	738,173

k. Recent accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.* ASU 2023-07, which is applicable to entities with a single reportable segment, will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023-09 will have on its consolidated financial statements and disclosures.

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	September 30, 2023

Compensation and benefits	$ 189,095	$ 2,091,196
Research and development	753,497	913,145
Professional fees	204,344	224,031
Other	2,556	2,550
	$ 1,149,492	$ 3,230,922

During the first quarter of 2024, the Company cancelled accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023, which has been accounted for as a change in estimate. The cancellation of bonuses reduced research and development expenses by $1.0 million and general and administrative expenses by $0.9 million for the nine months ended June 30, 2024.

4. Commitments and Contingencies

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 consolidated financial position, results of operations, or cash flows.

License agreements

In July 2012, the Company entered into a Discovery Collaboration Agreement (the "Collaboration Agreement") with XOMA (US) LLC ("XOMA"), pursuant to which XOMA granted to the Company a non-exclusive, non-transferable license and/or right to use certain materials, technologies and related information related to discovery, optimization and development of antibodies and related proteins and to develop and commercialize products thereunder. The Company is obligated to make contingent milestone payments to XOMA totaling $3.8 million on a product-by-product basis upon the achievement of certain development and approval milestones related to a product. The Company has also agreed to pay XOMA low single-digit royalties on net sales of products sold by the Company. Royalties on each product are payable on a country-by-country basis until the later of (i) a specified period of time after the first commercial sale, and (ii) the date of expiration of the last valid claim in the last-to-expire of the issued patents covered by the Collaboration Agreement. The first milestone was achieved in April 2022, at which time the Company incurred a $0.5 million license fee which was recorded as acquired in-process research and development. No license fees were incurred during the three and nine months ended June 30, 2024 and 2023.

In August 2015, the Company entered into a License Agreement (the "ARES License Agreement") with Ares Trading, a wholly-owned subsidiary of Merck KGaA ("ARES"). Under the terms of the ARES License Agreement, ARES has granted the Company a sublicensable, exclusive, worldwide, royalty-bearing license on proprietary patents to research, develop, use and commercialize products using atexakin alfa ("Atexakin"), a low dose formulation of human IL-6 in peripheral neuropathies and vascular complications. Pursuant to the ARES License Agreement, the Company will pay ARES high single-digit royalties on net sales of products sold by the Company. Royalties are payable on a product-by-product and country-by-country basis until the later of (i) a specified period of time after the first commercial sale in such country, and (ii) the last date on which such product is covered by a valid claim in such country.

In January 2019, the Company entered into a Frame Services and License Agreement (the "Cellca Agreement") with Sartorius Stedim Cellca GMBH ("Cellca"), pursuant to which Cellca has granted the Company a worldwide, non-exclusive, perpetual, non-transferable license to develop, manufacture or have manufactured, use, sell, import, export and/or otherwise commercialize product based on Cellca's work to generate a specified transfected cell line and develop an upstream production process for such cell line. The Cellca Agreement is effective unless terminated by either party by giving six months notice, or by giving 14 days notice if terminated for good cause. The Company is obligated to make milestone payments to Cellca totaling up to $0.7 million upon the achievement of certain development and approval milestones if the Buy-Out Option is not exercised. The Company has a Buy-Out Option that will be effective between the time of completion of a clinical trial and the receipt of regulatory approval for commercialization of product. The cost to exercise the Buy-Out Option increases on each anniversary of the commencement date of the Buy-Out Option Period, and ranges from $0.1 million to $0.6 million. The cost to exercise the Buy-Out Option will replace the $0.6 million contingent milestone payment due upon final regulatory approval. The first milestone was achieved in April 2022, at which time the Company incurred a $0.1 million license fee which was recorded as acquired in-process research and development. No license fees were incurred during the three and nine months ended June 30, 2024 and 2023.

In October 2021, the Company entered into a Non-Exclusive License Agreement (the "Brink Agreement") with Brink Biologics Inc. ("Brink"), pursuant to which Brink has granted the Company a non-exclusive, non-transferable license and limited right to sublicense certain materials and related information to develop cell-based assays for batch, quality control, stability, efficacy, potency or any other type of assay required for production and commercialization of products. During the product development phase, the Company was obligated to make annual product development license fee payments of approximately $0.1 million. In April 2023, the Brink Agreement was amended, effective November 2022, to reduce the annual license fee payments to $12,000 for storage. If materials are removed from storage during the product development phase, the annual product development license fee of approximately $0.1 million will apply. If a product achieves commercial status, the Company is obligated to make a commercial product license fee payment of approximately $0.1 million per commercial product. The amended agreement has an initial term of one year and will automatically renew for one additional year unless terminated or converted to a product development license. After the second year, the license will automatically convert to a full license requiring a product development or a commercial product license fee unless the parties mutually agree to terminate the agreement. No license fees were incurred during the three months ended June 30, 2024 and 2023. The Company incurred $12,000 in license fees during the nine months ended June 30, 2024 and 2023, which were recorded as acquired in-process research and development and included in research and development expenses in the unaudited interim consolidated statements of operations.

In February 2022, the Company entered into a Biological Materials License Agreement (the "InvivoGen Agreement") with InvivoGen SAS ("InvivoGen"), pursuant to which InvivoGen has granted the Company a worldwide, non-exclusive license to use certain reporter cells for research, development and/or quality control purposes. The InvivoGen Agreement has an initial term of three years and may be extended for two additional three-year periods upon written notice by the Company and payment of an approximately €0.1 million fee per extension (approximately $0.1 million as of June 30, 2024). No license fees were incurred during the three and nine months ended June 30, 2024 and 2023.

In March 2022, the Company entered into a Material Transfer and License Agreement (the "ProteoNic Agreement") with ProteoNic B.V. ("ProteoNic"), pursuant to which ProteoNic has granted to the Company a non-exclusive, non-transferable, non-sublicensable (except as provided for in the ProteoNic Agreement) license for certain materials, including plasmids and DNA sequences used to generate the vectors used in the Company's cell lines, for the Company's use in research, development and commercialization of product. The Company incurred a $24,600 license fee upon obtaining the license. No license fees were incurred during the three and nine months ended June 30, 2024. In January 2024, the Company terminated the ProteoNic Agreement and has no further obligations under the arrangement.

Research and development agreement

In December 2021, the Company entered into a Research and Development Agreement (the "Navigo Agreement"), as subsequently amended, with Navigo Proteins GmbH ("Navigo"), pursuant to which Navigo will perform specified evaluation and development procedures to evaluate certain materials to determine their commercial potential. Under the terms of the Navigo Agreement, the Company has granted Navigo a royalty-free, non-exclusive, worldwide, non-sublicensable, non-transferable right and license to use certain technology to perform the evaluation and development activities, and Navigo has granted the Company (i) an exclusive, worldwide, perpetual, irrevocable,

sublicensable, transferable, royalty-free right and license to research, develop, use, sell, have sold, distribute, import or otherwise commercially exploit certain materials, and (ii) a non-exclusive, worldwide, perpetual, sublicensable, non-transferable right and license to make or have made such materials. The Company incurred a $0.1 million technology access fee upon execution of the Navigo Agreement, at which time it was recorded as acquired in-process research and development. The Company is obligated to make contingent milestone payments to Navigo, totaling up to $1.0 million upon the achievement of certain evaluation and development milestones as outlined in the Navigo Agreement. Certain evaluation milestones were achieved in 2023, including $0.2 million and $0.3 million, respectively, in license fees which were recorded as acquired in-process research and development and included as research and development expenses in the unaudited interim consolidated statement of operations for the three and nine months ended June 30, 2023. No milestones were achieved and no license fees were incurred during the three and nine months ended June 30, 2024.

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.

5. Collaboration Revenue

Under the New Life Agreement, the Company granted New Life an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in Malaysia, Singapore, Indonesia, Thailand, Philippines, Vietnam, Brunei, Myanmar, Lao PDR and Cambodia (the "Exclusive Territory"). New Life had the option to expand (1) the field of the exclusive license to include the prevention, treatment or palliation of chemotherapy-induced peripheral neuropathy in humans (the "CIPN Field"), which option was non-exclusive and expired on December 31, 2021; and/or (2) the territorial scope of the license to include the People's Republic of China, Hong Kong and/or India, which option was exclusive and expired on December 31, 2021.

The Company will retain all rights to manufacture Compounds and Products anywhere in the world. The Company and New Life shall enter into a follow-on supply agreement pursuant to which the Company shall supply to New Life Products for development and commercialization thereof in the DPN Field in the Exclusive Territory on terms to be negotiated by the parties. The Company will also assist in transferring certain preclinical and clinical development know-how that is instrumental in New Life's ability to benefit from the license.

