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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended September 30, 2025

Or

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

For the transition period from to

Commission file number: 001-35570

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

Delaware **(State or other jurisdiction of incorporation or organization)**	**20-2932652** **(I.R.S. Employer Identification No.)**
100 Overlook Center, Suite 102 **Princeton, NJ** **(Address of principal executive offices)**	**08540** **(Zip Code)**

Registrant's telephone number, including area code: (609) 375-2227

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**SONN**	**The Nasdaq Capital Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark if the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $4,150,174 on March 31, 2025, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of $1.34 on that date.

Indicate the number of shares outstanding of each of the registrant's classes of common equity, as of December 12, 2025:

Class	Number of Shares
Common Stock, $0.0001 par value	1

Documents incorporated by reference

None.

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Except as otherwise indicated herein or as the context otherwise requires, references in this Annual Report on Form 10-K to "the Company," "we," "us" and "our" refer to Sonnet BioTherapeutics Holdings, Inc. and our consolidated subsidiaries.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential," or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect the Company's current views with respect to future events and are based on assumptions and subject to risks and uncertainties including those set forth below and under Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent the Company's estimates and assumptions only as of the date of this Annual Report on Form 10-K and, except as required by law, the Company undertakes no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents referenced in this Annual Report on Form 10-K and filed as exhibits completely and with the understanding that the Company's actual future results may be materially different from what the Company expects. The Company qualifies all of its forward-looking statements by these cautionary statements. Such statements may include, but are not limited to, statements concerning the following:

- 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.

PART I

Item 1. Business.

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 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*. 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 proteins 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 us 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 our platform start with 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 have negotiated the cost to be significantly less than the expense incurred from a similar US- or European-based vendor. We have conducted three of our four clinical trials in Australia, one of which is ongoing (SB221). Running clinical trials there offers a substantial cost reduction relative to US trials via the Australian government's R&D tax credit program. We are also coordinating the Indian and Australian execution of various aspects of our programs with top R&D vendors from the US, 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. We have completed a non-human primate (NHP) toxicity study, conducted under current Good Laboratory Practices (cGLP), and have successfully manufactured both liquid and lyophilized forms of the drug product for clinical use. 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 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 the data from SB102 was published in February 2024. We announced the topline safety data from SB101 and completion of dose escalation in December 2024, at the maximum administered dose to date as 1200 ng/kg. Clinical benefit, defined as stable disease (SD) for at least 4 months, was seen in 48% of the patients overall and in 83% at the highest dose, including one patient with sarcoma who had a partial response (PR) to SON-1010. On February 13, 2025, we announced the addition of an expansion cohort in SB101 that uses SON-1010 with trabectedin (Yondelis®), and on March 26, 2025, the successful completion of the first safety review of that cohort. We expect to report topline efficacy data from this combination in the second half of calendar year 2025.

- In January 2023, we announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 in combination 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/ 2a combination safety, dose-escalation, and preliminary efficacy study (SB221). That trial consists of a modified 3+3 design in Part 1 that combines dose-escalation of SON-1010 in six steps with a fixed dose of atezolizumab. One patient in the highest dose group had a PR and one had a CR. Clinical benefit in PROC is being studied in an expansion group to help establish the recommended Phase 2 dose (RP2D). On August 4, 2025, we announced the addition of a seventh dose level cohort using SON-1010 at a 50% higher dose combined with the same fixed dose of atezolizumab in PROC to consider using that dose as the RP2D. Part 2 of the study will be used to 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) in a larger population. Overall, we have dosed 103 patients and healthy volunteers with SON-1010 to date in these three Phase 1 studies. As part of our ongoing cost-cutting strategy, all antiviral development with SON-1010 has been suspended.

- 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, SB211, was started in October 2022 but has been terminated. Enrollment of the first nine randomized patients in the first portion of SB211 study was completed, which allowed the DSMB to complete its review of the preliminary blinded safety data during the first calendar quarter of 2024. In May 2021, we entered into a license agreement with New Life Therapeutics Pte., Ltd ("New Life") of Singapore (the "New Life Agreement"), pursuant to which we agreed to 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. On December 2, 2024, New Life provided written notice to us of New Life's intention to exercise its Give Back Option (as defined herein) under the New Life Agreement, subject to the negotiation and mutual agreement of the terms of such Give Back Option by us and New Life, as the latter elected to move its business in a different direction. In addition, on October 8, 2024, we signed a licensing agreement with an India-based company, Alkem Laboratories Limited ("Alkem"), providing it with the right to develop and commercialize SON-080 in DPN and/or CIPN in India (the "Alkem Agreement").

- 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 pancreatic and colorectal cancer. In February 2023, we announced the successful completion of two IND-enabling toxicology studies with SON-1210 in NHPs. In August 2024, we announced a clinical collaboration agreement to commence an investigator-initiated and funded Phase 1/2a study of SON-1210 in combination with chemotherapy for the treatment of pancreatic ductal adenocarcinoma (PDAC). We are prepared to initiate commercial development of SON-1210, pending the outcome of any partnering activity.

  In our discovery pipeline, we are investigating:

- 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 ($IL\text{-}18^{BPR}$ = Binding Protein Resistant) linked to the F_HAB domain. SON-1411 is a proprietary bifunctional fusion protein consisting of IL-18BPR combined with single-chain wild-type IL-12, each linked to our F_HAB platform, which will replace SON-1410 as a development candidate. SON-1400 is a monofunctional fusion protein comprising the same IL-18BPR domain, also linked to the F_HAB domain. 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 much 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 potential for the discovery of IL-18 variant compositions that could harness the therapeutic promise of IL-18 for the treatment of cancers. Our 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-18 Rc, compared to the wild-type IL-18 reference molecule, concomitant with no or reduced binding to IL-18BP. We elected to place the SON-1400 program on hold for expense reduction purposes.

- The SON-1411 program is in cell line development, and has also been placed on hold for the time being.

We face numerous challenges and uncertainties with respect to the development and commercialization of our therapeutic compounds, including our F_HAB technology. Please see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K for more information.

Lead Clinical Programs Update

SON-1010: Targeted Immune Activation Cancer Therapy, Turning 'Cold' Tumors 'Hot', Initially Targeting Solid Tumors and PROC

Phase 1 Trial (SB101 Trial): Advanced Solid Tumors (Monotherapy) and Combination with Trabectedin

This first-in-human study is primarily designed to evaluate the safety, tolerability, PK, and PD of multiple ascending doses of SON-1010 in cancer patients and is being conducted at several sites across the United States. We recently completed dose escalation in the Phase 1 SB101 clinical trial of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors and are expanding that study using SON-1010 monotherapy with trabectedin in certain types of soft-tissue sarcoma (STS). We reported that results of SON-1010 at the highest dose have been formally evaluated by the Safety Review Committee. We announced topline safety data and the completion of dose escalation in December 2024, at a dose of 1200 ng/kg. Clinical benefit, defined as stable disease for at least 4 months, was seen in 48% of the patients overall and in 83% at the highest dose, including one patientwith sarcoma who had a partial response to SON-1010.

Phase 1b/2a Trial (SB221 Trial): Advanced Solid Tumors and PROC (Combo with Atezolizumab)

A global Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study is being performed to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered subcutaneously (SC) in combination with atezolizumab given intravenously (IV) (in collaboration with Genentech, a member of the Roche Group). This study was recently expanded to add a higher dose of SON-1010 in combination with atezolizumab. Enrollment remains ongoing and an update on safety and topline efficacy in that trial is expected in the second half of calendar year 2025.

Program Highlights:

- PK data reveals about 10-fold extended half-life for SON-1010 compared with rhIL-12 and suggests tumor targeting by the F_HAB domain based on target-mediated drug disposition analysis.

- A controlled, dose-related, and sustained IFNγ response to SON-1010 has been seen that may allow improved efficacy, compared to the many studies that have used rhIL-12 since the late 1990's.

- The SON-1010 trials have collectively dosed 103 subjects, with 5 of 6 patients at the highest dose (83%) achieving clinical benefit with SON-1010 monotherapy (defined as stable disease at 4 months). Two patients with PROC had a partial response to SON-1010 at the highest dose used to date in combination with atezolizumab, and another SB221 cohort is currently being enrolled at a 50% higher dose of SON-1010.

- Patients have received up to 24 cycles of SON-1010 as monotherapy and up to 19 cycles of SON-1010 with atezolizumab 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 associated with rhIL-12, which allows higher maintenance doses and potential improvements in efficacy.

- A favorable safety profile has been seen in every context with no dose-related safety signals.
- Dose escalation has been evaluated up to 1200 ng/kg; a 50% higher dose cohort is currently being enrolled to help prepare for Phase 2.

Upcoming Milestones:

- Phase 1: Solid Tumors (Monotherapy)
    - H2 calendar year 2025: Topline efficacy data in STS with trabectedin
- Phase 1b/2a: PROC (Combo with Atezolizumab)
    - H2 calendar year 2025: Safety & topline efficacy data

SON-080: Low dose of rhIL-6 for CIPN and DPN

Phase 1b/2a Trial (SB211 Trial): CIPN

The completed SB211 study was 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 with atexakin alfa. The goal of the Phase 1b portion of the SB211 study was to confirm safety and tolerability before continued development in Phase 2. As announced in March 2024, a DSMB 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 in neuropathy including CIPN and/or DPN.

In October 2024, we entered into the Alkem Agreement for the research, development, manufacturing, marketing, and commercialization of our SON-080 molecule for the treatment of DPN in India as well as the manufacturing, marketing, and commercialization of SON-080 for CIPN and autonomic neuropathy in India. Alkem will conduct all clinical trials it believes appropriate to obtain regulatory approval in India of SON-080 for the treatment of DPN.

Phase 1b Data Highlights:

- SON-080 was demonstrated to be well-tolerated in a small group of patients with CIPN at both 20 µg and 60 µg/dose, which was about 10-fold lower than the therapeutic MTD for IL-6 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:

- Subsequent to the partnership established with Alkem, preparations are being made in support of their initiation of a Phase 2 clinical trial in DPN, a mechanistically synergistic and larger, high-value indication with unmet medical need.

SON-1210: Proprietary, Bifunctional Version of Human Interleukins 12 (IL-12) and 15 (IL-15), Configured Using Our F_HAB Platform, in Combination with Chemotherapy for the Treatment of Advanced Solid Tumors and Metastatic Pancreatic Cancer

As previously announced, we successfully completed two IND-enabling toxicology studies of SON-1210 in non-human primates (NHPs), which demonstrated no overt toxicity in the GLP study apart from the expected and mild, on-target changes in hematology and clinical chemistry parameters that resolved completely within 14 to 21 days post-dosing. A significant increase in interferon gamma (IFNγ), which was controlled and prolonged, was noted as early as one day following administration, with no apparent increase in other proinflammatory cytokines. IFNγ is a well-known pharmacodynamic biomarker that is required for anti-tumor efficacy in preclinical models. Other 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.

In August 2024, we entered into the Sarcoma Agreement with the Sarcoma Oncology Center to conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to NALIRIFOX® (the combination of liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin) for the specific treatment of metastatic PDAC. The NALIRIFOX regimen is U.S. FDA-approved for the treatment of metastatic pancreatic cancer in the front-line and refractory settings.

Overall Corporate Strategy

Our goal is to 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 reduced operating expenses during fiscal year 2024 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 April 2022, SON-1010 is currently being studied as monotherapy with trabectedin in STS and as an immunotherapy in combination with atezolizumab in patients with PROC, both representing indications with significant unmet medical need.

F_HAB program advancement: SON-1010 is being used as monotherapy or in combination with trabectedin in STS and has entered Phase 1b/2a clinical development to establish the RP2D and to assess clinical benefit in PROC. Regarding our first bifunctional candidate, SON-1210, two IND-enabling toxicology studies in NHPs have been successfully completed. Subsequent to raising adequate funding expected in 1H 2026, we expect to initiate the first clinical trial to study dose escalation of SON-1210 monotherapy.

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 (SB211). The first portion of SB211 to assess primarily the safety of SON-080 administration was successfully completed.

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 F_HAB-binding ligand for efficient down-stream processing, as well as stable lyophilized formulations, for which we have secured 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 cytokine 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 in these and other indications. We believe the platform has potential applications in other areas, such as vaccines, antibody drug conjugates (ADC's), 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 could be readily reconfigured for different therapeutic payloads. As is the case with all biologic drugs, dose level and frequency of administration are critical variables that often times 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 is 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 antibody fragments 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, we panned millions of scFv binders to HSA to generate our 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 our 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. The next projected clinical development milestone of $750K is expected to be due upon initiation of enrollment of a Product (i.e., SON-1010) in a Phase 2 Trial. We have 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. 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 our 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, our 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 well as potential production levels in mammalian cell culture.

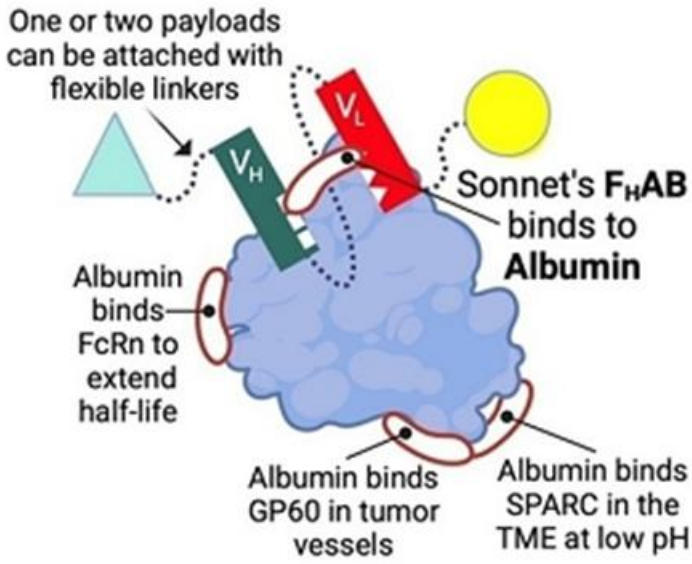

Figure 1: Our F_HAB binds to a unique site on albumin without interfering with its physiologic functions. Albumin is the most abundant protein in human serum, primarily due to binding to the FcRn, which extends the half-life. Tumor vessels have abundant FcRn and GP60 receptors that provide targeting of the F_HAB. SPARC is present in the tumor microenvironment of many solid tumors, enhancing the retention of the F_HAB complex in the tumor.