New Life will bear the cost of, and be responsible for, among other things, conducting clinical studies and additional non-clinical studies and other developmental and regulatory activities for and commercializing Products in the DPN Field in the Exclusive Territory.

New Life paid the Company a $0.5 million non-refundable upfront cash payment in August 2020 upon executing a letter of intent to negotiate a license agreement and a $0.5 million non-refundable upfront cash payment in June 2021 in connection with the execution of the New Life Agreement. New Life is also obligated to pay a non-refundable deferred license fee of an additional $1.0 million at the time of the satisfaction of certain milestones, as well as potential additional milestone payments to the Company of up to $19.0 million subject to the achievement of certain development and commercialization milestones. In addition, during the Royalty Term (as defined below), New Life is obligated to pay the Company tiered double-digit royalties ranging from 12% to 30% based on annual net sales of Products in the Exclusive Territory. The "Royalty Term" means, on a Product-by-Product and a country-by-country basis in the Exclusive Territory, the period commencing on the date of the first commercial sale (subject to certain conditions) of such Product in such country in the Exclusive Territory and continuing until New Life ceases commercialization of such Product in the DIPN Field.

The New Life Agreement will remain in effect on a Product-by-Product, country-by-country basis and will expire upon the expiration of the Royalty Term for the last-to-expire Product in the last-to-expire country, subject to (i) each party's early termination rights including for material breach or insolvency or bankruptcy of the other party and (ii) the Company's Buy Back Right and New Life's Give Back Right (as defined below).

In addition, New Life granted to the Company an exclusive option to buy back the rights granted by the Company to New Life and the Company granted New Life the right to give back the rights with respect to Products in the DPN Field in one or more countries in the Exclusive Territory on terms to be agreed upon, which options will expire upon the initiation of a Phase III Trial for the applicable Product.

Revenue recognition

The Company first assessed the New Life Agreement under ASC 808, *Collaborative Arrangements* ("ASC 808"), to determine whether the New Life Agreement or units of accounts within the New Life Agreement represent a collaborative arrangement based on the risks and rewards and activities of the parties. The Company applied relevant guidance from ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), to evaluate the appropriate accounting for the collaborative arrangement with New Life. In accordance with this guidance, the Company identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the "License"); and (ii) transfer of know-how and clinical development and regulatory activities ("R&D Activities"). The options to expand the CIPN Field and territory as well as the future supply agreement represent optional purchases, which are accounted for as separate contracts. The Company evaluated these separate contracts and did not identify any material right to be present. The Company determined that the License and the R&D Activities are not distinct from each other and therefore combined these material promises into a single performance obligation.

The Company determined the initial transaction price of the single performance obligation to be $1.0 million, as the future development and commercialization milestones, which represent variable consideration, are subject to constraint at inception. At the end of each subsequent reporting period, the Company will reevaluate the probability of achievement of the future development and commercialization milestones subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. Any such adjustments will be recorded on a cumulative catch-up basis. For the sales-based royalties, the Company will recognize revenue when the related sales occur.

Collaboration revenue from the single performance obligation is being recognized over the estimated performance of the R&D Activities. There was no collaboration revenue for the three months ended June 30, 2024. The Company recognized $36,850 of collaboration revenue for the three months ended June 30, 2023. The Company recognized $18,626 and $0.1 million of collaboration revenue for the nine months ended June 30, 2024 and 2023, respectively.

6. Stockholders' Equity (Deficit)

On May 2, 2024, the Company entered into a ChEF Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement"), each with Chardan Capital Markets, LLC ("Chardan") related to a "ChEF," Chardan's committed equity facility (the "Facility"). Pursuant to the Purchase Agreement, the Company has the right from time to time at its option to sell to Chardan up to the lesser of (i) $25.0 million in aggregate gross purchase price of newly issued shares of the Company's common stock and (ii) 622,168 shares of the Company's common stock, which is equal to 19.99% of the shares of common stock outstanding immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) the average price of such shares sold to Chardan under the Facility equals or exceeds the base price set forth in the Purchase Agreement, so that the Exchange Cap limitation would not apply to such issuances and sales pursuant to the Purchase Agreement under the rules of the Nasdaq Stock Market or (ii) the Company's stockholders approve the issuance of common stock pursuant to the Purchase Agreement in excess of the

Exchange Cap. The Facility will allow the Company to raise primary equity on a periodic basis at its sole discretion depending on a variety of factors including, among other things, market conditions, the trading price of the common stock, and determinations by the Company regarding the use of proceeds of such common stock. The purchase price of the shares of common stock will be determined by reference to the Volume Weighted Average Price ("VWAP") of the common stock during the applicable purchase period, less a fixed 4% discount to such VWAP, and the total shares to be purchased on any day may not exceed 20% of the trading volume of the Company's common stock during the applicable purchase period. The Purchase Agreement will be effective for a 36-month period ending May 16, 2027. During the three and nine months ended June 30, 2024, the Company sold 37,654 shares of common stock pursuant to the Purchase Agreement for net proceeds of $0.1million. The Company incurred $0.4 million of costs in connection with the Purchase Agreement during the three and nine months ended June 30, 2024, which are included in general and administrative expenses in the unaudited interim consolidated statements of operations.

On October 26, 2023, the Company closed a public offering of common stock and certain warrants through Chardan Capital Markets, LLC and Ladenburg Thalmann & Co. Inc. as underwriters, for net proceeds of $3.9 million through the issuance and sale of 1,306,250 shares of its common stock and, to certain investors, pre-funded warrants to purchase 1,537,500 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 5,687,500 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was $1.60 and the public offering price of each pre-funded warrant and accompanying common warrant was $1.5999. The common warrants were immediately exercisable at a price of $1.60 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision. In connection with the June 2024 inducement offer discussed further below, the exercise price was decreased to $1.20 per share of common stock for common warrants that remained unexercised at the time of the offer. The pre-funded warrants were immediately exercisable at any time, until exercised in full, at a price of $0.0001 per share of common stock. In addition, warrants to purchase 85,312 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of $2.00 per share and expire five years from the date of issuance.

On June 30, 2023, the Company closed a registered direct offering of common stock (and common stock equivalents in lieu thereof) and a concurrent private placement of certain common stock warrants through Chardan Capital Markets, LLC as placement agent, for gross proceeds of $2.3 million and net proceeds of $1.9 million through the issuance and sale of 166,363 shares of its common stock, pre-funded warrants to purchase 60,909 shares of common stock and accompanying common warrants to purchase up to an aggregate of 227,272 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $9.90. The common stock warrants were exercisable beginning December 30, 2023 at a price of $14.8478 per share of common stock, had an original expiration of three and a half years from the date of issuance and contain an alternative cashless provision. In connection with the June 2024 inducement offer discussed further below, the exercise price was decreased to $1.55 per share of common stock for common warrants and the expiration date was extended by approximately two and a half years. The pre-funded warrants were immediately exercisable at any time, until exercised in full, at a price of $0.0022 per share of common stock. All of the pre-funded warrants have been exercised. In addition, warrants to purchase 6,818 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants have an exercise price of $14.8478 per share, were exercisable beginning December 30, 2023 and expire three and a half years from the date of issuance.

On February 10, 2023, the Company closed a public offering of common stock and certain warrants through Chardan Capital Markets, LLC and EF Hutton, division of Benchmark Investments LLC as underwriters, for gross proceeds of $15.0 million and net proceeds of $13.6 million through the issuance and sale of 530,222 shares of its common stock and, to certain investors, pre-funded warrants to purchase 101,090 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 1,262,618 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was $23.76 and the public offering price of each pre-funded warrant and accompanying common warrant was $23.7578. The common stock warrants were immediately exercisable at a price of $23.76 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision whereby, subject to certain conditions, a warrant may be exercised in a cashless transaction for shares of common stock at the rate of half a share of common stock per full share otherwise issuable upon a cash exercise. The pre-funded warrants were immediately exercisable at any time, until exercised in full, at a price of $0.0022 per share of common stock. In addition, warrants to purchase 44,190 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of $29.70 per share and expire five years from the date of issuance.

The Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") on August 15, 2022 (the "2022 Sales Agreement"). Pursuant to the 2022 Sales Agreement, the Company could offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of its common stock having an aggregate offering price of up to $25.0 million, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the 2022 Sales Agreement. Due to the offering limitations applicable to the Company, the Company filed prospectus supplements for the sale of shares of its common stock for an aggregate offering price of up to $7.8 million pursuant to the 2022 Sales Agreement. During the nine months ended June 30, 2023, the Company sold 136,702 shares of common stock pursuant to the 2022 Sales Agreement for gross proceeds of $5.7 million and net proceeds of $5.5 million. There are no registered shares remaining to be sold under the 2022 Sales Agreement.