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 or antibodies, such as IL-12, IL-15, IL-18, anti-IL-6, and anti-TGFβ). Recombinant therapeutic proteins, including cytokines, have shown great therapeutic potential and are quite potent 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 our targeted 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.

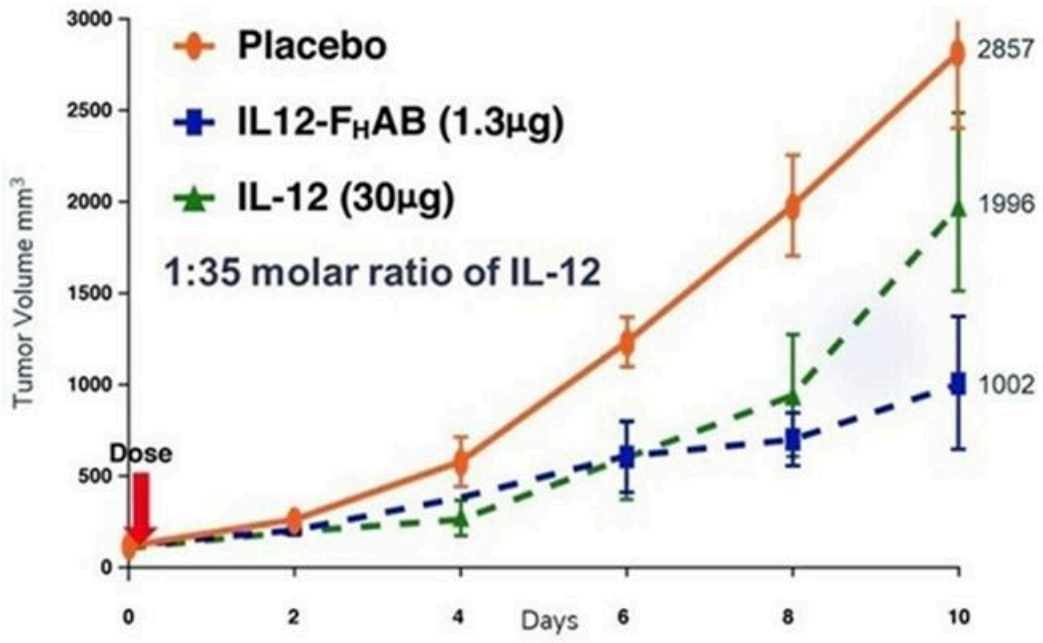

Figure 2: The molar equivalent for IL-12 (0.9µg) is IL12-F_HAB (1.3 µg) and they have similar bioactivity in vitro; however, in vivo, IL12- F_HAB is approximately 35-fold more potent than IL-12 (at day 10, 1.3µg IL12-F_HAB > IL-12 30µg).

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.

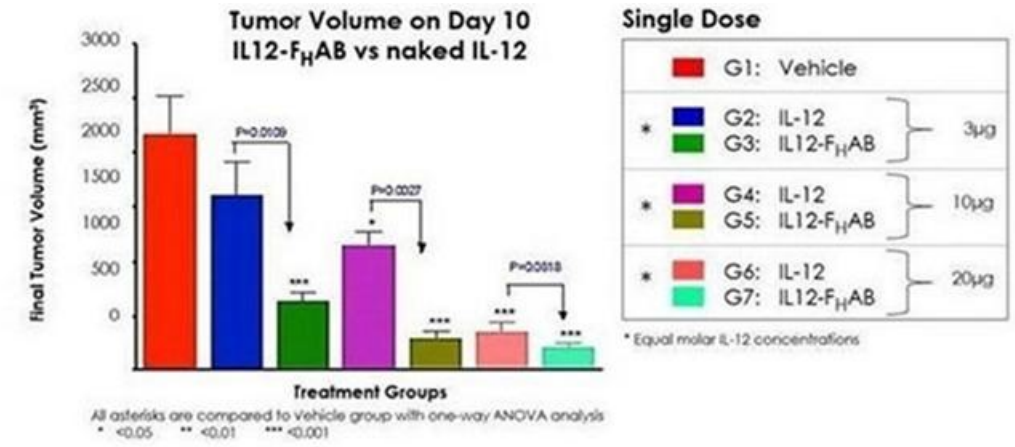

Figure 3: Analysis of tumor volumes shows dose-dependent decreases in tumors in both m*IL-12 and* m*IL12-F$_H$AB-treated mice, as compared to vehicle control. IL12-F$_H$AB-treated mice showed statistically significant decreases in tumor volumes when analyzed against equimolar-dosed,* m*IL-12-treated 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.

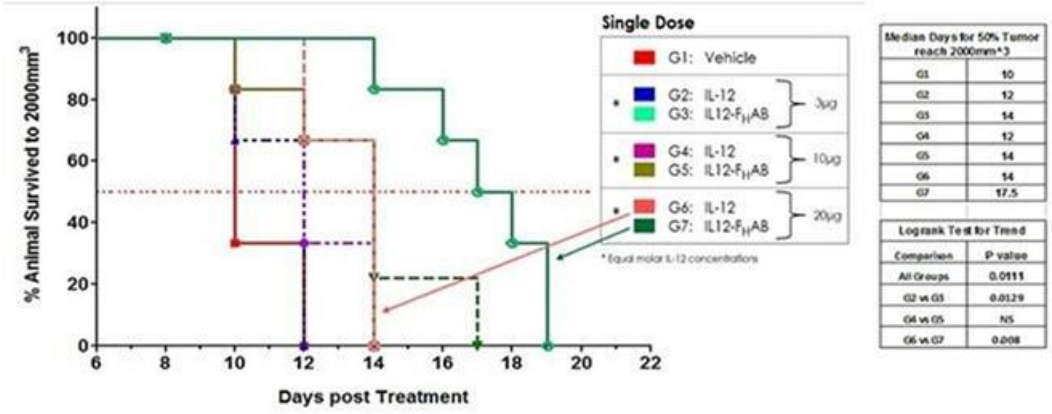

Figure 4: Kaplan-Meier evaluation of mouse B16F tumor survivability shows an increase in survival with IL12- F$_H$AB treatment. Doses of 10µg and 20µg of standalone mIL-12 exhibited 50% survival at 2 and 4 days over vehicle control (10 days). All doses of IL12- F$_H$AB showed 50% survival over vehicle 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 was 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 30-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 our F_HAB 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 and 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 maximum dose 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 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 went on to add an expansion cohort using SON-1010 with trabectedin in STS and announced the first safety review on March 26, 2025. We expect to report topline efficacy data from this trial in the second half of calendar year 2025.

We started a single-ascending dose (SAD) Phase 1 clinical study (SB102) in Australian healthy volunteers in July 2022 to carefully study the PK and PD without interference from the impact of chemotherapy. 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 electrochemiluminescence assay (Meso Scale Diagnostics (MSD)) after SC administration. Between the SON-1010 lowest- (50 ng/kg) and highest- (300 ng/kg) dose cohorts (a 6x escalation in dose), the serum Cmax increased by 4.5x, and the time to reach that (Tmax) was approximately 11 h. This was associated with a corresponding 4.5× increase in the exposure area under the concentration time curve (AUC) from time zero to the time of last observable concentration (AUC0-t), and the shape of the curves indicated typical two-compartment elimination kinetics (Figure 5). The mean T½ across all dose cohorts was 104 h, and the serum concentrations for the majority of the participants remained above the lower limit of quantitation (LLOQ) for 336 h. The mean Cmax value increased in a less than proportional manner between dose cohorts, yielding nonlinear PK.

The MSD assay was also used to study repeat dosing in patients with advanced solid tumors in study SB101, including dose escalation up to the same maximum dose used in SB102. Interestingly, the SON-1010 concentration curves, compared with a single dose in healthy volunteers showed an atypically dissimilar contour (Figure 5). Single-compartment elimination kinetics were noted in patients with cancer, compared to the two-compartment elimination kinetics observed in the healthy volunteers. The unusual PK results comparing these two clinical studies suggest the potential for an improved local immune response due to targeting of the drug in the TME in patients, which could make SON-1010 more effective than prior efforts with systemic immunotherapy using rIL-12. The dose relationship also suggests target-mediated drug disposition (TMDD), perhaps due to the retention of SON-1010 caused by albumin binding to SPARC in the TME and its slow release from the tumor tissue.

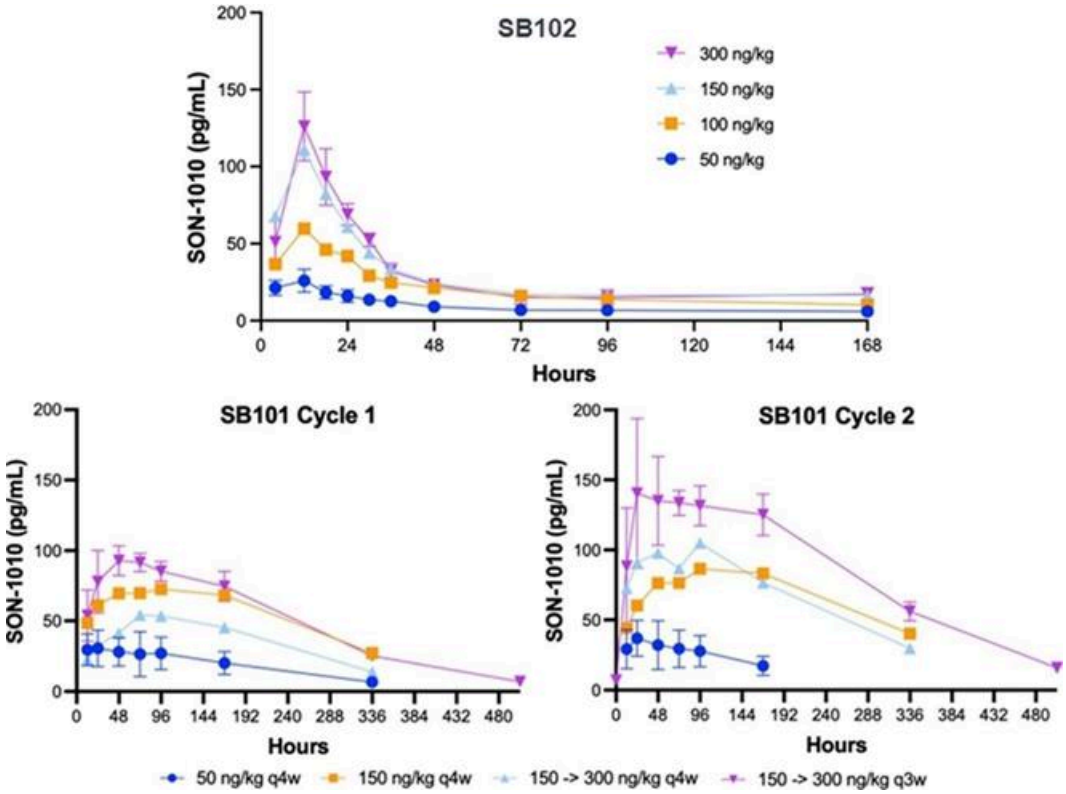

Figure 5: SON-1010 levels were assessed frequently after dosing, then followed at the times indicated in each study. Subjects in study SB102 received a single dose, while patients in study SB101 were administered a fixed dose of SON-1010 (in the first two groups) or a desensitizing first dose followed by a higher maintenance dose (in the last two groups) in the next cycle. Error bars (geometric mean CV%) are shown for the lowest and highest groups, respectively.

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). IFN-ɣ was the most prominent cytokine responding. The mean C_{max} value disproportionately increased between the wide range of doses tested, peaking at 977 pg/mL in the highest dose cohort (300 ng/kg). The time taken to achieve maximal IFN-ɣ blood concentrations varied greatly between cohorts and did not correlate with the dose, with the mean time required to peak ranging from 28.8 to 85.0 hours. The $AUC_{0\text{-}t}$ also increased disproportionately following the cohort doses and rose to 106,000 h*pg/mL in the highest-dose cohort. However, the partial areas under the concentration-time curve from time zero to 24 h, 48 h, and 168 h increased in a dose-dependent manner. The C_{max} and AUC PK parameters in SB101 were similar after the second dose compared to the first dose in SB102, while the IFN-ɣ PD parameters of C_{max} and AUC were suppressed in SB101, presumably by induction of the intracellular suppressors of cytokine signaling (SOCS) proteins.

There were small transient increases in IL-6, IL-8, IL-10, 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.

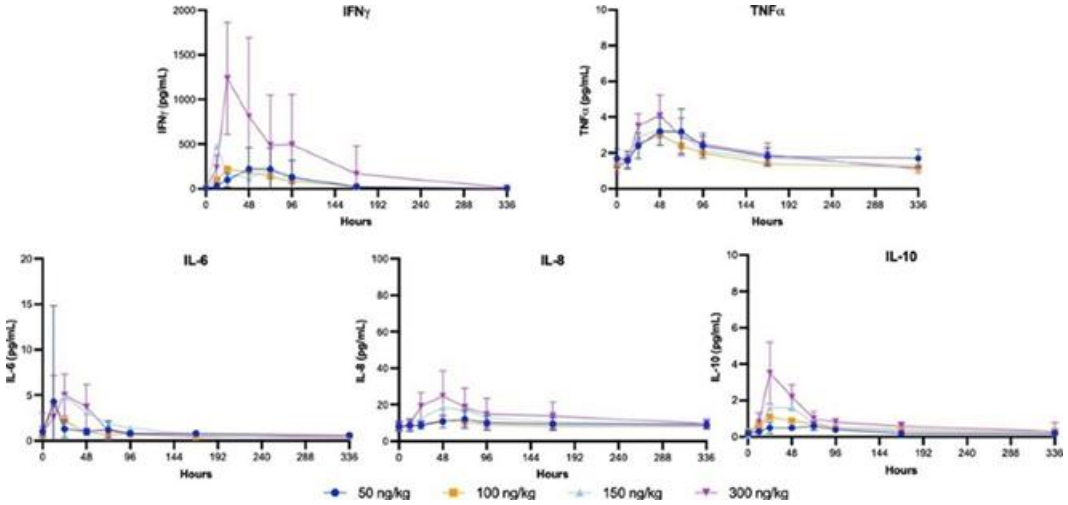

Figure 6: Cytokine levels were assessed frequently after dosing for PD, then followed on the days indicated for the rest of the SB102 study.

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) in combination with atezolizumab given intravenously (IV). SON-1010 has been safe and tolerable at all doses tested to date and a higher dose cohort (E7) was recently added. 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 77 cancer patients dosed to date and evaluable for follow-up at the latest cutoff overall, 41 (53%) had stable disease at their first follow-up scan, 32 of whom were progressing at study entry. At four months follow-up, 33 of 73 evaluable patients remained stable at the second CT scan, suggesting clinical benefit of SON-1010 in 45% of the patients overall, including 2 with PRs and 1 with a CR. A total of 19 of the 23 evaluable patients with sarcoma (83%) had clinical benefit at the 1200 ng/kg dose.

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 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. Our comparable version has advanced 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 8) 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.

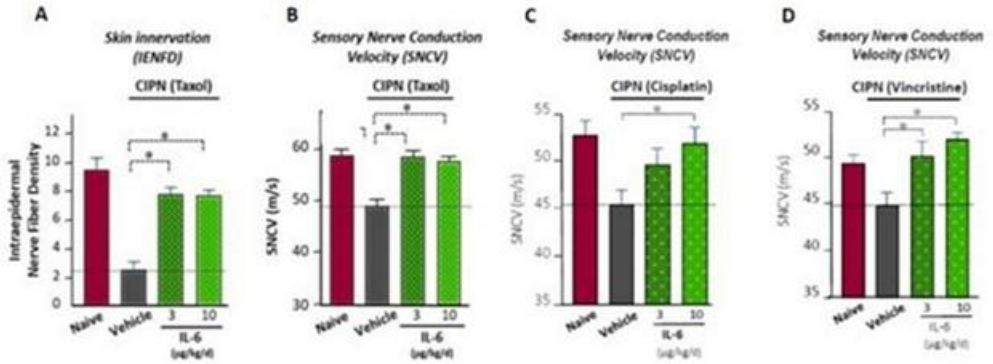

Figure 7: *Activity of IL-6 on neuropathy induced by taxol or cisplatin in rats measured at the histological (IENFD) or physiological (SNCV) levels.*

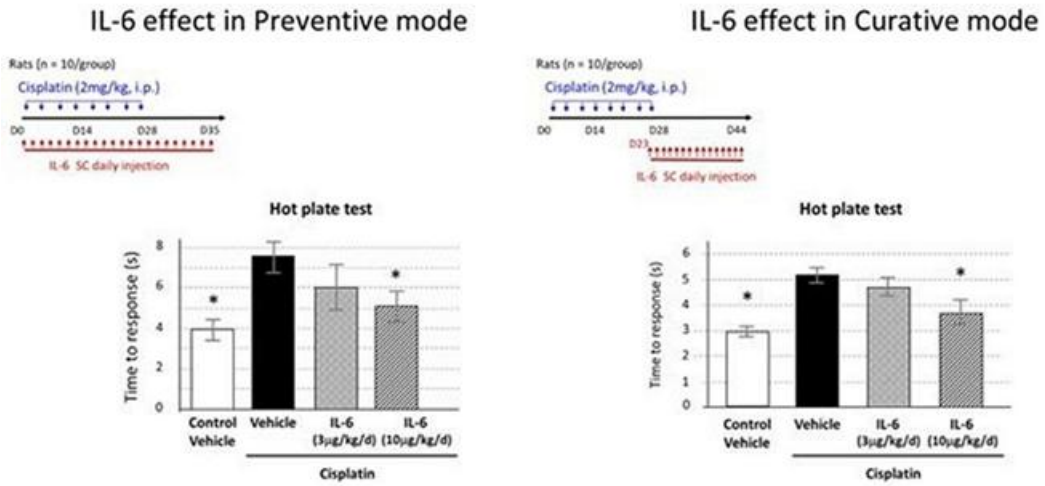

Figure 8: Data show preventive and curative activity potentiating restoration of normal sensitivity (here, using a behavioral response to hot stimulus in cisplatin-induced peripheral neuropathy).

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 therapeutic 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 10- to 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 conducted in Australia. We defined the two doses used to be significantly below the MTD, as supported by preclinical studies. For comparison, our target dose was to 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. We 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 will explore the clinical utility of IL-6 in diabetic peripheral neuropathy (DPN) through execution of the Alkem Agreement. 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. We have 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).

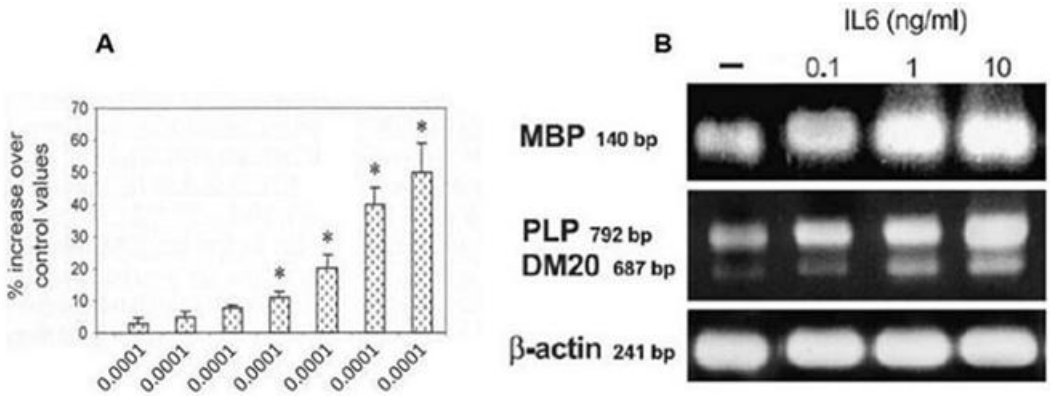

Figure 9: Illustration of survival (A) and differentiation of oligodendrocytes as assessed by myelin basic protein (MBP), proteolipid protein (PLP) and its spliced variant expression (B).

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).

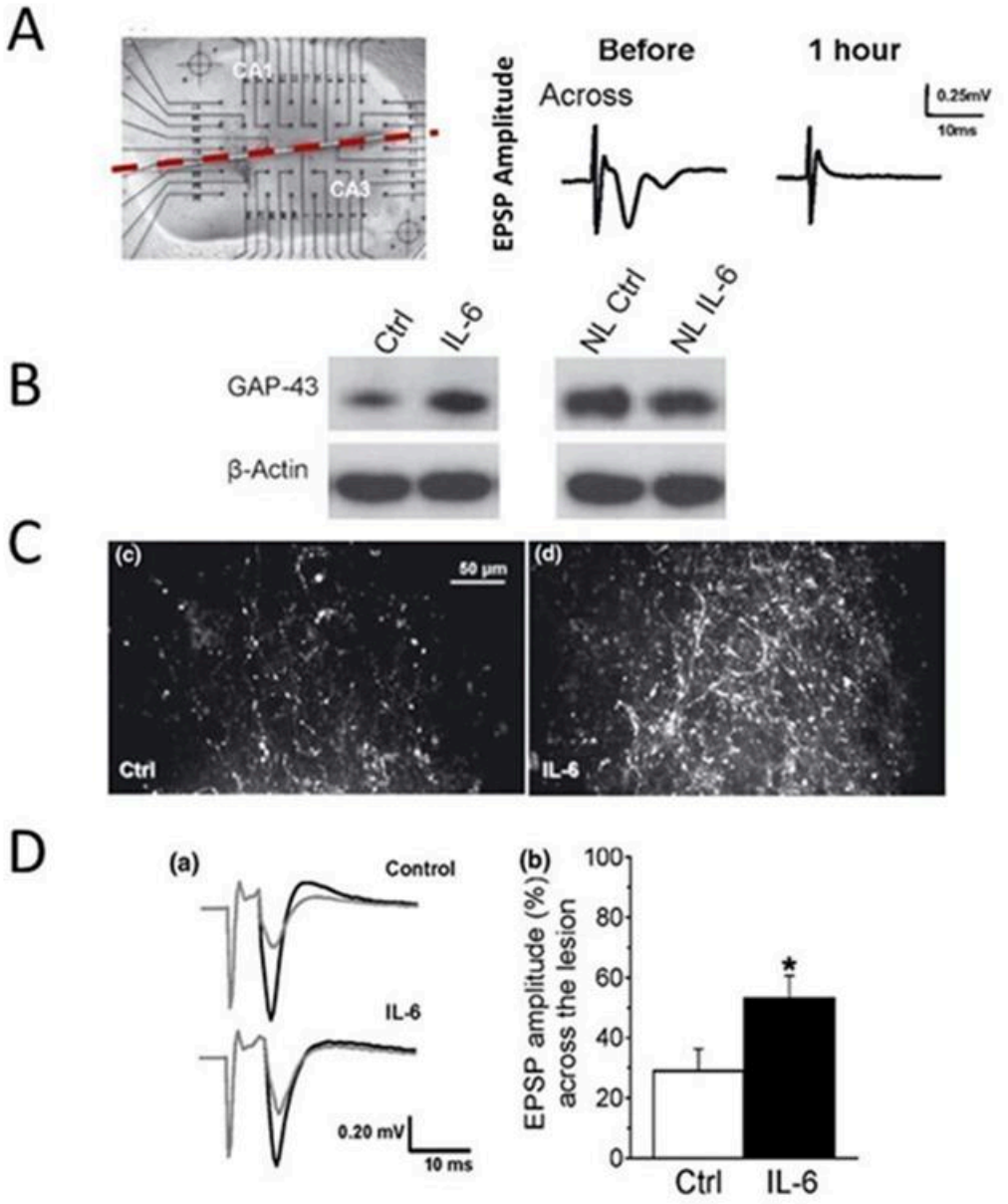

Figure 10: Axonal regeneration activity in hemi-sectioned slices of the hippocampus (A), with increased expression of growth-associated protein 43 (GAP43) in injured slices but not in normal slices (NL) (B). Axonal regeneration activity across the lesion (C) and functional recovery (D) of suppressed (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 and tactile 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 11C-E), 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.

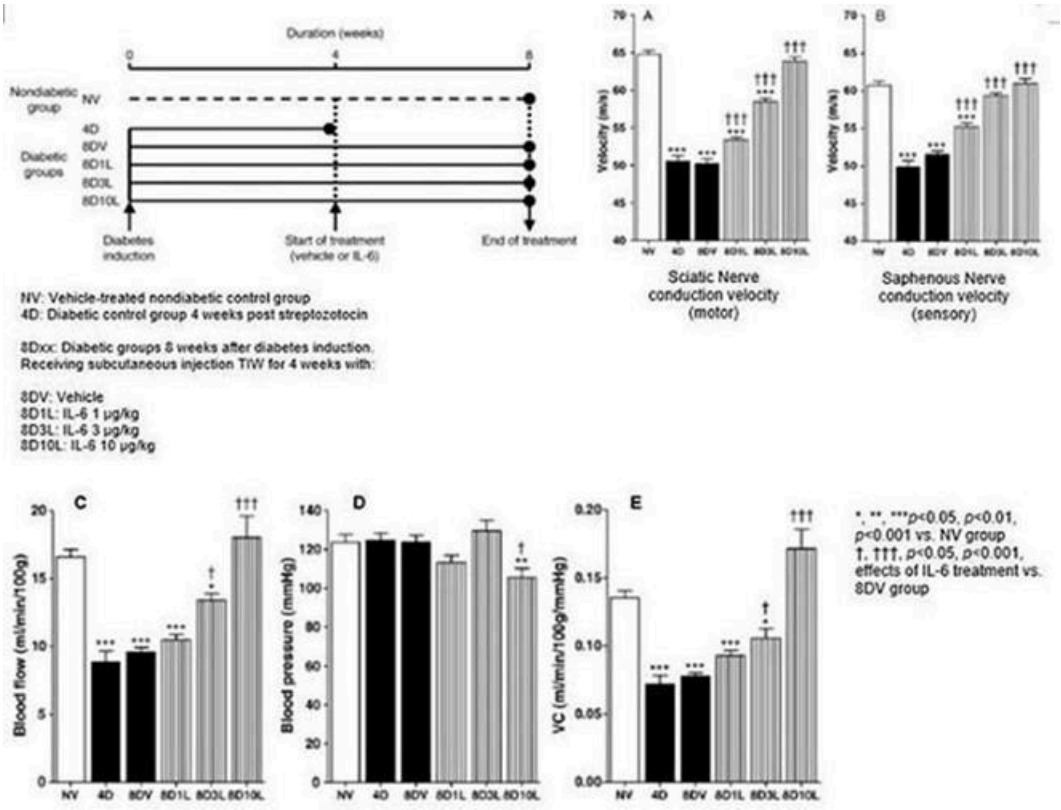

Figure 11: Curative treatment with IL-6 in rats with established diabetic neuropathy induced by streptozotocin. Cameron et al, Exp Neurol 207 (2007) 23-29.

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 us 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.

SON-080: Alkem Agreement

In October 2024, we announced the execution of the Alkem Agreement for the treatment of DPN in India as well as 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 $1.0 million upfront non-refundable cash payment, of which $0.5 million was paid in October 2024 and another $0.5 million was paid in May, 2025, which after tax withholdings resulted in a net payment of $0.8 million. Pursuant to the licensing agreement with ARES Trading, we will pay a sublicensing fee corresponding to 14% of the aggregate upfront amount received from Alkem. In addition, Alkem has agreed to pay Sonnet potential additional milestone payments totaling up to $1.0 million, subject to the achievement of certain development and regulatory milestones. Furthermore, 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 Intermittent 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 the New Life Agreement, described in detail below, which resulted in the out-license of our IL-6 (SON-080) asset for DPN to New Life. 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 $0.5 million received by us upon signing of the LOI in August 2020, an additional $0.5 million non-refundable upfront payment was received by us upon execution of the New Life Agreement. These payments were not subject to the sublicensing fee obligations owed Merck KGaA as set forth in the ARES License Agreement and subsequent amendments (see 'ARES' below). According to the terms of the New Life Agreement, we could receive a $1.0 million deferred license fee within 30 days of the achievement of an early commercial sales milestone, a total of up to $19.0 million in milestone payments and a tiered royalty ranging from 12% to 30% on commercial sales. On December 2, 2024, New Life provided us with written notice of its intention to exercise its Give Back Option pursuant to the New Life Agreement. We were informed by New Life that it has elected to move its business in a different direction. We are negotiating the terms of the Give Back Option with New Life. If we and New Life are unable to reach a mutual agreement on such terms prior to initiation of a Phase III Trial, the Give Back Option will expire unexercised, and New Life will retain the rights granted subject to the terms and conditions of the New Life Agreement. Furthermore, the New Life Agreement will remain in effect unless otherwise terminated by either us or New Life pursuant to the terms and conditions of the New Life Agreement.