Common stock warrants

As of June 30, 2024, the following equity-classified warrants and related terms were outstanding:

	Warrants Outstanding		Exercise Price	Expiration Date
Common stock warrants August 2021	112,429	$	261.80	August 24, 2026
Underwriter warrants August 2021	2,287	$	327.25	August 19, 2026
Chanticleer warrants	57	$	18,018.00 - 28,028.00	April 30, 2027 - December 17, 2028
Series C warrants	18,391	$	982.52	October 16, 2025
Series 3 warrants	12,548	$	89.628	August 15, 2027
Common stock warrants February 2023	271,883	$	23.76	February 10, 2028
Underwriter warrants February 2023	15,466	$	29.70	February 8, 2028
Common stock private placement warrants June 2023	227,272	$	1.55	June 21, 2029
Placement agent warrants June 2023	6,818	$	14.8478	December 30, 2026
Common stock warrants October 2023	2,840,000	$	1.20	October 27, 2028
Pre-funded warrants October 2023	797,500	$	0.0001	—
Underwriter warrants October 2023	85,312	$	2.00	October 24, 2028
Placement agent warrants June 2024	113,140	$	1.86	June 19, 2029
Common stock warrants June 2024	5,625,000	$	1.55	June 21, 2029
Total	10,128,103			

On June 19, 2024, the Company entered into inducement offer letter agreements with holders of certain existing warrants issued in October 2023 having an original exercise price of $1.60 per share to purchase up to an aggregate of 2,828,500 shares of the Company's common stock at a reduced exercise price of $1.20 per share. The transaction closed on June 21, 2024, resulting in gross proceeds to the Company of $3.4 million and net proceeds of $2.9 million. Due to beneficial ownership limitations, 1,500,000 shares

of common stock related to the exercise of warrants in this transaction are being held in abeyance as of June 30, 2024. Also in connection with this inducement offer, the Company (i) issued to holders who participated in the transaction new common stock warrants to purchase an aggregate of 5,625,000 shares of common stock, (ii) reduced the exercise price of existing warrants to purchase 2,840,000 shares of common stock for those holders who did not exercise warrants in the transaction from $1.60 per share to $1.20 per share for the remaining term of the warrants, and (iii) reduced the exercise price of certain existing warrants issued in June 2023 to purchase 227,272 shares of common stock from $14.8478 per share to $1.55 per share and extended the expiration date of these warrants from December 30, 2026 to June 21, 2029. The new common stock warrants are immediately exercisable at a price of $1.55 per share and expire five years from the date of issuance. Warrants to purchase 113,140 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants are immediately exercisable at a price of $1.86 per share and expire five years from the date of issuance. The incremental fair value associated with the modification of certain existing June and October 2023 warrants to purchase common stock has been accounted for in additional paid-in capital as an equity cost because the modification was done in order to raise equity by inducing the exercise of warrants.

During the nine months ended June 30, 2024, an aggregate of 768,724 warrants were net share settled, resulting in the issuance of 754,312 shares of common stock, 2,863,500 warrants were exercised on a cash basis (including 1,500,000 warrants for which the related shares are being held in abeyance as of June 30, 2024 due to beneficial ownership limitations), resulting in proceeds of $3.0 million, and 34,458 warrants were abandoned by the warrant holder.

During the nine months ended June 30, 2023, an aggregate of 1,014,872 warrants were net share settled, resulting in the issuance of 519,492 shares of common stock, 137,998 warrants were exercised on a cash basis, resulting in insignificant proceeds, and 332 warrants expired.

7. Share-Based Compensation

In April 2020, the Company adopted the 2020 Omnibus Equity Incentive Plan (the "Plan"). On January 1, 2024, the total number of shares authorized under the Plan increased to 137,260. There was one share available for issuance under the Plan as of June 30, 2024. The Plan increases the amount of shares issuable under the Plan by four percent of the outstanding shares of common stock at each January 1, each year. The Plan permits the granting of share-based awards, including stock options, restricted stock units and awards, stock appreciation rights and other types of awards as deemed appropriate, in each case, in accordance with the terms of the Plan. The terms of the awards are determined by the Company's Board of Directors.

Restricted stock units and awards

On January 1, 2024, 73,440 restricted stock units ("RSUs") and 63,819 restricted stock awards ("RSAs") were granted, 100% of which vest on January 1, 2025. Any unvested RSUs or RSAs will be forfeited upon termination of services. The fair value of an RSU or RSA is equal to the fair market value of the Company's common stock on the date of grant. RSU and RSA expense is amortized straight-line over the vesting period.

The Company recorded share-based compensation expense associated with the RSUs and RSAs in its accompanying unaudited interim consolidated statements of operations as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 28,268	$ 24,554	$ 81,089	$ 102,807
General and administrative	32,127	25,451	89,706	95,813
	$ 60,395	$ 50,005	$ 170,795	$ 198,620

The following table summarizes RSU activity under the Plan:

	RSU	Weighted Average Grant Date Fair Value
Unvested balance at October 1, 2023	2,326	$ 21.78
Granted	73,440	$ 1.76
Vested	(2,326)	$ 21.78
Unvested balance at June 30, 2024	73,440	$ 1.76

As of June 30, 2024, total unrecognized compensation expense relating to unvested RSUs granted was $0.1 million which is expected to be recognized over a weighted-average period of 0.5 years.

The following table summarizes RSA activity under the Plan:

	RSA	Weighted Average Grant Date Fair Value
Unvested balance at October 1, 2023	5,514	$ 28.27
Granted	63,819	$ 1.76
Vested	(5,514)	$ 28.27
Unvested balance at June 30, 2024	63,819	$ 1.76

As of June 30, 2024, total unrecognized compensation expense relating to unvested RSAs granted was $0.1 million which is expected to be recognized over a weighted-average period of 0.5 years.

8. Income Taxes

In August 2022, the U.S. enacted the Inflation Reduction Act of 2022 ("IRA"). The IRA contains a number of tax-related provisions that will be effective for tax years beginning after December 31, 2022, including a corporate alternative minimum tax of 15% on certain large corporations and an excise tax of 1% on corporate stock repurchases. The Company is currently evaluating the various provisions of the IRA and does not anticipate a material impact on its consolidated financial statements.

9. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through August 14, 2024, the date at which the unaudited interim consolidated financial statements were available to be issued.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Sonnet BioTherapeutics Holdings, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Sonnet BioTherapeutics Holdings, Inc. and subsidiaries (the Company) as of September 30, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations since inception and will require substantial additional financing to continue to fund its research and development activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Prepaid development expenses and accrued research and development expense

As discussed in Notes 2 and 3 to the consolidated financial statements, research and development costs are expensed as incurred, which include amounts due to third parties for research, development, and manufacturing services. At the end of each reporting period, the Company compares the payments made to third-party service providers to the estimated progress towards completion of the related project, based on the measure of progress as defined in the contract. Factors the Company considers in preparing the estimates include costs incurred by the service provider, milestones achieved, and other criteria related to the efforts of its service providers. Depending on the timing of payments to the third-party service providers and the progress the Company estimates has been made as a result of the services provided, the Company will record a prepaid expense or accrued liability related to these costs. As of September 30, 2023, the Company reported prepaid expenses and other current assets of $1.7 million, a portion of which related to these costs, and accrued research and development expenses of $0.9 million.

We identified the evaluation of certain prepaid and accrued research and development expenses for third- party service providers as a critical audit matter. Evaluating the estimated progress toward completion of research and development projects, including the factors described above, required especially subjective auditor judgment.