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-12 is known to increase IL-15Rα receptor and IFN-ɣ, activate NK and T_H1 (tumor killing) cells, and decreases Tregs. 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
- Upregulate IL-12β1 receptor expression

We have conducted a number of preclinical studies with SON-1210 and the murine version (mIL12-F_HAB-hIL15), and this work was published in December 2023. Mice injected once or three times with the doses indicated had suppressed tumor growth in the B16F10 melanoma model compared to controls (Figure 12). Compared to placebo-treated mice, mIL12-F_HAB-hIL15 mice showed slower tumor growth in a dose-dependent manner. A single dose of 5 µg was fully effective, whereas a single dose of 10 µg did not further slow the tumor volume increase. The 3x group showed an even more effective response, with tumor growth delayed until day 14. All groups treated with mono- or bifunctional cytokine(s) linked to F_HAB showed significant growth inhibition, starting on day 4. A time-to-event efficacy approach in the mice revealed an increase in survival following mIL12-F_HAB-hIL15 treatment, with 1 µg inducing 12-day median survival, whereas 10 µg induced 19-day survival, compared to 10 days in the tumor-bearing placebo mice. The median survival with a single mIL12-F_HAB-hIL15 dose of 5 µg was 18.5 days, which was prolonged to 21 days after 3 doses. Thus, there was a clear dose-dependent effect of mIL12-F_HAB-hIL15 treatment on survival ($p < 0.01$).

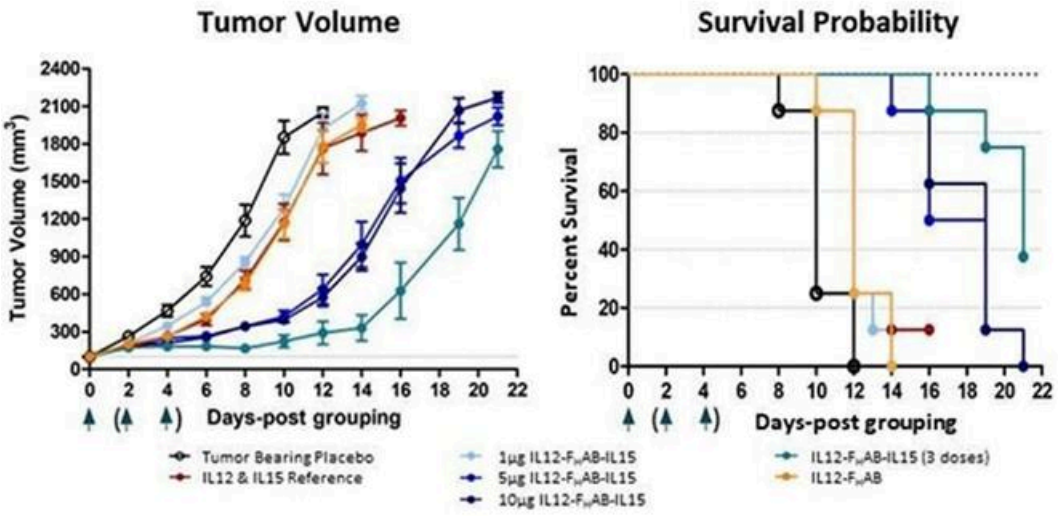

Figure 12: *These data show an enhanced reduction in tumor growth with mIL12-F_HAB-hIL15 compared to concomitantly administered, naked mIL-12 and hIL-15 in a mouse model of melanoma.*

Analysis of PD cytokine response 3 days after dosing (Figure 13) showed that mIL12-F_HAB-hIL15 increased IFN-ɣ, IL-10, IL-12, IL-6, and TNFα levels in a dose-dependent manner compared to the tumor-bearing placebo group, with no evidence of cytokine release syndrome. There was a substantial increase in IFN-ɣ levels with a single dose of mIL12-F_HAB-hIL15 to over 2000 pg/mL at 3 days, whereas mild increases were observed in other cytokines. Two doses of 5 µg increased the peak response to almost 9000 pg/mL. By day 8, the cytokine response pattern was sustained but generally dampened, with maximal IFN-ɣ levels returning to 500 pg/mL after a single dose or 2100 pg/mL after three doses of mIL12-F_HAB-hIL15 at 5 µg. However, TNFα levels remained elevated.

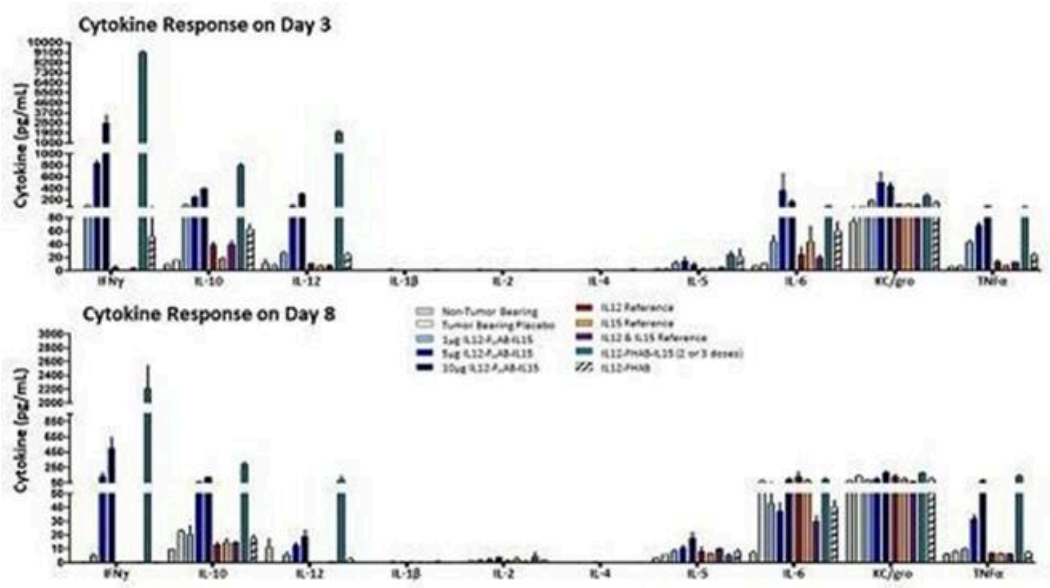

Figure 13: The combination of IL-12 and IL-15 in cis *linked to the F_HAB displayed synergistic activity, leading to enhanced IFN-γ activity versus the combined cytokines or IL12-F_HAB alone in a mouse model of melanoma.*

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. The 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 regulatory authorization process for SON-1210 is scheduled to commence with the Sarcoma Oncology Center as they plan to conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with NALIRIFOX® (the combination of liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin), which is licensed for the treatment of front line metastatic PDAC.

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. Under the terms of the Sarcoma Agreement, the IIOC, in collaboration with us, will prepare a protocol and conduct 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), SON-1411 (IL18^{BPR}-F_HAB-IL12) and SON-1400 (IL18^{BPR}-F_HAB)

In August 2021, we announced the selection of a novel development candidate after completing comparative studies in a mouse melanoma model. The candidate represents our second bifunctional compound integrating IL-12 and IL-18 with our F_HAB platform. 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.

IL18-F_HAB-IL12 (SON-1410) 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. However, published IL-18 clinical trials have shown that while it is well tolerated, IL-18 has shown 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 much higher affinity, compared with the IL-18 receptor (IL-18Rc) complex, thereby causing a negative feedback loop with IL-18 and inhibiting IL-18-mediated TIL activation. Thus, there exists potential for the discovery of IL-18 variant compositions that could harness the therapeutic potential of IL-18 for the treatment of cancers. Our 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.

We face numerous challenges and uncertainties with respect to the development and commercialization of our therapeutic compounds, including our F_HAB technology. Please see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K for more information.

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 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. Regarding DPN, there are several companies selling commercially approved drugs, including but not limited to Eli Lilly, Ono Pharmaceuticals, Pfizer, Collegium Pharmaceuticals and Daiichi Sankyo, as well as a number of companies with compounds in clinical development, including but not limited to Avanir Pharmaceuticals, Pfizer, Vertex Pharmaceuticals, Applied Therapeutics, and Helixsmith.

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 and SON-1411, 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, the 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 Q3 calendar year 2024. 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 our 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-FHAB), 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* CAR-T efficacy studies. If successful and subject to provisions of the agreement, Janssen could exercise its option and we could then seek a license and/or an expanded collaboration.

Alkem Laboratories Limited

On October 8, 2024, we entered into the Alkem Agreement with 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 will enter into a follow-on supply agreement with Alkem pursuant to which we will 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 $1.0 million upfront non-refundable cash payment, of which two $0.5 million payments were paid in October 2024 and April 2025, which after tax withholdings resulted in a net payment of $0.8 million, as well as potential additional milestone payments totaling up to $1.0 million 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 will 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 will 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®). 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).

New Life

In May 2021, we entered into the New Life Agreement with New Life. Under the New Life Agreement, we 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 ability to 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. New Life and us will enter into a follow-on supply agreement pursuant to which we will supply to New Life Products for development and commercialization thereof in the DPN Field (if applicable) (and the CIPN Field, if applicable) in the Exclusive Territory on terms to be negotiated by the parties. We 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 (if applicable) (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. These payments were not subject to the sublicensing fee obligations owed Merck KGaAas set forth in the ARES License Agreement and subsequent amendments(see below under'ARES'). 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 us 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 us 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) our Buy Back Option and New Life's Give Back Option (as defined below).

In addition, New Life granted to us an exclusive option to buy back the rights granted by us to New Life (the "Buy Back Option") 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 (the "Give Back Option"), which options will expire upon the initiation of a Phase III Trial for the applicable Product. On December 2, 2024, New Life provided us with written notice of its intention to exercise its Give Back Option pursuant to the New Life Agreement. We were informed by New Life that it has elected to move its business in a different direction. We are negotiating the terms of the Give Back Option with New Life. If we and New Life are unable to reach a mutual agreement on such terms prior to the initiation of a Phase III Trial, the Give Back Option will expire unexercised, and New Life will retain the rights granted subject to the terms and conditions of the New Life Agreement. Furthermore, the New Life Agreement will remain in effect unless otherwise terminated by either us or New Life pursuant to the terms and conditions of the New Life Agreement.

XOMA

We (as successor-in-interest to Oncobiologics, Inc. ("Oncobiologics"), after Oncobiologics spun-off certain assets into us and concurrently distributed all of its shares in us 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"). 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 $0.5 million for initiation of enrollment of a Product (*i.e.,* SON-1010) in a Phase 1 Trial. We have 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) 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. 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 we 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 (U.S., Japan, China, New Zealand and Russia), and we have filed patent applications in nine (9) other major markets which are directed to numerous fusion proteins that include the Fully Human Albumin Binding (F_HAB) domain. If granted, these resulting patents would expire on dates ranging from 2038 to 2041, subject to patent term extensions under certain circumstances. The patent application filings include:

- National filings corresponding to WO/2018/151868 (PCT/US2018/00085) - 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-7, 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. A patent was issued in China on April 26, 2024, as Chinese Patent No. ZL201880016019.1. 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, Chinese Patent No. ZL201880016019.1 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 us. Thus, we have opted to pursue EP patent validation using the classic national EP validation procedure whereby countries that we wish to have validated (i.e., patent filings and requisite foreign patent translations) are selected and the necessary documentation submitted to the EU patent office. Applications are also pending in Australia, Brazil, Canada, 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, 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 June 11, 2024, the U.S. Patent and Trademark Office 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.

- U.S. 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 U.S. 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.

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

- U.S. 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 application (PCT/US22/32215; Publication No. WO2022/25688) on June 3, 2022, then to a U.S. National Stage application (U.S. Pat. Application No. 18/566,029) on November 30, 2023.

- U.S. 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.

- U.S. 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.

- U.S. provisional patent application directed to Low Dose IL-6 Formulations and Methods of Use Thereof was filed on September 30, 2022, as Application no. 63/377,971. This provisional patent was converted to a PCT application (PCT/US2023/075593; Publication No. WO02024/073718) on September 29, 2023.

- U.S. 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; Publication No. WO2024/097767) on November 1, 2023.

- U.S. 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.

- U.S. provisional patent application directed to Methods of Making Recombinant IL-12 Albumin Binding Domain Fusion Proteins was filed on March 14, 2023, as Application no. 63/490,202, and converted to a PCT application (PCT/US2024/19798; Publication No. WO2024-192171) on March 13, 2024.

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

- U.S. provisional patent applications directed to Interleukin 18 (IL-18) Variants and Fusion Proteins Comprising Same were filed December 29, 2023, as Application no. 63/616,148, and June 10, 2024, as Application no. 63/658,322. A patent titled "Interleukin 18 (IL-18) Variants and Fusion Proteins Comprising Same" was issued in the United States on November 5, 2024, as U.S. Patent No. 12134635.

- U.S. provisional patent application directed to Methods For The Treatment Of Diabetes-Associated Autonomic Neuropathy was filed March 6, 2024, as Application no. 63/561,924.

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 November 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 F_HAB marks on September 14, 2021, and October 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 F_HAB 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 September 17, 2020 and a renewal date of September 17, 2030. Likewise, the F_HAB 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 September 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 September 30, 2025, we had 9 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

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 BioTherapeutics, Inc. ("former Sonnet"), pursuant to which former 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." Former 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 former Sonnet and its direct and indirect subsidiaries and the ongoing business of the Company is the former Sonnet business.

In addition, in connection with and prior to the Merger, on April 1, 2020, former Sonnet completed its acquisition of the global development rights for Atexakin Alfa (low dose formulation of Interleukin-6, IL-6, now "SON-080") from Relief Therapeutics Holding SA ("Relief Holding") through its acquisition of Relief Holding's wholly-owned subsidiary, Relief Therapeutics SA ("Relief"), in exchange for the issuance to Relief Holding of shares of former Sonnet common stock that converted into an aggregate of 307 shares of Company common stock in the Merger.