The following are the primary procedures we performed to address this critical audit matter. To evaluate the Company's estimate of costs incurred as of September 30, 2023, for a selection of prepaid and accrued research and development expenses, we (1) examined the provisions in the contracts, invoices and communications received from third party service providers related to the project status; (2) sent confirmations to the third-party service providers; and (3) inquired of the individuals who are responsible for monitoring and tracking the status of research and development activities

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Philadelphia, Pennsylvania
December 14, 2023

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Balance Sheets

	September 30,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,274,259	$ 3,052,879
Prepaid expenses and other current assets	1,677,396	1,643,743
Incentive tax receivable	786,574	717,305
Total current assets	4,738,229	5,413,927
Property and equipment, net	33,366	46,211
Operating lease right-of-use asset	193,689	256,594
Deferred offering costs	49,988	113,280
Other assets	414,206	—
Total assets	$ 5,429,478	$ 5,830,012
Liabilities and stockholders' deficit		
Current liabilities:		
Related party notes	$ —	$ 748
Accounts payable	2,201,999	4,752,340
Accrued expenses and other current liabilities	3,230,922	3,193,972
Current portion of operating lease liability	73,048	51,328
Deferred income	18,626	166,431
Total current liabilities	5,524,595	8,164,819
Operating lease liability, net of current portion	130,863	203,912
Total liabilities	5,655,458	8,368,731
Commitments and contingencies (Note 4)		
Stockholders' deficit:		
Common stock, $0.0001 par value: 125,000,000 shares authorized; 1,750,426 and 251,955 issued and outstanding at September 30, 2023 and 2022, respectively	175	25
Additional paid-in capital	110,017,598	88,872,315
Accumulated deficit	(110,243,753)	(91,411,059)
Total stockholders' deficit	(225,980)	(2,538,719)
Total liabilities and stockholders' deficit	$ 5,429,478	$ 5,830,012

See accompanying notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations

	Years ended September 30,	
	2023	2022
Collaboration revenue	$ 147,805	$ 349,943
Operating expenses:		
Research and development	11,814,690	21,444,019
General and administrative	7,125,732	8,575,283
Total operating expense	18,940,422	30,019,302
Loss from operations	(18,792,617)	(29,669,359)
Foreign exchange loss	(40,077)	(52,482)
Net loss	$ (18,832,694)	$ (29,721,841)
Per share information:		
Net loss per share, basic and diluted	$ (18.14)	$ (150.52)
Weighted average shares outstanding, basic and diluted	$ 1,038,188	$ 197,462

See accompanying notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount	Shares	Amount			
Balance at October 1, 2021	—	$ —	195,579	$ 19	$ 83,949,046	$ (61,689,218)	$ 22,259,847
Sale of preferred stock and common stock warrants, net of issuance costs	22,500	1,540,640	—	—	597,574	—	2,138,214
Conversion of preferred stock into common stock	(22,500)	(1,540,640)	25,101	3	1,540,637	—	—
Sale of common stock, net of issuance costs	—	—	30,206	3	1,908,690	—	1,908,693
Issuance of common stock on vesting of restricted stock units	—	—	1,087	—	—	—	—
Share-based compensation	—	—	—	—	876,368	—	876,368
Net loss	—	—	—	—	—	(29,721,841)	(29,721,841)
Balance at September 30, 2022	—	—	251,973	25	88,872,315	(91,411,059)	(2,538,719)
Sale of common stock, net of issuance costs	—	—	833,287	83	20,895,875	—	20,895,958

Net share settlement of warrants	—	—	519,492	52	(52)	—	—
Issuance of common stock on vesting of restricted stock units	—	—	7,676	1	(1)	—	—
Exercise of warrants	—	—	137,998	14	835	—	849
Share-based compensation	—	—	—	—	248,626	—	248,626
Net loss	—	—	—	—	—	(18,832,694)	(18,832,694)
Balance at September 30, 2023	—	$ —	1,750,426	$ 175	$ 110,017,598	$ (110,243,753)	$ (225,980)

See accompanying notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Cash Flows

	Years ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (18,832,694)	$ (29,721,841)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	282,000	971,477
Depreciation	12,845	12,845
Amortization of operating lease right-of-use asset	62,905	80,412
Share-based compensation	248,626	876,368
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(33,653)	(454,269)
Income tax receivable	(69,269)	(717,305)
Other assets	(414,206)	—
Accounts payable	(2,631,215)	971,041
Accrued expenses and other current liabilities	231,953	641,372
Operating lease liability	(51,329)	(83,685)
Deferred income	(147,805)	(349,943)
Net cash used in operating activities	(21,341,842)	(27,773,528)
Cash flows from investing activities:		
Purchases of in-process research and development	(443,250)	(810,227)
Net cash used in investing activities	(443,250)	(810,227)
Cash flows from financing activities:		
Proceeds from sale of preferred stock and common stock warrants, net of issuance costs	—	2,172,649
Proceeds from sale of common stock, net of issuance costs	21,006,371	1,841,918
Proceeds from exercise of warrants, net of issuance costs	849	—
Repayments of related party notes	(748)	—
Net cash provided by financing activities	21,006,472	4,014,567
Net decrease in cash	(778,620)	(24,569,188)
Cash, beginning of year	3,052,879	27,622,067
Cash, end of year	$ 2,274,259	$ 3,052,879
Supplemental disclosure of non-cash operating, investing and financing activities:		
Change in operating lease right-of-use asset and liability due to amended lease	$ —	$ 213,793
Deferred offering costs charged against proceeds from sale of common stock	$ 32,340	$ —
Deferred offering costs in accounts payable and accrued expenses	$ 49,988	$ 80,940
Net settlement of warrants	$ 52	$ —
In-process research and development in accrued expenses	$ —	$ 161,250
Common stock issuance costs in accounts payable and accrued expenses	$ 78,073	$ —

See accompanying notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of Business

Description of business

Sonnet BioTherapeutics, Inc. ("Prior Sonnet") was incorporated as a New Jersey corporation on April 6, 2015. Prior Sonnet completed a merger with publicly-held Chanticleer Holdings, Inc. ("Chanticleer") on April 1, 2020. After the merger, Chanticleer changed its name to Sonnet BioTherapeutics Holdings, Inc. ("Sonnet" or the "Company"). Sonnet is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single or bifunctional 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.

Sonnet's lead proprietary asset, SON-1010, is a fully human version of Interleukin 12 ("IL-12"), covalently linked to the F_HAB construct, for which Sonnet is pursuing clinical development in solid tumor indications, including ovarian cancer, non-small cell lung cancer and head and neck cancer. In March 2022, the FDA cleared Sonnet's Investigational New Drug ("IND") application for SON-1010. This allowed the Company to initiate a U.S. clinical trial (SB101) in oncology patients with solid tumors during the second calendar quarter of 2022. In September 2021, the Company created a wholly-owned Australian subsidiary, SonnetBio Pty Ltd ("Subsidiary"), for the purpose of conducting certain clinical trials. Sonnet received approval and initiated an Australian clinical study (SB102) of SON-1010 in healthy volunteers during the third calendar

quarter of 2022. Interim safety and tolerability data from the SB101 and SB102 studies were reported in April 2023.

In January 2023, Sonnet announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). The companies have entered into a Master Clinical Trial and Supply Agreement ("MCSA"), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer ("PROC") patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). Part 1 of this 2-part study was approved in June 2023 by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. In August 2023, the FDA accepted the IND for SB221. The trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose (MTD) of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose (RP2D). Part 2 of the study will then investigate SON-1010 monotherapy, its use in combination with atezolizumab, or the standard of care (SOC) for PROC in a randomized comparison to show proof-of-concept (POC).

As part of the ongoing cost-cutting evaluations, all antiviral development with SON-1010 has been suspended.

The Company acquired the global development rights to its most advanced compound, SON-080, a fully human version of Interleukin 6 ("IL-6"), in April 2020 through its acquisition of the outstanding shares of Relief Therapeutics SA. Sonnet is advancing SON-080 in target indications of Chemotherapy-Induced Peripheral Neuropathy ("CIPN") and Diabetic Peripheral Neuropathy ("DPN"). Sonnet received approval to initiate an ex-U.S. Phase 1b/2a study with SON-080 in CIPN during the third quarter of 2022. The Data Safety Monitoring Board ("DSMB") overseeing the study is expected to meet during the first calendar quarter of 2024. Following the completion of the DSMB review, Sonnet anticipates announcing initial safety data from the CIPN study. Pursuant to a license agreement the Company entered into with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, Sonnet and New Life will be jointly responsible for developing SON-080 in DPN. The objective will be to analyze the data and to consider initiating a Phase 2 study once the CIPN safety data has been evaluated.

SON-1210 (IL12-F_HAB-IL15), Sonnet's lead bi-specific construct, combines F_HAB with fully human IL-12 and fully human Interleukin 15 ("IL-15"). This compound is being developed for solid tumor indications, including colorectal cancer. In February 2023, the Company announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. Sonnet is prepared to initiate the regulatory authorization process for SON-1210 pending the outcome of any partnering activity.

SON-1410 (IL18-F_HAB-IL12) is a bi-specific combination of Interleukin 18 ("IL-18") and IL-12 for solid tumor cancers. Cell line development and process development are ongoing, with early experimental drug supply suitable for formulation and analytical method development activities. After some delays in 2023, activities will continue into 2024 with the potential to generate a drug suitable for preclinical studies and subsequent human studies.