Recent Developments

Business Combination with Hyperliquid Strategies Inc and Rorschach I LLC

On December 2, 2025 (the "Closing Date"), we completed our previously announced business combination (the "Closing"), pursuant to the Business Combination Agreement, dated as of July 11, 2025 (as amended on September 22, 2025, the "BCA"), by and among the Company, Hyperliquid Strategies Inc ("HSI"), Rorschach I LLC ("Rorschach"), TBS Merger Sub Inc. ("Sonnet Merger Sub") and Rorschach Merger Sub, LLC ("Rorschach Merger Sub"). The common stock of HSI, par value $0.01 per share ("HSI Common Stock") began trading on the Nasdaq Capital Market under the symbol "PURR" on December 3, 2025. The BCA, among other things, provided for (i) the merger of Rorschach Merger Sub with and into Rorschach (the "Rorschach Merger"), with Rorschach surviving the Rorschach Merger as a direct wholly owned subsidiary of HSI, and (ii) immediately following the Rorschach Merger, the merger of Sonnet Merger Sub with and into Sonnet (the "Sonnet Merger" and, together with the Rorschach Merger, the "Mergers" or "Business Combination"), with Sonnet surviving the Sonnet Merger as a direct wholly owned subsidiary of HSI.

In addition, as previously disclosed, concurrently with the execution of the BCA, certain accredited investors (the "Subscribers") entered into subscription agreements with us and HSI (the "Subscription Agreements"), pursuant to which we agreed to issue, and the Subscribers agreed to purchase, immediately prior to the Closing, an aggregate of 239,921,355 shares of our common stock at a purchase price of $1.25 per share, pursuant to a private placement in accordance with Section 4(a)(2) of the Securities Act (the "Closing PIPE"). The Closing PIPE was consummated on the Closing Date immediately prior to the Closing and we issued 239,921,355 shares of our common stock to the Subscribers pursuant to the Subscription Agreements.

In connection with the Business Combination and pursuant to the terms of the BCA, Donald Giffith, Nailesh Bhatt, Albert Dyrness and Lori McNeill resigned and ceased to serve as directors of Sonnet as of the Closing Date. As a result, our board of directors currently consists of one member, Raghu Rao, our Chief Executive Officer. In addition, pursuant to the terms of the BCA, Donald Griffith, John K. Cini, Susan Dexter, Richard Kenney and Stephen McAndrew resigned and ceased to serve as Chief Financial Officer, Chief Scientific Officer, Chief Technical Officer, Chief Medical Officer and President and Chief Business Officer, respectively, of Sonnet as of the Closing Date.

As a result of the Closing, Nasdaq filed a notification of removal from listing and deregistration of our common stock on Form 25 with the SEC on December 2, 2025. After the Form 25 becomes effective, we intend to file with the SEC a Form 15 to request deregistration of our common stock under Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and suspension of our reporting obligations under Sections 13 and 15(d) of the Exchange Act.

Exercise of Warrants

In the fourth quarter of 2025, holders exercised outstanding warrants to purchase 3,744,624 shares of our common stock, from which we received gross proceeds of $11.2 million. In accordance with the BCA, we may not spend any cash proceeds in excess of $3.0 million received from the exercise of warrants without the prior written consent of Rorschach.

July 2025 Convertible Notes and Warrants

In July 2025, we completed a private placement of zero-interest convertible notes (the "Convertible Notes"), raising an aggregate of $2.0 million in gross proceeds. The Convertible Notes were scheduled to mature on June 30, 2026, and were convertible at any time into an aggregate of up to 1,730,104 shares of common stock at a fixed price of $1.156 per share. If, at any time while the Convertible Notes remained outstanding, we issued shares of common stock or common stock equivalents in an offering for gross proceeds of at least $5.0 million (a "Subsequent Issuance"), the entire unpaid principal amount of the Convertible Notes would convert automatically into the same securities issued pursuant to the Subsequent Issuance. In connection with the Convertible Notes, investors also received five-year warrants to purchase an aggregate of 865,052 shares of common stock at the same $1.156 exercise price, providing approximately $0.1 million in additional cash proceeds. The Convertible Notes were converted into shares of Series 5 Preferred Stock (as defined below) and warrants in connection with the PIPE described below.

July 2025 Preferred Stock and Warrant Private Placements

We raised an aggregate of $5.5 million in a private placement (the "PIPE") to accredited investors through the issuance and sale of an aggregate of 5,500 shares of Series 5 Convertible Preferred Stock (the "Series 5 Preferred Stock"), stated value $1,000 per share, initially convertible at a conversion price of $1.25 per share, or 4,400,000 shares of common stock, and warrants to purchase up to an aggregate of 8,800,000 shares of common stock. At the closing of the PIPE, the $2.0 million principal amount of the Convertible Notes automatically converted into an aggregate of 2,000 shares of Series 5 Preferred Stock and warrants to purchase up to 3,200,000 shares of common stock, on the same terms as the PIPE investors.

December 2024 Registered Direct and PIPE Offering

On December 9, 2024, we entered into a securities purchase agreement for a registered direct offering, pursuant to which we sold an aggregate of (i) 768,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 317,325 shares of common stock. Pursuant to the registered direct purchase agreement, in a concurrent private placement, we also sold warrants to purchase up to 1,085,325 shares of common stock. Each registered direct share (or registered direct pre-funded warrant in lieu thereof) was sold in the registered direct offering together with one registered direct common warrant at a combined offering price of $2.23, priced at-the-market under the rules of the Nasdaq Stock Market. The registered direct pre-funded warrants had an excise price of $0.0001 per share, were immediately exercisable and were exercised in full on December 10, 2024. The registered direct common warrants have an exercise price of $2.10 per share, are immediately exercisable and will expire five years from the date of issuance.

In addition, on December 9, 2024, we also entered into a securities purchase agreement for a concurrent private placement with an existing securityholder, pursuant to which we sold an aggregate of (i) 127,500 shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 545,500 shares of common stock, and (iii) common warrants to purchase up to an aggregate of 673,000 shares of common stock. Each private placement share (or private placement pre-funded warrant in lieu thereof) was sold in the private placement together with one private placement common warrant at a combined offering price of $2.23, priced at-the-market under the rules of the Nasdaq Stock Market. The private placement pre-funded warrants have an excise price of $0.0001 per share, are immediately exercisable and may be exercised at any time from the closing date of the private placement until all of the private placement pre-funded warrants are exercised in full. The private placement common warrants have an exercise price of $2.10 per share, are immediately exercisable and will expire five years from the date of issuance.

The registered direct offering and the concurrent private placement closed on December 10, 2024 for aggregate gross proceeds to us of approximately $3.9 million, before deducting the placement agent fees and estimated offering expenses paid by us.

November 2024 Underwritten Public Offering

On November 6, 2024, we entered into an underwriting agreement with Chardan, as the underwriter, pursuant to which we agreed to sell to Chardan, in a firm commitment underwritten public offering, an aggregate of (i) 155,000 shares of common stock, (ii) pre-funded warrants to purchase up to 956,111 shares of common stock, and (iii) accompanying warrants to purchase up to 2,222,222 shares of common stock at the combined public offering price of $4.50 per share and accompanying common warrant and $4.4999 per pre-funded warrant and accompanying common warrant, in each case less underwriting discounts and commissions. The offering closed on November 7, 2024. Pursuant to the underwriting agreement, we agreed to pay Chardan (i) a commission of 7.0% of the gross proceeds of the offering, (ii) all reasonable out-of-pocket expenses of Chardan relating to the offering, including a maximum of $125,000 for the fees and disbursements of counsel to Chardan, and (iii) a non-accountable expense allowance equal to 1% of the gross proceeds of the offering. The net proceeds to us from the offering were approximately $4.2 million, after deducting underwriting discounts and commissions and estimated offering expenses. We expect to use the proceeds from the offering for research and development, including clinical trials, working capital, the repayment of all or a portion of our liabilities, and general corporate purposes.

Nasdaq Letters

On May 30, 2025, we received notice (the "Notice") from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") advising that we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires companies listed on The Nasdaq Capital Market to maintain stockholders' equity of at least $2.5 million (the "Minimum Stockholders' Equity Rule"). In our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, we reported stockholders' equity of $0.7 million, which is below the Minimum Stockholders' Equity Rule for continued listing. Additionally, as of May 30, 2025, we did not meet the alternative Nasdaq compliance standards relating to the market value of listed securities of at least $35.0 million or net income of $0.5 million from continuing operations in the most recently completed fiscal year, or in two of the last three most recently completed fiscal years. Pursuant to the Notice, Nasdaq had given us 45 calendar days, or until July 14, 2025, to submit to Nasdaq a plan to regain compliance.

On July 15, 2025, we closed the PIPE for gross proceeds of $5.5 million (the "PIPE Proceeds"). In addition to the PIPE Proceeds, as of July 18, 2025, we received proceeds of approximately $10.5 million in connection with the exercise of outstanding warrants (the "Warrant Proceeds" and together with the PIPE Proceeds, the "Proceeds"). On July 18, 2025, we filed a Current Report on Form 8-K stating that as of the date of the Form 8-K, we believed that we had stockholders' equity in excess of the $2.5 million required pursuant to the Minimum Stockholders' Equity Rule as a result of the Proceeds. On July 23, 2025, we received a letter from Nasdaq stating that based on the Form 8-K, the Staff determined that we complied with the Minimum Stockholders' Equity Rule. The letter also stated that Nasdaq will continue to monitor our ongoing compliance with the Minimum Stockholders' Equity Rule and, if at the time of our next periodic report we do not evidence compliance, we may be subject to delisting. At that time, the Staff will provide written notification to us, and we may then appeal the Staff's determination to a Hearings Panel.

Corporate and Available Information

We were organized on October 21, 1999, under our original 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. As described above, on April 1, 2020, we completed our business combination with former Sonnet, with former Sonnet surviving as a wholly owned subsidiary of us (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 former Sonnet.

Our principal executive offices are located at 100 Overlook Center, Suite 102, Princeton, New Jersey 08540. Our telephone number is (609) 375-2227 and the corporate website address is https://www.sonnetbio.com/. We included the website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website. The information on the website is not incorporated by reference in this Annual Report on Form 10-K.

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, as well as other documents we file with the SEC, are available free of charge through the Investors section of our website as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The public can obtain documents that we file with the SEC at *www.sec.gov.*

Item 1A. 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 report 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.

Summary of Risk Factors

- 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.
- 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.

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, 2025 and 2024 were approximately $16.0 million and $7.4 million, respectively. As of September 30, 2025, we had an accumulated deficit of approximately $133.7 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 stockholders' equity (deficit) and working capital.

We anticipate that our expenses will increase 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 September 30, 2025, we had cash and cash equivalents of $5.1 million and stockholders' equity of $10.8 million. We believe our cash and cash equivalents at September 30, 2025 will fund our projected operations into February 2026.

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 fiscal years ended September 30, 2025 and 2024, we used $12.8 million and $8.6 million, 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. 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.

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 F_HAB 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 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 stockholders 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 December 17, 2024, our intellectual property portfolio includes 20 total pending patent applications and issued patents, inclusive of 5 issued patents in the U.S., Japan, China, Russia and New Zealand, and 9 PCT applications within the 5007 patent family - also, 9 pending provisional applications covering formulations, manufacturing processes 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 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, Hong Kong and India, 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 September 30, 2025, we had 9 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

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.

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 business, strategy, and access to capital may be adversely affected by the business, financial condition, and decisions of HSI.

As a result of the Business Combination, we are a wholly owned subsidiary of HSI and depend on HSI for strategic direction, funding and other resources. HSI's business model and treasury strategy, including a significant focus on HYPE and other digital assets, expose it to market volatility, liquidity constraints, evolving and uncertain regulatory regimes, heightened cybersecurity and custodial risks, and complex accounting and tax outcomes that may affect its financial results and cash flows. Adverse developments affecting HSI, such as declines in the value or liquidity of its digital asset holdings, regulatory or enforcement actions impacting digital asset activities or counterparties, restrictions on custodial or trading venues, increased earnings volatility (including fair value adjustments), potential tax obligations, or limitations on its access to external financing, could reduce or delay HSI's ability or willingness to fund our operations or support our growth initiatives. In addition, shifts in HSI's strategic priorities or risk tolerance, or constraints arising from its public company obligations and market conditions, may lead to changes in our business plans, capital allocation, or risk profile that could negatively impact our operating results, competitiveness, and financial condition.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 1C. Cybersecurity.

Cybersecurity Risk Management

Like many companies, we face significant and persistent cybersecurity risks. The small size of our organization and limited resources could exacerbate these risks. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property. To effectively prevent, detect, and respond to cybersecurity threats, we maintain a cyber risk management strategy, which is comprised of a wide array of policies, standards, architecture, processes, and governance. Under the guidance and supervision of our Interim Chief Executive Officer, we further limit risk by delegating our information technology and cybersecurity to a leading third-party IT consultant to safeguard our networks. Additionally, as an added layer of security, all of our data is stored on the cloud.

Despite being a small organization, we are committed to maintaining governance and oversight of these risks and to implementing standard operating procedures ("SOPs") and training to help us assess, identify, monitor and respond to these risks. Employees are trained to avoid phishing emails, and our internal controls system is designed to mitigate the risk of payments of fraudulent invoices.

Governance

We aim to incorporate industry best practices for companies of our size and financial strength throughout our cybersecurity program. Our Board has ultimate oversight of cybersecurity risk. The Interim Chief Executive Officer reports to our Board. Our Interim Chief Executive Officer provides periodic updates to the Board on (1) any critical cybersecurity risks; (2) ongoing cybersecurity initiatives and strategies; (3) applicable regulatory requirements; and (4) industry standards. The Interim Chief Executive Officer also notifies the Board of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities as appropriate.

Item 2. Properties.

The Company relies on short term office use contracts to procure office and meeting space.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

Item 4. Mine Safety Disclosures.

Not applicable.

Part II

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

Market Information

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

Holders

As of the Closing Date, we had one holder of record of our common stock. The transfer agent of our common stock was Securities Transfer Corporation, 2901 N Dallas Parkway, Suite 380, Plano, TX 75093.

Dividends

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the common stock will rest solely within the discretion of our Board and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help facilitate an understanding of our financial condition and our historical results of operations for the periods presented. This MD&A should be read in conjunction with the financial statements and notes thereto included in this Annual Report on Form 10-K. This MD&A may contain forward-looking statements that involve risks and uncertainties. For a discussion on forward-looking statements, see the information set forth above under the caption "*Special Note Regarding Forward-Looking Statements*," which information is incorporated herein by reference.

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 human serum albumin for transport to target tissues. We designed the construct to extend the half-life in serum and to improve drug delivery to and retention in solid tumors, which extends the duration of cytokine activity in the microenvironment. F_HAB development candidates can be produced in mammalian cell culture, which enables glycosylation of the interleukins, thereby reducing the risk of immunogenicity and in certain instances, improves the cytokine's biological activity. 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, linked to the F_HAB domain. 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, soft tissue sarcoma, colorectal cancer, and breast 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 and published the final results of that study in February 2024. Interim safety, tolerability, and efficacy data from the SB101 study was most recently reported in March 2025.

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 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 ("POC") 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. Since the highest dose has been well tolerated, the Safety Review Committee ("SRC") recommended adding a seventh cohort using a maintenance dose that is now 50% higher to study its safety and effect before proceeding to the randomized Part 2 in patients with PROC at one of the two highest doses versus the standard of care ("SOC") for PROC. Interim safety, tolerability, and efficacy data from the SB221 study was most recently reported in August 2025 following initiation of enrollment of a higher dose cohort.

In January 2025, we announced an expansion of our Phase 1 SB101 clinical study of SON-1010 to add a new cohort to evaluate its effect in combination with trabectedin (Yondelis®), following the successful monotherapy dose escalation above the IL-12 MTD molar equivalent. Trabectedin is an alkylating DNA-binding agent that was approved as a second-line treatment in early 2024 for patients with unresectable, metastatic liposarcoma or leiomyosarcoma who have received a prior anthracycline-containing regimen. It is also known to convert tumor macrophages into a pro-inflammatory phenotype. We believe that SON-1010 has the potential to complement that activity by activating the NK and T cells in the TME to secrete more interferon-gamma (IFNγ), which is considered to be important for anti-tumor control. The initial safety and tolerability of this approach was reported in March 2025 and top line data is expected by the end of calendar 2025. This cohort is also fully enrolled, bringing the total number of people exposed to SON-1010 to103 to date, including 42 with soft tissue sarcoma and 32 with PROC. Partial responses have been seen in both indications at the highest dose, along with one complete response ("CR") with PROC.

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 (SB211) during the third quarter of 2022. The Data Safety Monitoring Board ("DSMB") completed its review of the preliminary safety data during the first calendar quarter of 2024 and cleared the trial to proceed to Part 2. Following the completion of the DSMB review, we announced initial safety data from the CIPN study. On the basis of the DSMB review of both initial safety and a preliminary trend of efficacy data, an outreach program was initiated to identify a potential partner to develop SON-080 in the DPN indication. Until new clinical data are generated in the DPN indication, we have decided to delay further direct development of this program.

On October 8, 2024, we entered into a license agreement (the "Alkem Agreement") with Alkem Laboratories Limited ("Alkem") for the development and commercialization of SON-080 in DPN and/or CIPN and/or autonomic neuropathy in India. Pursuant to the terms of the Alkem Agreement, Alkem will bear the cost of, and be responsible for, among other things, conducting clinical studies, preparing and filing applications for regulatory approval aiming at commercializing SON-080 in the DPN indication in India.

Pursuant to a license agreement (the "New Life Agreement") we entered into with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, we agreed to be jointly responsible for developing SON-080 in DPN with New Life, with the objective to analyze the data and to consider initiating a Phase 2 study, pending the outcome of any partnering activity. We were informed by New Life that it has elected to move its business in a different direction. Consequently, on December 2, 2024, New Life provided written notice to us of its intention to exercise its right to give back the rights with respect to the Products under the New Life Agreement (the "Give Back Option") under the New Life Agreement, subject to the negotiation and mutual agreement of the terms of such Give Back Option by us and New Life. We are negotiating the terms of the Give Back Option with New Life. If we and New Life are unable to reach a mutual agreement on such terms prior to initiation of a Phase III Trial, the Give Back Option will expire unexercised, and New Life will retain the rights granted subject to the terms and conditions of the New Life Agreement. Furthermore, the New Life Agreement will remain in effect unless otherwise terminated by either us or New Life pursuant to the terms and conditions of the New Life Agreement.

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 drug candidate 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 non-human primates. In August 2024, we entered into a Master Clinical Collaboration Agreement (the "SOC Agreement") with the Sarcoma Oncology Center ("SOC") to advance the development of SON-1210. Based on the FDA feedback of approving the basic study design, preparations for the full IND submission package are underway.

SON-1411 (IL18-F_HAB-IL12) is a bifunctional combination of human Interleukin 18 ("IL-18"), which was modified to resist inhibitory interaction with the IL-18 binding protein while maintaining biological activity, along with single-chain human IL-12 for solid tumor cancers. Cell line development and titer/bioactivity assessments are underway. We have elected to put the SON-1411 development program on hold to preserve cash.

On July 11, 2025, we entered into a definitive Business Combination Agreement (as amended, the "BCA") with Rorschach I LLC ("Rorschach"), Hyperliquid Strategies Inc. ("HSI"), TBS Merger Sub Inc., and Rorschach Merger Sub, LLC, pursuant to which, on December 2, 2025 (the "Closing Date"), subject to the terms and conditions contained in the BCA, Rorschach Merger Sub, LLC, merged with and into Rorschach with Rorschach surviving as a direct wholly owned subsidiary of HSI and TBS Merger Sub Inc. merged with and into Sonnet, with Sonnet surviving as a direct wholly owned subsidiary of HSI. The common stock of HSI, par value $0.01 per share ("HSI Common Stock") began trading on the Nasdaq Capital Market under the symbol "PURR" on December 3, 2025. On the Closing Date, Nasdaq filed a notification of removal from listing and deregistration of our common stock on Form 25 with the SEC on December 2, 2025. After the Form 25 becomes effective, we intend to file with the SEC a Form 15 to request deregistration of our common stock under Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and suspension of our reporting obligations under Sections 13 and 15(d) of the Exchange Act. Following the Closing Date, we will operate as a wholly owned subsidiary of HSI and will continue to focus on the development of our existing biotech assets, including SON-1010, while disposing of other assets.

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 $16.0 million and $7.4 million for the years ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had cash and cash equivalents of $5.1 million. In accordance with the BCA, we may not spend cash proceeds of $8.2 million received from the exercise of outstanding warrants without the prior written consent of Rorschach.

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 ChEF Purchase Agreement (the "Purchase Agreement") with Chardan related to a "ChEF," Chardan's committed equity facility (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 and preferred stock, warrants and proceeds from the issuance of convertible debt.

Lead Clinical Programs Update

SON-1010

Phase 1 Trial (SB101 Trial): in Solid Tumors (SON-1010 Monotherapy) and in Sarcoma (with Trabectedin)

This first-in-human study is primarily designed to evaluate the safety of multiple ascending doses of SON-1010 in cancer patients and is being conducted at several sites across the United States. The highest dose group studied to date was enrolled at 1200 ng/kg in December 2024 and one patient has had a partial response ("PR") at that dose. We recently announced an expansion of this trial to study the combination of SON-1010 with trabectedin (Yondelis®) in certain advanced soft-tissue sarcomas ("STS"), following the successful completion of monotherapy dose escalation. Enrollment in this cohort is complete and topline safety data of the combination with trabectedin is expected in H2 calendar year 2025. No new safety concerns have been reported to date.

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

The second cancer trial is a global Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study to assess the safety, tolerability, PK, PD, and preliminary efficacy of SON-1010 administered subcutaneously ("SC") in combination with atezolizumab given intravenously ("IV"). Enrollment remains ongoing and an update on safety in that trial was released on August 4, 2025 after the maximum dose to date was established at 1200 ng/kg. One of the three patients with PROC who was enrolled at that dose had a PR and one had a CR.

Program Highlights:

- PK data reveals about 10-fold extended half-life for SON-1010 compared with rhIL-12 and suggests tumor targeting by F_HAB binding to albumin.
- Dose-related, controlled, and prolonged IFNγ response.
- The SB101, SB102, and SB221 trials have collectively enrolled 103 subjects, with 13 of 24 evaluable monotherapy patients (54%) with cancer suggesting clinical benefit of SON-1010 monotherapy (stable disease ["SD"] at four months). At the highest dose, five of six patients (83%) had clinical benefit and one patient had a PR.
- Patients have received up to 24 cycles of SON-1010 as monotherapy and up to 19 cycles of SON-1010 with atezolizumab without dose-limiting toxicity at any dose level.
- Toxicity is minimized in both trials with the use of a lower '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.
- Dose escalation to 1200 ng/kg has been archived safely in both trials, which is higher than the rhIL-12 MTD molar equivalent.
- The 1200 ng/kg dose-escalation cohort in SB101 was increased in size to six patients to enhance the assessment of PK and PD. An expansion cohort was also added to study the dosing of SON-1010 alternating with trabectedin in certain types of soft tissue sarcoma.
- 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 AEs seen to date have been transient, with no evidence of cytokine release syndrome.

Upcoming Milestones:

- Phase 1: Solid Tumors (SON-1010 Monotherapy and Combination with Trabectedin)
  - H2 calendar year 2025: Topline Safety and Efficacy Data
- Phase 1b/2a: PROC (SON-1010 in Combination with Atezolizumab)
  - H2 calendar year 2025: RP2D Safety & Topline Efficacy

SON-080

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

The SB211 study was 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 with atexakin-alfa. The goal of the first portion of the SB211 study was to confirm safety and tolerability before continued development in Phase 2. As previously announced in March 2024, a DSMB 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. Given the business priorities at the time, the SB211 study was put on hold.

In October 2024, we entered into the Alkem Agreement with Alkem for the research, development, manufacturing, marketing, and commercialization of our SON-080 molecule for the treatment of DPN in India and the manufacturing, marketing, and commercialization of SON-080 for CIPN and autonomic neuropathy in India. Alkem will conduct all clinical trials it believes appropriate to obtain regulatory/commercial approval in India of SON-080 for the treatment of DPN. Subsequent to the partnership established with Alkem, preparations are being made to support initiation of a Phase 2 clinical trial in DPN, a mechanistically synergistic and larger, high-value indication with unmet medical need.

Phase 1b Data Highlights:

- SON-080 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 was 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:

- H2 calendar year 2025: Alkem's Initiation of Phase 2 trial

SON-1210: Proprietary, Bifunctional Version of Human Interleukins 12 (IL-12) and 15 (IL-15), Configured Using Our $F_{H}AB$ Platform, in Combination with Chemotherapy for the Treatment of Advanced Solid Tumors and Metastatic Pancreatic Cancer

In August 2024, we entered into the SOC Agreement with the SOC to conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to NALIRIFOX (the combination of liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin) for the specific treatment of metastatic pancreatic cancer. The NALIRIFOX regimen is U.S. FDA-approved for the treatment of metastatic pancreatic cancer in the front-line and refractory settings.

Components of Results of Operations

Collaboration Revenue

Collaboration revenue was earned from the license arrangement entered into with New Life in May 2021, which granted an exclusive license to New Life for rights (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 "New Life License"); and (ii) transfer of know-how and clinical development and regulatory activities ("R&D Activities"). We determined that the New Life License and the R&D Activities are not distinct from each other and, therefore, combined these material promises comprise 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 were recognized over the estimated performance period of R&D services, which ended in the first fiscal quarter of 2024.

Collaboration revenue was also earned from the Alkem Agreement entered into in October 2024, which granted an exclusive license to Alkem for rights (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 DPN (the "DPN Field") and to manufacture, import, export, market, use and commercialize Products for the treatment of CIPN and autonomic neuropathy (together with the DPN Field, the "Fields") in India. We identified the following obligations under the Alkem Agreement: (i) License to research, develop, market, import, use and commercialize the Product in the DPN Field in India (the "Alkem License") and (ii) supply of Compound for a Phase 2 clinical trial ("Supply"). We determined that the Alkem License and Supply are not distinct from each other and, therefore, combined these material promises comprise a single performance obligation. Under the Alkem Agreement, we received upfront cash payments totaling $1.0 million, which were fully allocated to the single performance obligation and were recognized at the point-in-time at which the Company transferred the Alkem License and Supply to Alkem.

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, contract research organizations, contract manufacturing organizations 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 risks 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;
- 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 health epidemics or outbreaks of communicable diseases 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 (Expenses)

Other Income

We have participated in the Program sponsored by the New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused net operating losses ("NOLs") 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 NOLs through the Program. We plan to sell additional NOLs under the Program in the future, subject to program availability and state approval.

Foreign Exchange Gain (Loss)

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

Amortization of Debt Discount

Amortization of debt discount consists of amortization expense related to the discount recorded in connection with the issuance of convertible notes in July 2025.

Provision for Income Taxes

Provision for income taxes consists of foreign withholding taxes incurred on collaboration revenue.

Results of Operations

Comparison of the Years Ended September 30, 2025 and 2024

The following table summarizes our results of operations for the years ended September 30, 2025 and 2024:

	Years ended September 30,		
	2025	**2024**	**Change**
Collaboration revenue	$ 1,000,000	$ 18,626	$ 981,374
Operating expenses:			
Research and development	8,355,304	5,737,252	$ 2,618,052
General and administrative	8,488,811	6,130,845	2,357,966
Total operating expenses	16,844,115	11,868,097	4,976,018
Loss from operations	(15,844,115)	(11,849,471)	(3,994,644)
Foreign exchange (loss) gain	(112,985)	84,293	(197,278)
Other income	720,102	4,327,946	(3,607,844)
Amortization of debt discount	(556,089)	—	(556,089)
Loss before provision for income taxes	(15,793,087)	(7,437,232)	$ (8,355,855)
Provision for income taxes	(218,400)	—	(218,400)
Net loss	$ (16,011,487)	$ (7,437,232)	$ (8,574,255)

Collaboration Revenue

We recognized $1.0 million of revenue related to the Alkem Agreement during the year ended September 30, 2025 compared to $18,626 of revenue related to the New Life Agreement during the year ended September 30, 2024. Revenue of $1.0 million for the year ended September 30, 2025 was due to our transfer of the Alkem License and Supply to Alkem during the first quarter of fiscal 2025. Revenue of $18,626 for the year ended September 30, 2024 was due to our completion of R&D Activities related to New Life during the first quarter of fiscal 2024.