The Company has completed sequence confirmation for SON-3015 (anti-IL6-F_HAB-anti-TGFβ). Early stage bi-specific drug has been generated and is being stored for future use in *in vivo* mice studies. Sonnet has elected to place the SON-3015 development program on hold for expense reduction purposes.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations 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. The Company believes its cash of $2.3 million at September 30, 2023, in addition to the $4.1 million in net proceeds received from the October Offering described below, will fund the Company's projected operations into March 2024. The Company also expects to receive a $0.8 million net cash refund from the research and development tax incentive program in Australia (see Note 2) and recently received preliminary approval of its application to sell up to $4.8 million of its New Jersey state net operating losses through the Technology Business Tax Certificate Transfer Program (the "Program"), subject to execution of such sale (see Note 10). 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 consolidated 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On October 26, 2023, the Company closed a public offering of common stock and certain warrants through Chardan Capital Markets, LLC and Ladenburg Thalmann & Co. Inc. as underwriters, for net proceeds of $4.1 million through the issuance and sale of 1,306,250 shares of its common stock and, to certain investors, pre-funded warrants to purchase 1,537,500 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 5,687,500 shares of its common stock (the "October Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was $1.60 and the public offering price of each pre-funded warrant and accompanying common warrant was $1.5999. The common warrants are immediately exercisable at a price of $1.60 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of $0.0001 per share of common stock. In addition, warrants to purchase 85,312 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of $2.00 per share and expire five years from the date of issuance.

The Company plans to secure 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 available 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 product 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 technologies through 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 consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU")

promulgated by the Financial Accounting Standards Board ("FASB").

b. Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

c. Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant estimates and assumptions reflected in these consolidated financial statements include the accrual of research and development expenses. Estimates and assumptions are periodically reviewed in-light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from management's estimates.

d. Reclassifications

Certain amounts from the prior period have been reclassified to conform with the current period presentation.

e. 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 and assess performance. The Company views its operations and manages its business in one segment.

f. Fair value of financial instruments

Management believes that the carrying amounts of the Company's financial instruments, including accounts payable, approximate fair value due to the short-term nature of those instruments.

g. Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets. 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 consolidated statement of operations.

h. Impairment of long-lived assets

The Company reviews long-lived assets, such as property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the undiscounted future cash flows expected to be generated by that asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. There were no impairment charges recorded during the fiscal years ended September 30, 2023 and 2022.

i. Deferred offering costs

Legal and other costs incurred in relation to equity offerings are capitalized as deferred offering costs and charged against the proceeds from equity offerings when received. If a financing is abandoned, deferred offering costs are expensed. As of September 30, 2023, the Company had $49,988 in deferred offering costs associated with the October Offering. As of September 30, 2022, the Company had $0.1 million in deferred offering costs associated with the 2022 Sales Agreement (see Note 7).

j. Incentive tax receivable

Subsidiary is eligible to participate in an Australian research and development tax incentive program. As part of this program, Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by Subsidiary in Australia. The cash refund is available to eligible companies with annual aggregate revenues of less than $20.0 million (Australian) during the reimbursable period. The Company estimates the amount of cash refund it expects to receive related to the Australian research and development tax incentive program and records the incentive when it is probable (i) the Company will comply with relevant conditions of the program and (ii) the incentive will be received. As of both September 30, 2023 and 2022, the Company's estimate of the amount of cash refund it expects to receive for eligible spending related to the Australian research and development tax incentive program was $0.8 million. For each of the years ended September 30, 2023 and 2022, $0.8 million for the expected net cash refund related to the tax incentive program was included in research and development expenses. In January 2023, the Company received $1.1 million from the Australian government related to eligible research and development expenses for the year ended September 30, 2022. In April 2023, the Company refunded the Australian government for $0.2 million due to new information on the Company's clinical trial studies.

k. Collaboration revenue

Collaboration arrangements may contain multiple components, which may include (i) licenses; (ii) research and development activities; and (iii) the manufacturing and supply of certain materials. Payments pursuant to these arrangements may include non-refundable payments, upfront payments, milestone payments upon the achievement of significant regulatory and development events, sales milestones and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under a collaboration arrangement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue as the Company satisfies each performance obligation.

The Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, and assessing the recognition of variable consideration. When consideration is received prior to the Company completing its performance obligation under the terms of a contract, a contract liability is recorded as deferred income. Deferred income expected to be recognized as revenue within the twelve months following the balance sheet date is classified as a current liability. In May 2021, the Company entered into a License Agreement (the "New Life Agreement") with New Life. See Note 6 for further discussion of the New Life Agreement.

l. Research and development expense

Research and development expenses include all direct and indirect costs associated with the development of the Company's biopharmaceutical products. These expenses include personnel costs, consulting fees, and payments to third parties for research, development, and manufacturing services. These costs are charged to expense as incurred.

At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the related project, based on the measure of progress as defined in the contract. Factors the Company considers in preparing the estimates include costs incurred by the service provider, milestones achieved, and other criteria related to the efforts of its service providers. Such estimates are subject to change as additional information becomes available. Depending on the timing of payment to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company will record a prepaid expense or accrued liability relating to these costs. Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Contingent development or regulatory milestone payments are recognized upon the related resolution of such contingencies.

m. Foreign currency

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the U.S. dollar are included in operations in the period in which the transaction occurs and reported within the foreign exchange loss line item in the consolidated statements of operations.

n. Share-based compensation

The Company measures equity classified share-based awards granted to employees and nonemployees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is the vesting period of the respective award. The Company accounts for forfeitures as they occur. For share-based awards with service-based vesting conditions, the Company recognizes compensation expense on a straight-line basis over the service period. The Company classifies share-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

o. Income taxes

The Company uses the asset-and-liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on its income tax return if such a position is more likely than not to be sustained.

p. Reverse stock split

On August 31, 2023, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware, which effected a 1-for -22 reverse stock split of the Company's issued and outstanding shares of common stock. As a result of the reverse stock split, every 22 shares of common stock issued and outstanding was converted into one share of common stock. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity. No fractional shares were issued in connection with the reverse stock split. Stockholders who would otherwise be entitled to a fractional share of common stock were instead entitled to receive a proportional cash payment. The reverse stock split did not change the par value or authorized number of shares of common stock. All common share and per share amounts presented in the consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

q. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period (and potential shares of common stock that are exercisable for little or no consideration).

Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities such as common stock warrants and stock options which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted shares of common stock outstanding as they would be anti-dilutive:

	September 30,	
	2023	**2022**
Common stock warrants August 2021	128,500	128,500
Underwriter warrants August 2021	2,287	2,287
Private warrants	—	332
Chanticleer warrants	57	57
Series C warrants	36,778	36,778
Series 3 warrants	12,548	12,548
Unvested restricted stock units and awards	2,326	2,162

Common stock warrants February 2023	271,883	—
Underwriter warrants February 2023	44,190	—
Common stock private placement warrants June 2023	227,272	—
Placement agent warrants June 2023	6,818	—
	732,659	182,664

r. Recent accounting pronouncements

Recently adopted

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The amendments in ASU 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The adoption of ASU 2021-04 on October 1, 2022 did not have any impact on the consolidated financial statements.

In November 2021, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2021-10, Government Assistance (Topic 832): Disclosure by Business Entities about Government Assistance, or ASU 2021-10, which improves the transparency of government assistance received by most business entities by requiring the disclosure of: (1) the types of government assistance received; (2) the accounting for such assistance; and (3) the effect of the assistance on a business entity's financial statements. This guidance is effective for financial statements issued for annual periods beginning after 15 December 2021. The adoption of the guidance on October 1, 2022 did not have a material impact on our consolidated financial statements.

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30,	
	2023	**2022**
Compensation and benefits	$ 2,091,196	$ 1,218,530
Research and development	913,145	1,593,922
Professional fees	224,031	378,890
Other	2,550	2,630
	$ 3,230,922	$ 3,193,972

4. Leases

In December 2019, the Company entered into a 36-month lease for office space in Princeton, New Jersey, which commenced February 1, 2020. In May 2022, the Company amended the existing lease agreement in order to increase the lease term by approximately three years, which has been accounted for as a lease modification. The operating lease right-of-use asset and liability were remeasured at the modification date, resulting in an increase to both balances of $0.2 million.

The components of lease expense for the years ended September 30, 2023 and 2022 are as follows:

Lease expense	**2023**	**2022**
Operating lease expense	$ 90,837	$ 94,828
Variable lease expense	5,978	5,339
Total lease cost	$ 96,815	$ 100,167

At September 30, 2023, the weighted average remaining lease term was 2.6 years and the weighted average discount rate was 12%.