Research and Development Expenses

Research and development expenses were $8.4 million for the year ended September 30, 2025, compared to $5.7 million for the year ended September 30, 2024. The increase of $2.6 million was primarily related to a $3.0 million increase in costs for our SB101 and SB221 clinical trials and a $1.0 million increase resulting from the cancellation in 2024 of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023, partially offset by a $1.6 million reduction in non-clinical expenses as we have tightened our focus on research and development projects that we have assessed to have the greatest near-term potential and have placed certain development projects on hold while we seek partnering opportunities.

General and Administrative Expenses

General and administrative expenses were $8.5 million for the year ended September 30, 2025, compared to $6.1 million for the year ended September 30, 2024. The increase of $2.4 million was primarily due to an increase of $1.8 million in professional fees primarily related to costs incurred in connection with the BCA and related registration statements filed with the SEC, as well as costs incurred in connection with the Purchase Agreement, and the cancellation in 2024 of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 in the amount of $0.9 million.

Other Income

Other income was $0.7 million for the year ended September 30, 2025, compared to $4.3 million for the year ended September 30, 2024. The decrease of $3.6 million was due to a reduction in the sale of unused New Jersey state NOLs available for sale under the Program.

Amortization of Debt Discount

Amortization of debt discount was $0.6 million for the year ended September 30, 2025 as a result of the discount recorded in connection with the issuance of convertible notes.

Provision for Income Taxes

Provision for income taxes was $0.2 million for the year ended September 30, 2025 as a result of withholding taxes from collaboration revenue earned under the Alkem Agreement.

Liquidity and Capital Resources

We have funded operations to date primarily with proceeds from sales of common and preferred 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. In addition, we have requested that our stockholders approve the merger transactions contemplated by the BCA, pursuant to which, if approved, Sonnet will operate as a wholly owned subsidiary of HSI and we will continue to focus on the development of our existing biotech assets. There is no certainty that equity or debt financing will be available in the future or that it will be at acceptable terms, or that our stockholders will approve the merger transactions and, at this time, it is not possible to predict the outcome of these matters.

We have incurred net losses of $16.0 million and $7.4 million for the years ended September 30, 2025 and 2024, 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 and cash equivalents of $5.1 million at September 30, 2025 will fund our projected operations into February 2026. 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 following table summarizes our sources and uses of cash for each of the periods presented:

	Year ended September 30,	
	2025	**2024**
Net cash used in operating activities	$ (12,827,199)	$ (8,607,723)
Net cash used in investing activities	(12,000)	(12,000)
Net cash provided by financing activities	26,047,009	6,494,920
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 13,207,810	$ (2,124,803)

Operating Activities

During the year ended September 30, 2025, we used $12.8 million of cash in operating activities which was primarily attributable to our net loss of $16.0 million, partially offset by a combined decrease in prepaid expenses and other assets and incentive tax receivable of $1.0 million related to deposits applied to research and development expenses, an increase of $0.8 million in accounts payable and accrued expenses primarily due to professional fees incurred in connection with the transactions contemplated in the BCA, $0.6 million in amortization of debt discount, $0.5 million in financing costs associated with the Purchase Agreement that are classified as financing activities, and $0.2 million in share-based compensation expense.

During the year ended September 30, 2024, we used $8.6 million of cash in operating activities which was primarily attributable to our net loss of $7.4 million, a $2.2 million net decrease in accounts payable and accrued expenses primarily due to the decrease in research and development expenses, offset by an increase of $0.5 million from a decrease in prepaid expenses and other assets, $0.4 million in financing costs associated with the Purchase Agreement that are classified as financing activities and $0.2 million in share-based compensation expense.

Investing Activities

During each of the years ended September 30, 2025 and 2024, we used $12,000 of cash in investing activities for the purchase of acquired in-process research and development.

Financing Activities

During the year ended September 30, 2025, net cash provided by financing activities was $26.0 million, consisting of $15.3 million in net proceeds from the sale of common and preferred stock and pre-funded warrants through a combination of public, registered direct and PIPE offerings and $11.2 million received from the exercise of warrants, partially offset by the payment of $0.5 million of financing costs related to the Facility.

During the year ended September 30, 2024, net cash provided by financing activities was $6.5 million, consisting of $3.5 million in net proceeds from the sale of common stock through the Purchase Agreement and in an underwritten public offering. In addition, we received proceeds of $3.0 million from the exercise of warrants.

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. 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, 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, the ownership interest of ours 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.

Exercise of Warrants

In the fourth quarter of 2025, holders exercised outstanding warrants to purchase 3,744,624 shares of our common stock, from which we received gross proceeds of $11.2 million. In accordance with the BCA, we may not spend any cash proceeds in excess of $3.0 million received from the exercise of warrants without the prior written consent of Rorschach.

July 2025 Convertible Notes and Warrants

In July 2025, we completed a private placement of zero-interest convertible notes (the "Convertible Notes"), raising an aggregate of $2.0 million in gross proceeds. The Convertible Notes were scheduled to mature on June 30, 2026, and were convertible at any time into an aggregate of up to 1,730,104 shares of common stock at a fixed price of $1.156 per share. If, at any time while the Convertible Notes remained outstanding, we issued shares of common stock or common stock equivalents in an offering for gross proceeds of at least $5.0 million (a "Subsequent Issuance"), the entire unpaid principal amount of the Convertible Notes would convert automatically into the same securities issued pursuant to the Subsequent Issuance. In connection with the Convertible Notes, investors also received five-year warrants to purchase an aggregate of 865,052 shares of common stock at the same $1.156 exercise price, providing approximately $0.1 million in additional cash proceeds. The Convertible Notes were converted into shares of Series 5 Preferred Stock (as defined below) and warrants in connection with the PIPE described below.

July 2025 PIPE Offering

We raised an aggregate of $5.5 million in a private placement (the "PIPE") to accredited investors through the issuance and sale of an aggregate of 5,500 shares of Series 5 Convertible Preferred Stock (the "Series 5 Preferred Stock"), stated value $1,000 per share, initially convertible at a conversion price of $1.25 per share, or 4,400,000 shares of common stock, and warrants to purchase up to an aggregate of 8,800,000 shares of common stock. At the closing of the PIPE, the $2.0 million principal amount of the Convertible Notes automatically converted into an aggregate of 2,000 shares of Series 5 Preferred Stock and warrants to purchase up to 3,200,000 shares of common stock, on the same terms as the PIPE investors.

December 2024 Registered Direct and PIPE Offering

On December 10, 2024, we closed a registered direct offering with institutional investors for the issuance and sale of 768,000 shares of our common stock, pre-funded warrants to purchase up to 317,325 shares of common stock, and accompanying warrants to purchase up to an aggregate of 1,085,325 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 one share of common stock. The offering price of each share of common stock and accompanying common warrant was $2.23 and the offering price of each pre-funded warrant and accompanying common warrant was $2.2299, priced at-the-market under the rules of the Nasdaq Stock Market. The registered direct warrants were immediately exercisable at a price of $2.10 per share, expire five years from the date of issuance and contain an alternative cashless exercise provision. 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.

We closed a concurrent private placement with an existing investor for the issuance and sale of 127,500 shares of our common stock, pre-funded warrants to purchase up to 545,500 shares of common stock, and accompanying warrants to purchase up to an aggregate 673,000 shares of our common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold in the PIPE together with a common warrant to purchase one share of common stock. The PIPE offering price of each share of common stock and accompanying common warrant was $2.23 and the PIPE offering price of each pre-funded warrant and accompanying common warrant was $2.2299, priced at-the-market under the rules of the Nasdaq Stock Market. The PIPE warrants were immediately exercisable at a price of $2.10 per share, expire five years from the date of issuance and contain an alternative cashless exercise provision. 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.

We raised net proceeds of approximately $3.4 million from the registered direct and PIPE offering.

November 2024 Underwritten Public Offering

On November 7, 2024, we closed a public offering of common stock and certain warrants through Chardan, as underwriter, for net proceeds of $4.2 million through the issuance and sale of 155,000 shares of our common stock, pre-funded warrants to purchase up to 956,111 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 2,222,222 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 $4.50 and the public offering price of each pre-funded warrant and accompanying common warrant was $4.4999. The common warrants were immediately exercisable at a price of $4.50 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision. 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.

Alkem Licensing Agreement

In October 2024, we executed the Alkem Agreement for the treatment of DPN in India as well as 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 paid us $1.0 million in upfront non-refundable cash payments, which after tax withholdings resulted in net payments of $0.8 million, and will pay us potential additional milestone payments totaling up to $1.0 million 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 intermittent low dose IL-6 compound as set forth in the Alkem Agreement.

Committed Equity Facility

On May 2, 2024, we entered into the Purchase Agreement and a Registration Rights Agreement (the "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, of which $24.7 million is available to be sold as of September 30, 2025. 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. We sold 153,020 shares of common stock pursuant to the Purchase Agreement for net proceeds of approximately $0.2 million during the year ended September 30, 2025.

Contractual Obligations and Commitments

Our contractual obligations as of September 30, 2025 that will affect our future liquidity consist of an operating lease. As of September 30, 2025, we had a current operating lease liability of $46,573.

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. 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 consolidated financial statements included elsewhere in this Annual Report on Form 10-K, 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 September 30, 2025, 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 Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Sonnet BioTherapeutics Holdings, Inc. and Hyperliquid Strategies, Inc. and subsidiaries (the Company) as of September 30, 2025 and 2024, the related consolidated statements of operations, stockholders' equity (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, 2025 and 2024, 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 that 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.

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, 2025, the Company reported accrued research and development expenses of $0.6 million.

We identified the evaluation of certain 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, 2025, for a selection of 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 16, 2025

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Balance Sheets

	September 30,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 5,120,264	$ 149,456
Restricted cash	8,237,002	—
Prepaid expenses and other current assets	470,615	1,206,409
Incentive tax receivable	514,845	762,078
Total current assets	14,342,726	2,117,943
Property and equipment, net	10,906	20,523
Operating lease right-of-use asset	43,775	123,417
Deferred offering costs	—	15,000
Other assets	487,151	494,147
Total assets	$ 14,884,558	$ 2,771,030
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,942,331	$ 2,183,416
Accrued expenses and other current liabilities	1,108,075	942,489
Current portion of operating lease liability	46,573	84,291
Total current liabilities	4,096,979	3,210,196
Operating lease liability, net of current portion	—	46,573
Total liabilities	4,096,979	3,256,769
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value: 5,000,000 shares authorized; 7,500 and no shares issued and outstanding at September 30, 2025 and 2024, respectively (Liquidation value of $7,601,250 as of September 30, 2025)	1	—
Common stock, $0.0001 par value: 125,000,000 shares authorized; 7,077,352 and 650,284 issued and outstanding at September 30, 2025 and 2024, respectively	708	65
Additional paid-in capital	144,479,342	117,195,181
Accumulated deficit	(133,692,472)	(117,680,985)
Total stockholders' equity (deficit)	10,787,579	(485,739)
Total liabilities and stockholders' equity (deficit)	$ 14,884,558	$ 2,771,030

See accompanying notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations

	Years ended September 30,	
	2025	**2024**
Collaboration revenue	$ 1,000,000	$ 18,626
Operating expenses:		
Research and development	8,355,304	5,737,252
General and administrative	8,488,811	6,130,845
Total operating expenses	16,844,115	11,868,097
Loss from operations	(15,844,115)	(11,849,471)
Foreign exchange (loss) gain	(112,985)	84,293
Other income	720,102	4,327,946
Amortization of debt discount	(556,089)	—
Loss before provision for income taxes	(15,793,087)	(7,437,232)
Provision for income taxes	(218,400)	—
Net loss	(16,011,487)	(7,437,232)
Accrual of cumulative dividends on Series 5 convertible preferred stock	(101,250)	—
Net loss attributable to common stockholders	$ (16,112,737)	$ (7,437,232)
Per share information:		
Net loss per share, basic and diluted	$ (3.95)	$ (11.35)
Weighted average shares outstanding, basic and diluted	4,081,296	655,240

See accompanying notes to consolidated financial statements

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

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount	Shares	Amount			
Balance at October 1, 2023	—	$ —	218,786	$ 22	$ 110,017,751	$ (110,243,753)	$ (225,980)
Sale of common stock, net of issuance costs	—	—	167,987	17	3,976,365	—	3,976,382
Retirement of shares in connection with reverse stock split	—	—	(190)	—	—	—	—
Issuance of common stock on vesting of restricted stock units and restricted stock awards	—	—	976	—	—	—	—
Net share settlement of warrants	—	—	94,288	9	(9)	—	—
Exercise and modification of warrants, net of issuance costs	—	—	168,437	17	2,969,884	—	2,969,901
Share-based compensation	—	—	—	—	231,190	—	231,190
Net loss	—	—	—	—	—	(7,437,232)	(7,437,232)
Balance at September 30, 2024	—	—	650,284	65	117,195,181	(117,680,985)	(485,739)
Sale of common stock, net of issuance costs	—	—	1,203,520	120	7,806,377	—	7,806,497
Retirement of shares in connection with reverse stock split	—	—	(373)	—	—	—	—
Shares released from abeyance	—	—	187,500	19	(19)	—	—
Issuance of common stock on vesting of restricted stock units and restricted stock awards	—	—	17,152	2	(2)	—	—
Sale of warrants in connection with convertible notes, net of issuance costs	—	—	—	—	578,874	—	578,874
Net share settlement of warrants	—	—	1,209	—	—	—	—
Exercise of warrants	—	—	5,018,060	502	11,199,337	—	11,199,839
Sale of preferred stock, net of issuance costs	5,500	1	—	—	5,499,999	—	5,500,000
Conversion of convertible notes into preferred stock	2,000	—	—	—	2,000,000	—	2,000,000
Share-based compensation	—	—	—	—	199,595	—	199,595
Net loss	—	—	—	—	—	(16,011,487)	(16,011,487)
Balance at September 30, 2025	7,500	$ 1	7,077,352	$ 708	$ 144,479,342	$ (133,692,472)	$ 10,787,579

See accompanying notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Cash Flows

	Years ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (16,011,487)	$ (7,437,232)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	114,399	12,000
Depreciation	9,617	12,843
Amortization of operating lease right-of-use asset	79,642	70,272
Share-based compensation	199,595	231,190
Financing costs related to ChEF Purchase Agreement	520,200	370,426
Non-cash financing costs	3,044	1,732
Amortization of debt discount	556,089	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	735,794	470,987
Incentive tax receivable	247,233	24,496
Other assets	6,996	(79,941)
Accounts payable	630,384	48,423
Accrued expenses and other current liabilities	165,586	(2,241,246)
Deferred income	—	(18,626)
Operating lease liability	(84,291)	(73,047)
Net cash used in operating activities	(12,827,199)	(8,607,723)
Cash flows from investing activities:		
Purchases of in-process research and development	(12,000)	(12,000)
Net cash used in investing activities	(12,000)	(12,000)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	7,803,453	3,896,577
Proceeds from sale of preferred stock and warrants, net of issuance costs	5,500,000	—
Proceeds from issuance of convertible notes and warrants, net of issuance costs	2,022,785	—
Payment of deferred offering costs	—	(15,000)
Payment of financing costs related to ChEF Purchase Agreement	(465,200)	(370,426)
Proceeds from exercise of warrants, net of issuance costs	11,185,971	2,983,769
Net cash provided by financing activities	26,047,009	6,494,920
Net increase (decrease) in cash, cash equivalents and restricted cash	13,207,810	(2,124,803)
Cash, cash equivalents and restricted cash at beginning of year	149,456	2,274,259
Cash, cash equivalents and restricted cash at end of year	$ 13,357,266	$ 149,456
Cash and cash equivalents	$ 5,120,264	$ 149,456
Restricted cash	8,237,002	—
Total cash, cash equivalents and restricted cash	$ 13,357,266	$ 149,456
Supplemental disclosure of non-cash operating, investing and financing activities:		
Conversion of convertible notes into preferred stock	$ 1,443,911	$ —
Net settlement of warrants	$ —	$ 9
ChEF Purchase Agreement financing costs in accounts payable	$ 40,000	$ —
In-process research and development in accounts payable	$ 102,399	$ —
Warrant issuance costs in accounts payable	$ —	$ 13,868

See accompanying 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 designed the F_HAB 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, soft tissue sarcoma, colorectal cancer, and breast cancer. In March 2022, the U.S. Food and Drug Administration (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 and published the final results of that study in February 2024. Interim safety, tolerability, and efficacy data from the SB101 study was most recently reported in March 2025, following successful completion of dose escalation in December 2024.