Cash flow information related to operating leases for the years ended September 30, 2023 and 2022 is as follows:

Cash paid for amounts included in the measurement of lease liabilities:	**2023**	**2022**
Operating cash flows from operating leases	$ 79,259	$ 98,101

Future minimum lease payments under non-cancellable leases at September 30, 2023 are as follows:

Fiscal year	
2024	$ 93,614
2025	95,487
2026	48,216
Total undiscounted lease payments	237,317
Less: imputed interest	(33,406)
Total lease liabilities	$ 203,911

5. Commitments and Contingencies

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 consolidated financial position, results of operations, or cash flows.

License agreements

In July 2012, the Company entered into a Discovery Collaboration Agreement (the "Collaboration Agreement") with XOMA (US) LLC ("XOMA"), pursuant to which XOMA granted to the Company a non-exclusive, non-transferable license and/or right to use certain materials, technologies and related information related to discovery, optimization and development of antibodies and related proteins and to develop and commercialize products thereunder. The Company is obligated to make contingent milestone payments to XOMA totaling $3.8 million on a product-by-product basis upon the achievement of certain development and approval milestones related to a product. The Company has also agreed to pay XOMA low single-digit royalties on net sales of products sold by the Company. Royalties on each product are payable on a country-by-country basis until the later of (i) a specified period of time after the first commercial sale, and (ii) the date of expiration of the last valid claim in the last-to-expire of the issued patents covered by the Collaboration Agreement. The first milestone was achieved in April 2022, at which time the Company incurred a $0.5 million license fee which was recorded as acquired in-process research and development and included as research and development expenses in the consolidated statement of operations for the year ended September 30, 2022. No license fees were incurred during the year ended September 30, 2023.

In August 2015, the Company entered into a License Agreement (the "ARES License Agreement") with Ares Trading, a wholly-owned subsidiary of Merck KGaA ("ARES"). Under the terms of the ARES License Agreement, ARES has granted the Company a sublicensable, exclusive, worldwide, royalty-bearing license on proprietary patents to research, develop, use and commercialize products using atexakin alfa ("Atexakin"), a low dose formulation of human IL-6 in peripheral neuropathies and vascular complications. Pursuant to the ARES License Agreement, the Company will pay ARES high single-digit royalties on net sales of products sold by the Company. Royalties are payable on a product-by-product and country-by-country basis until the later of (i) a specified period of time after the first commercial sale in such country, and (ii) the last date on which such product is covered by a valid claim in such country.

In January 2019, the Company entered into a Frame Services and License Agreement (the "Cellca Agreement") with Sartorius Stedim Cellca GMBH ("Cellca"), pursuant to which Cellca has granted the Company a worldwide, non-exclusive, perpetual, non-transferable license to develop, manufacture or have manufactured, use, sell, import, export and/or otherwise commercialize product based on Cellca's work to generate a specified transfected cell line and develop an upstream production process for such cell line. The Cellca Agreement is effective unless terminated by either party by giving six months notice, or by giving 14 days notice if terminated for good cause. The Company is obligated to make milestone payments to Cellca totaling up to $0.7 million upon the achievement of certain development and approval milestones if the Buy-Out Option is not exercised. The Company has a Buy-Out Option that will be effective between the time of completion of a clinical trial and the receipt of regulatory approval for commercialization of product. The cost to exercise the Buy-Out Option increases on each anniversary of the commencement date of the Buy-Out Option Period, and ranges from $0.1 million to $0.6 million. The cost to exercise the Buy-Out Option will replace the $0.6 million contingent milestone payment due upon final regulatory approval. The first milestone was achieved in April 2022, at which time the Company incurred a $0.1 million license fees which was recorded as acquired in-process research and development and included in research and development expenses in the consolidated statement of operations for the year ended September 30, 2022. No license fees were incurred during the year ended September 30, 2023.

In October 2021, the Company entered into a Non-Exclusive License Agreement (the "Brink Agreement") with Brink Biologics Inc. ("Brink"), pursuant to which Brink has granted the Company a non-exclusive, non-transferable license and limited right to sublicense certain materials and related information to develop cell-based assays for batch, quality control, stability, efficacy, potency or any other type of assay required for production and commercialization of products. During the product development phase, the Company was obligated to make annual product development license fee payments of approximately $0.1 million. In April 2023, the Brink Agreement was amended, effective November 2022, to reduce the annual license fee payments to $12,000 for storage. If materials are removed from storage during the product development phase, the annual product development license fee of approximately $0.1 million will apply. If a product achieves commercial status, the Company is obligated to make a commercial product license fee payment of approximately $0.1 million per commercial product. The amended agreement has an initial term of one year and will automatically renew for one additional year unless terminated or converted to a product development license. After the second year, the license will automatically convert to a full license requiring a product development or a commercial product license fee unless the parties mutually agree to terminate the agreement. The Company incurred $12,000 and $0.2 million in license fees during the years ended September 30, 2023 and 2022, respectively, which were recorded as acquired in-process research and development and included in research and development expenses in the consolidated statements of operations.

In February 2022, the Company entered into a Biological Materials License Agreement (the "InvivoGen Agreement") with InvivoGen SAS ("InvivoGen"), pursuant to which InvivoGen has granted the Company a worldwide, non-exclusive license to use certain reporter cells for research, development and/or quality control purposes. The InvivoGen Agreement has an initial term of three years and may be extended for two additional three-year periods upon written notice by the Company and payment of an approximately €0.1 million fee per extension (approximately $0.1 million as of September 30, 2023). The Company incurred a $0.1 million license fee which was recorded as acquired in-process research and development and included in research and development expenses in the consolidated statement of operations for the year ended September 30, 2022. No license fees were incurred for the year ended September 30, 2023.

In March 2022, the Company entered into a Material Transfer and License Agreement (the "ProteoNic Agreement") with ProteoNic B.V. ("ProteoNic"), pursuant to which ProteoNic has granted to the Company a non-exclusive, non-transferable, non-sublicensable (except as provided for in the ProteoNic Agreement) license for certain materials, including plasmids and DNA sequences used to generate the vectors used in the Company's cell lines, for the Company's use in research, development and commercialization of product. The license will continue until terminated by either party. The Company incurred a $24,600 license fee upon obtaining the license. The Company is obligated to make contingent milestone payments to ProteoNic totaling up to €1.2 million (approximately $1.3 million as of September 30, 2023) upon the achievement of certain development and commercialization milestones as outlined in the ProteoNic Agreement. The Company incurred a $24,600 license fee which was recorded as acquired in-process research and development and included in research and development expenses in the consolidated statement of operations for the year ended September 30, 2022. No license fees were incurred during the year ended September 30, 2023.

Research and development agreement

In December 2021, the Company entered into a Research and Development Agreement (the "Navigo Agreement") with Navigo Proteins GmbH ("Navigo"), pursuant to which Navigo will perform specified evaluation and development procedures to evaluate certain materials to determine their commercial potential. Under the terms of the Navigo Agreement, the Company has granted Navigo a royalty-free, non-exclusive, worldwide, non-sublicensable, non-transferable right and license to use certain technology to perform the evaluation and development activities, and Navigo has granted the Company (i) an exclusive, worldwide, perpetual, irrevocable, sublicensable, transferable, royalty-free right and license to research, develop, use, sell, have sold, distribute, import or otherwise commercially exploit certain materials, and (ii) a non-exclusive, worldwide, perpetual, sublicensable, non-transferable right and license to make or have made such materials. The Company incurred a $0.1 million technology access fee upon execution of the Navigo Agreement, at which time it was recorded as acquired in-process research and development and included in research and development expenses in the

consolidated statement of operations for the year ended September 30, 2022. The Company is obligated to make contingent milestone payments to Navigo, as amended in March 2023, totaling up to $1.0 million upon the achievement of certain evaluation and development milestones as outlined in the Navigo Agreement. Certain evaluation milestones were achieved in 2023, totaling $0.3 million in license fees, which were recorded as acquired in-process research and development and included as research and development expenses in the consolidated statement of operations for the year ended September 30, 2023.

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.

6. Collaboration Revenue

Under the New Life Agreement, the Company granted New Life an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in Malaysia, Singapore, Indonesia, Thailand, Philippines, Vietnam, Brunei, Myanmar, Lao PDR and Cambodia (the "Exclusive Territory"). New Life had the option to expand (1) the field of the exclusive license to include the prevention, treatment or palliation of chemotherapy-induced peripheral neuropathy in humans (the "CIPN Field"), which option was non-exclusive and expired on December 31, 2021; and/or (2) the territorial scope of the license to include the People's Republic of China, Hong Kong and/or India, which option was exclusive and expired on December 31, 2021.

The Company will retain all rights to manufacture Compounds and Products anywhere in the world. The Company and New Life shall enter into a follow-on supply agreement pursuant to which the Company shall supply to New Life Products for development and commercialization thereof in the DPN Field in the Exclusive Territory on terms to be negotiated by the parties. The Company will also assist in transferring certain preclinical and clinical development know-how that is instrumental in New Life's ability to benefit from the license.

New Life will bear the cost of, and be responsible for, among other things, conducting clinical studies and additional non-clinical studies and other developmental and regulatory activities for and commercializing Products in the DPN Field in the Exclusive Territory.

New Life paid the Company a $0.5 million non-refundable upfront cash payment in August 2020 upon executing a letter of intent to negotiate a license agreement and a $0.5 million non-refundable upfront cash payment in June 2021 in connection with the execution of the New Life Agreement. New Life is also obligated to pay a non-refundable deferred license fee of an additional $1.0 million at the time of the satisfaction of certain milestones, as well as potential additional milestone payments to the Company of up to $19.0 million subject to the achievement of certain development and commercialization milestones. In addition, during the Royalty Term (as defined below), New Life is obligated to pay the Company tiered double-digit royalties ranging from 12% to 30% based on annual net sales of Products in the Exclusive Territory. The "Royalty Term" means, on a Product-by-Product and a country-by-country basis in the Exclusive Territory, the period commencing on the date of the first commercial sale (subject to certain conditions) of such Product in such country in the Exclusive Territory and continuing until New Life ceases commercialization of such Product in the DIPN Field.

The New Life Agreement will remain in effect on a Product-by-Product, country-by-country basis and will expire upon the expiration of the Royalty Term for the last-to-expire Product in the last-to-expire country, subject to (i) each party's early termination rights including for material breach or insolvency or bankruptcy of the other party and (ii) the Company's Buy Back Right and New Life's Give Back Right (as defined below).

In addition, New Life granted to the Company an exclusive option to buy back the rights granted by the Company to New Life and the Company granted New Life the right to give back the rights with respect to Products in the DPN Field in one or more countries in the Exclusive Territory on terms to be agreed upon, which options will expire upon the initiation of a Phase III Trial for the applicable Product.

Revenue recognition

The Company first assessed the New Life Agreement under ASC 808, *Collaborative Arrangements* ("ASC 808"), to determine whether the New Life Agreement or units of accounts within the New Life Agreement represent a collaborative arrangement based on the risks and rewards and activities of the parties. The Company applied relevant guidance from ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), to evaluate the appropriate accounting for the collaborative arrangement with New Life. In accordance with this guidance, the Company identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the "License"); and (ii) transfer of know-how and clinical development and regulatory activities ("R&D Activities"). The options to expand the CIPN Field and territory as well as the future supply agreement represent optional purchases, which are accounted for as separate contracts. The Company evaluated these separate contracts and did not identify any material right to be present. The Company determined that License and the R&D services are not distinct from each other and therefore combined these material promises into a single performance obligation.

The Company determined the initial transaction price of the single performance obligation to be $1.0 million, as the future development and commercialization milestones, which represent variable consideration, are subject to constraint at inception. At the end of each subsequent reporting period, the Company will reevaluate the probability of achievement of the future development and commercialization milestones subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. Any such adjustments will be recorded on a cumulative catch-up basis. For the sales-based royalties, the Company will recognize revenue when the related sales occur.

Collaboration revenue from the single performance obligation is being recognized over the estimated performance of the R&D services. The Company recognized $0.1 million and $0.3 million of collaboration revenue for the years ended September 30, 2023 and 2022, respectively.

7. Stockholders' Deficit

2023 events

The Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") on August 15, 2022 (the "2022 Sales Agreement"). Pursuant to the 2022 Sales Agreement, the Company could offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of its common stock having an aggregate offering price of up to $25.0 million, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the 2022 Sales Agreement. Due

to the offering limitations applicable to the Company, the Company filed prospectus supplements for the sale of shares of its common stock for an aggregate offering price of up to $7.8 million pursuant to the 2022 Sales Agreement. During the year ended September 30, 2023, the Company sold an aggregate of 136,702 shares of common stock pursuant to the 2022 Sales Agreement with BTIG for gross proceeds of $5.7 million and net proceeds of $5.5 million. There are no registered shares remaining to be sold under the 2022 Sales Agreement.

On February 10, 2023, the Company closed a public offering of common stock and certain warrants through Chardan Capital Markets, LLC and EF Hutton, division of Benchmark Investments LLC as underwriters, for gross proceeds of $15.0 million and net proceeds of $13.6 million through the issuance and sale of 530,222 shares of its common stock and, to certain investors, pre-funded warrants to purchase 101,090 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 1,262,618 shares of its common stock (the "February Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was $23.76 and the public offering price of each pre-funded warrant and accompanying common warrant was $23.7578.

The common stock warrants are immediately exercisable at a price of $23.76 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision whereby, subject to certain conditions, a warrant may be exercised in a cashless transaction for shares of common stock at the rate of half a share of common stock per full share otherwise issuable upon a cash exercise. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of $0.0022 per share of common stock.

In addition, warrants to purchase 44,190 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of $29.70 per share and expire five years from the date of issuance.

On June 30, 2023, the Company closed a registered direct offering of common stock (and common stock equivalents in lieu thereof) and a concurrent private placement of certain common stock warrants through Chardan Capital Markets, LLC as placement agent, for gross proceeds of $2.3 million and net proceeds of $1.9 million through the issuance and sale of 166,363 shares of its common stock and, to certain investors, pre-funded warrants to purchase 60,909 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 227,272 shares of its common stock (the "June Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $9.90.

The common stock warrants are exercisable beginning December 30, 2023 at a price of $14.8478 per share of common stock, expire three and half years from the date of issuance and contain an alternative cashless exercise provision. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of $0.0022 per share of common stock. All of the pre-funded warrants have been exercised.

In addition, warrants to purchase 6,818 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants have an exercise price of $14.8478 per share and expire three and a half years from the date of issuance.

2022 events

In August 2022, the Company entered into a securities purchase agreement (the "Preferred SPA") with several accredited investors for the issuance and sale of (i) an aggregate of 22,275 shares of its Series 3 Convertible Preferred Stock, stated value $100 per share, (ii) 225 shares of its Series 4 Convertible Preferred Stock, stated value $100 per share, and (iii) Series 3 warrants to purchase up to 12,548 shares of its common stock in a private placement for aggregate gross proceeds of $2.3 million, with $0.1 million of issuance costs for net proceeds of $2.1 million. The shares of Series 3 Convertible Preferred Stock were convertible into an aggregate of 24,850 shares of common stock of the Company and the shares of Series 4 Convertible Preferred Stock were convertible into an aggregate of 251 shares of common stock of the Company, in each case, at a conversion price of $89.628 per share. The Series 3 Warrants have an exercise price of $89.628 per share, are exercisable commencing six months after issuance, and will expire five years from the issuance date. The net proceeds from the private placement were allocated to the Series 3 Convertible Preferred Stock, Series 4 Convertible Preferred Stock and Series 3 warrants based on their relative fair values.

The shares of the Series 3 and Series 4 Convertible Preferred Stock had no voting rights other than the right to vote with common stockholders, as a single class, on a proposed amendment to the Company's Certificate of Incorporation, as amended, to effect a reverse split of the outstanding shares of common stock. Each share of Series 3 Convertible Preferred Stock was entitled to vote on an as-converted basis, and each share of Series 4 Convertible Preferred Stock was entitled to 811,688 votes per share, provided that the Series 4 Convertible Preferred Stock be automatically voted in the same proportions as the shares of common stock and Series 3 Convertible Preferred Stock on the reverse split proposal. The shares of the Series 3 and Series 4 Convertible Preferred Stock were convertible at the option of the holder at any time following the effective date of a reverse split of the Company's outstanding common stock. In addition, the Company could elect mandatory conversion on the date of the reverse stock split or the Company could force conversion of all or a part of the Series 3 and Series 4 Convertible Preferred Stock at any time after 120 days following the issuance of the preferred stock, in either case provided certain equity conditions were met.

The private placement closed on August 15, 2022, and the stockholders voted to approve a 1-for-14 reverse stock split on September 15, 2022. The Series 3 and Series 4 Convertible Preferred Stock were converted to 25,101 shares of common stock on September 30, 2022. As of September 30, 2023 and 2022, there were no shares of preferred stock issued and outstanding.

During the year ended September 30, 2022, the Company sold an aggregate of 30,206 shares of common stock pursuant to the 2022 Sales Agreement with BTIG for gross proceeds of $2.0 million and net proceeds of $1.9 million.

Also during the year ended September 30, 2022, the Company issued 1,087 shares of common stock upon the vesting of restricted stock units.

Common stock warrants

As of September 30, 2023, the following equity-classified warrants and related terms were outstanding:

	Warrants Outstanding	Exercise Price	Expiration Date
Common stock warrants August 2021	128,500	$ 261.80	August 24, 2024
Underwriter warrants August 2021	2,287	$ 327.25	August 19, 2024

Chanticleer warrants	57	$	18,018.00 -$28,028.00	April 30, 2027 - December 17, 2028
Series C warrants	36,778	$	982.52	October 16, 2025
Series 3 warrants	12,548	$	89.628	August 15, 2027
Common stock warrants February 2023	271,883	$	23.76	February 10, 2028
Underwriter warrants February 2023	44,190	$	29.70	February 8, 2028
Common stock private placement warrants June 2023	227,272	$	14.8478	December 30, 2026
Placement agent warrants June 2023	6,818	$	14.8478	December 30, 2026
Total	730,333			

During the year ended September 30, 2023, 1,014,872 warrants were net share settled, resulting in the issuance of 519,492 shares of common stock.

During the year ended September 30, 2023, 137,999 warrants were exercised on a cash basis. The Company received de minimus proceeds in exchange for the issuance of 137,998 shares of common stock.

During the year ended September 30, 2023, 332 of private warrants expired.

8. Share-Based Compensation

In April 2020, the Company adopted the 2020 Omnibus Equity Incentive Plan (the "Plan"). On January 1, 2023, the total number of shares authorized under the Plan increased to 14,480. There were 14,480 shares available for issuance under the Plan as of September 30, 2023. The Plan increases the amount of shares issuable under the Plan by four percent of the outstanding shares of common stock at each January 1, each year. The Plan permits the granting of share-based awards, including stock options, restricted stock units and awards, stock appreciation rights and other types of awards as deemed appropriate, in each case, in accordance with the terms of the Plan. The terms of the awards are determined by the Company's Board of Directors.

Restricted stock units and awards

In July of 2020, 2,115 restricted stock units ("RSUs") were granted, 50% of which vested on April 2, 2021 and the remaining 50% vested on April 2, 2022. In March of 2021, an additional 152 RSUs were granted, 50% of which vested on March 25, 2022 and the remaining 50% vested on March 25, 2023. In December of 2021, 2,103 RSUs were granted, 100% of which vested on January 1, 2023. In December of 2022, 7,840 RSUs were granted, 100% of which vest on January 1, 2024.

In January 2023, 5,514 of the RSUs granted in December 2022 were cancelled and subsequently reissued as restricted shares of the Company's common stock ("Restricted Stock Awards" or "RSAs"). The RSAs have the same vesting conditions as the original RSUs issued in December 2022. The Company accounted for this as a stock compensation modification resulting in $38,837 of incremental expense which will be recognized over the remaining vesting period.

Any unvested RSUs or RSAs will be forfeited upon termination of services. The fair value of an RSU or RSA is equal to the fair market value of the Company's common stock on the date of grant. RSU and RSA expense is amortized straight-line over the vesting period.

The Company recorded share-based compensation expense associated with the RSUs and RSAs in its accompanying consolidated statements of operations as follows:

	Years ended September 30,	
	2023	**2022**
Research and development	$ 121,265	$ 437,921
General and administrative	127,361	438,447
	$ 248,626	$ 876,368

The following table summarizes RSU activity under the Plan:

	RSU	**Weighted Average Grant Date Fair Value**
Unvested balance at October 1, 2021	1,179	$ 1,068.32
Granted	2,103	$ 155.54
Vested	(1,096)	$ 1,091.20
Forfeited	(24)	$ 1,118.04
Unvested balance at October 1, 2022	2,162	$ 175.56
Granted	7,840	$ 21.47
Vested	(2,162)	$ 12.55
Forfeited	(5,514)	$ 21.34
Unvested balance at September 30, 2023	2,326	$ 21.78

As of September 30, 2023, total unrecognized compensation expense relating to unvested RSUs granted was $12,194, which is expected to be recognized over a weighted-average period of three months.

The following table summarizes RSA activity under the Plan:

	RSA	**Weighted Average Grant Date Fair Value**
Unvested balance at October 1, 2022	—	—
Granted	5,514	$ 28.27
Unvested balance at September 30, 2023	5,514	$ 28.27

As of September 30, 2023, total unrecognized compensation expense relating to unvested RSAs granted was $37,812, which is expected to be recognized over a weighted-average period of three months.

Sonnet BioTherapeutics Holdings, Inc.
Notes to Consolidated Financial Statements

9. Income Taxes

As of September 30, 2023, the Company had $103.6 million, $69.5 million and $8.9 million of federal, state and foreign net operating losses, respectively. The federal and state net operating losses will begin to expire in 2030 and the foreign net operating losses begin to expire in 2027. As of September 30, 2023, the Company has federal and state research and development tax credit carryforwards of $2.4 million and $0.8 million available to reduce future tax liabilities which will begin to expire in 2035 and 2030, respectively. Realization of the deferred tax asset is contingent on future taxable income and based upon the level of historical losses, management has concluded that the deferred tax asset does not meet the more-likely-than-not threshold for realizability. Accordingly, a full valuation allowance continues to be recorded against the Company's deferred tax assets as of September 30, 2023 and 2022. The valuation allowance increased $5.8 million during the year ended September 30, 2023 and $8.3 million during the year ended September 30, 2022.

Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carryforwards may be subject to annual limitations, against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carryforwards are subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax assets with an offsetting reduction in the valuation allowance.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely-than-not be realized. The determination as to whether the tax benefit will more-likely-than-not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties accrued on any unrecognized tax benefits within the provision for income taxes in its consolidated statements of operations. No unrecognized tax benefits have been recorded.

The tax effects of the temporary differences that gave rise to deferred taxes were as follows:

	September 30,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 27,996,751	$ 25,858,311
Research and development credit carryforwards	3,106,675	2,151,942
Amortization	4,692,227	2,897,388
Share-based compensation	226	66,832
Operating lease liability	57,319	71,748
Accrued expenses and other	546,612	314,210
Section 163(j) disallowed interest expense	763,172	—
Property and equipment	—	4,790
Gross deferred tax assets	37,162,982	31,365,221
Less: valuation allowance	(37,100,582)	(31,293,092)
	62,400	72,129
Deferred tax liabilities:		
Property and equipment	(7,954)	—
Operating lease right-of-use asset	(54,446)	(72,129)
Net deferred tax assets	$ —	$ —

Sonnet BioTherapeutics Holdings, Inc.
Notes to Consolidated Financial Statements

The Company recorded no income tax expense or benefit for the years ended September 30, 2023 and 2022. A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements is as follows:

	Years ended September 30,	
	2023	2022
U.S. federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(7.1)	(6.0)
Change in valuation allowance	30.8	28.1
Research and development credit	(5.1)	(3.0)
Permanent differences	(1.6)	0.7
Foreign tax rate differential	0.3	0.8
State NOLs	3.7	—
Other	0.0	0.4
Effective income tax rate	—%	—%

In August 2022, the U.S. enacted the Inflation Reduction Act of 2022 ("IRA"). The IRA contains a number of tax-related provisions that will be effective for tax years beginning after December 31, 2022, including a corporate alternative minimum tax of 15% on certain large corporations and an excise tax of 1% on corporate stock repurchases. The Company is currently evaluating the various provisions of the IRA and does not anticipate a material impact on its consolidated financial statements.

10. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through December 14, 2023, the date at which the consolidated financial statements were available to be issued. Refer to Note 1 for information regarding the October Offering.

In December 2023, the Company received preliminary approval of its application to sell up to $4.8 million of its New Jersey state net operating losses through the Technology Business Tax Certificate Transfer Program (the "Program"). As outlined in the Program, although the sale has been approved and a buyer identified, the Company must still

execute an arrangement with such buyer to consummate a sale of the state net operating losses.

155,000 Shares of Common Stock
956,111 Pre-Funded Warrants to Purchase up to 956,111 Shares of Common Stock
1,111,111 Common Warrants to Purchase up to 2,222,222 Shares of Common Stock
956,111 Shares of Common Stock issuable upon exercise of the Pre-Funded Warrants
2,222,222 Shares of Common Stock issuable upon exercise of the Common Warrants

PROSPECTUS

Chardan

The date of this prospectus is November 6, 2024.