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 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 have provided SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and proof-of-concept ("POC") 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 a maximum tolerated dose ("MTD") of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group. Since the highest dose has been well tolerated, the Safety Review Committee recommended adding a seventh cohort using a maintenance dose that was 25% higher to study its safety and effect before proceeding to the randomized Phase 2a portion in patients with PROC at one of the two highest doses. 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 POC. Interim safety, tolerability, and efficacy data from the SB221 study was most recently reported in April 2025, following completion of the initial dose escalation series.

In January 2025, Sonnet announced an expansion of its Phase 1 SB101 clinical study of SON-1010 to add a new cohort to evaluate its effect in combination with trabectedin (Yondelis®), following the successful completion of monotherapy dose escalation. Trabectedin is an alkylating DNA-binding agent that was approved in the U.S. as a second-line treatment in early 2024 for patients with undetectable, metastatic liposarcoma or leiomyosarcoma who have received a prior anthracycline-containing regimen. It is also known to activate tumor macrophages toward a pro-inflammatory phenotype. The Company believes that SON-1010 has the potential to complement that activity by activating the NK and T cells in the TME to secrete more interferon-gamma (IFNγ), which is considered to be important for anti-tumor control. The initial safety and tolerability of this approach was reported in March 2025 and top line data is expected by the end of calendar 2025. This cohort is also fully enrolled, bringing the total number of people exposed to SON-1010 to 99 to date, including 45 with soft tissue sarcoma and 30 with PROC. Partial responses have been seen in both indications at the highest dose.

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 (SB211) 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. The objective was to consider completing the Phase 2 study, pending the outcome of any partnering activity; given the business priorities at the time, the SB211 study was put on hold. On October 8, 2024, the Company entered into a License Agreement (the "Alkem Agreement") with Alkem Laboratories Limited ("Alkem") to develop and commercialize SON-080 for DPN in India initially, and potentially CIPN as well as autonomic neuropathy. Alkem will conduct all clinical trials that it believes appropriate to obtain regulatory approval in India for SON-080 for the treatment of DPN.

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 and pancreatic cancer. In February 2023, Sonnet announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. In August 2024, the Company entered into a Master Clinical Collaboration Agreement (the "SOC Agreement") with the Sarcoma Oncology Center ("SOC") to advance the development of SON-1210. An Innovative Immuno Oncology Consortium ("IIOC") that is funded by the SOC will conduct an investigator-initiated Phase 1b/2a study of SON-1210 in pancreatic cancer. The IIOC submitted a pre-IND package to the FDA in November 2024. Based on the FDA feedback, preparations for the full IND submission package are underway.

SON-1411 (IL18-F_HAB-IL12) is a bifunctional combination of human Interleukin 18 ("IL-18"), which was modified to resist the inhibitory binding interaction with the IL-18 binding protein, and single-chain human IL-12 for solid tumor cancers. Cell line development and titer/bioactivity assessments are underway. The SON-1411 development program has been re-engaged with a focus on cell line development and *in vivo* evaluation in an appropriate humanized mouse model.

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.

Business combination

On July 11, 2025, the Company entered into a definitive Business Combination Agreement (as amended on September 22, 2025, the "BCA") with Rorschach I LLC ("Rorschach"), Hyperliquid Strategies Inc. ("HSI"), TBS Merger Sub Inc., and Rorschach Merger Sub, LLC, pursuant to which, subject to the terms and conditions contained in the BCA, Rorschach Merger Sub, LLC, will merge with and into Rorschach with Rorschach surviving as a direct wholly owned subsidiary of HSI and TBS Merger Sub Inc. will merge with and into Sonnet, with Sonnet surviving as a direct wholly owned subsidiary of HSI. Following the closing, the Company will operate as a wholly owned subsidiary of HSI and will continue to focus on the development of its existing biotech assets, including SON-1010, while disposing of other assets. The transaction was subject to customary closing conditions, including approval by the Company's stockholders, and closed on December 2, 2025. In connection with the transaction, legacy Sonnet stockholders and certain other equity holders of record will receive contingent value rights ("CVRs") tied to the potential future value of the Company's biotech assets. See Note 11 for additional details.

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 and cash equivalents at September 30, 2025 of $5.1 million will fund the Company's projected operations into February 2026. 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. However, substantial doubt about the Company's ability to continue as a going concern exists. The 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 or debt financings, including sales pursuant to its ChEF Purchase Agreement (the "Purchase Agreement") with Chardan Capital Markets, LLC ("Chardan"), related to a "ChEF," Chardan's committed equity facility (the "Facility"); partnerships; collaborations; or other sources to carry out the Company's planned development activities. In addition, the Company has completed the merger transactions contemplated by the BCA, pursuant to which the Company will operate as a wholly owned subsidiary of HSI and continue to focus on the development of its existing biotech assets. 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 and clinical first in human ("FIH") 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, 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. Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in deciding how to allocate resources and assess performance.

The Company's Interim Chief Executive Officer ("CEO"), as the CODM, manages the Company's business activities as a single operating and reportable segment at the consolidated level. The accounting policies of the Company's segment are the same as those described in the summary of significant accounting policies. To date, the Company has not generated any product revenue and expects to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seeks regulatory approval. Accordingly, the CODM uses forecast models in deciding how to invest into the segment. Such forecast models are reviewed to assess the Company's operating results and performance. The CODM is regularly provided with operating expenses and cash balances, which are reported on the consolidated statements of operations and consolidated balance sheets, respectively.

e. Fair value of financial instruments

The Company measures and records certain financial assets and liabilities at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. U.S. GAAP provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority, referred to as Level 1, to quoted prices in active markets for identical assets and liabilities. The next priority, referred to as Level 2, is given to quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active; that is, markets in which there are few transactions for the asset or liability. The lowest priority, referred to as Level 3, is given to unobservable inputs. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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

f. Cash and cash equivalents

The Company considers highly-liquid investments with original maturities of three months or less to be cash equivalents. The Company holds cash in highly-liquid bank accounts and invests excess cash in money market funds.

g. Restricted cash

The Company maintains certain cash balances that are restricted as to withdrawal or use. In accordance with the BCA, any cash proceeds in excess of $3.0 million received from the exercise of warrants may not be spent by the Company without the prior written consent of Rorschach.

h. 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.

i. 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, 2025 and 2024.

j. 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, 2024, the Company had $15,000 in deferred offering costs associated with a shelf registration statement. There were no deferred offering costs as of September 30, 2025.

k. 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 September 30, 2025 and 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 and $0.8 million, respectively. In November 2024, the Company received a cash refund of $0.7 million, with the $0.1 million difference attributable to a change in foreign exchange rates. For the years ended September 30, 2025 and 2024, $0.5 million and $0.8 million, respectively, for the expected net cash refund related to the tax incentive program was included in research and development expenses.

l. Derivative liability

The Company evaluates all features contained in financing agreements to determine if there are any embedded derivatives that require separate accounting from the underlying agreement. An embedded derivative that requires separation is accounted for as a separate asset or liability from the host agreement. The derivative asset or liability is accounted for at fair value, with changes in fair value recognized in the consolidated statement of operations. The Company determined that certain features under the convertible notes and the ChEF Purchase Agreement (see Note 7) qualified as embedded derivatives. The derivative liability associated with the convertible notes was deemed de minimis at the issuance date. The related notes were subsequently converted into preferred stock and are no longer outstanding as of September 30, 2025. The derivative liability associated with the ChEF Purchase Agreement is accounted for separately at fair value, which has been deemed de minimis.

m. 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. In October 2024, the Company entered into the Alkem Agreement. See Note 6 for further discussion of these agreements.

n. 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.

o. 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.

p. Share-based compensation

The Company measures equity classified share-based awards granted to employees and non-employees 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.

q. 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 $0.7 million and $4.3 million during the years ended September 30, 2025 and 2024, respectively, from the sale of New Jersey state net operating losses through the Program, which is included in other income in the consolidated statements of operations.

r. 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.

s. 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 year ended September 30, 2024 are the pre-funded October 2023 warrants to purchase 99,687 shares of common stock with an exercise price of $0.0008 per share and warrants exercised through the June 2024 inducement offer for 187,500 shares of common stock that were being held in abeyance as of September 30, 2024.

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,	
	2025	**2024**
Common stock warrants August 2021	14,031	14,031
Underwriter warrants August 2021	284	284
Chanticleer warrants	6	6
Series C warrants	2,297	2,297
Series 3 warrants	1,566	1,566
Unvested restricted stock units and awards	120,000	17,152
Common stock warrants February 2023	31,563	33,982
Underwriter warrants February 2023	1,933	1,933
Common stock private placement warrants June 2023	28,409	28,409
Placement agent warrants June 2023	852	852
Common stock warrants October 2023	354,994	354,994
Underwriter warrants October 2023	10,664	10,664
Placement agent warrants June 2024	14,142	14,142
Common stock warrants June 2024	623,125	703,125
Common stock warrants November 2024	611,110	—
Common stock PIPE warrants December 2024	350,000	—
Common stock warrants July 2025	865,052	—
Common stock PIPE warrants July 2025	8,800,000	—
Common stock warrants July 2025	3,200,000	—
	15,030,028	1,183,437

t. 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, primarily requires enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 was 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. The Company adopted the guidance in ASU 2023-07 on January 1, 2024, and it is being applied retrospectively to its consolidated financial statement 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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the consolidated statement of operations. The guidance in this ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the consolidated financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 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:

	September 30,	
	2025	**2024**
Compensation and benefits	$ 150,488	$ 149,802
Research and development	598,421	617,545
Professional fees	357,620	173,319
Other	1,546	1,823
	$ 1,108,075	$ 942,489

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 was 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, 2025 and 2024 are as follows:

Lease expense	**2025**	**2024**
Operating lease expense	$ 90,837	$ 90,837
Variable lease expense	3,285	1,472
Total lease cost	$ 94,122	$ 92,309

At September 30, 2025, the weighted average remaining lease term was 0.5 years and the weighted average discount rate was 12%.

Cash flow information related to operating leases for the years ended September 30, 2025 and 2024 is as follows:

Cash paid for amounts included in the measurement of lease liabilities:	**2025**	**2024**
Operating cash flows from operating leases	$ 95,487	$ 93,614

Future minimum lease payments under non-cancellable leases at September 30, 2025 are as follows:

Fiscal year	
2026	$ 48,216
Total undiscounted lease payments	48,216
Less: imputed interest	(1,643)
Total lease liabilities	$ 46,573

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. No license fees were incurred during the years ended September 30, 2025 and 2024.

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. Additionally, the Company will pay ARES a percentage of all revenue received through sublicensing the IL-6 compound, including revenue from any upfront, milestone, royalty, maintenance and similar payments, net of certain full time equivalent ("FTE") costs incurred by the Company pursuant to such sublicense. The percentage rate owed to ARES on sublicense revenue decreases depending on the point in time of execution of the relevant sublicense agreement and the development progress accomplished by the Company to that point in time. The upfront cash payments received by the Company pursuant to the New Life Agreement (see Note 6) were specifically excluded from the scope of the amended ARES License Agreement. The Company owes ARES $0.1 million in license fees related to sublicense revenue received pursuant to the Alkem Agreement (see Note 6), which is included in research and development expenses in the consolidated statement of operations for the year ended September 30, 2025. No license fees were incurred during the years ended September 30, 2025 and 2024.

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. No license fees were incurred during the years ended September 30, 2025 and 2024.

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 of the licensed cell line. 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 or extend the cell line storage fee of $12,000. The Company incurred $12,000 in license fees during each of the years ended September 30, 2025 and 2024, which were recorded as acquired in-process research and development and included in research and development expenses in the consolidated statements of operations. The Company cancelled the Brink Agreement effective November 1, 2025, and there are no remaining obligations with respect to this license.

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, 2025). In July 2025, the Company exercised its first option to extend the InvivoGen Agreement for an additional three-year term, extending the agreement through February 2028. In connection with the extension, the Company incurred $0.1 million in license fees during the year ended September 30, 2025, which was recorded as acquired in-process research and development and included in research and development expenses in the consolidated statements of operations. No license fees were incurred during the year ended September 30, 2024.

In May 2025, 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 is obligated to make contingent milestone payments to ProteoNic of €0.2 million (approximately $0.2 million as of September 30, 2025) upon the initial submission of an IND or clinical trial application to a regulatory authority for each distinct product. No license fees were incurred during the year ended September 30, 2025.

Collaboration agreement

In August 2024, the Company entered into the SOC Agreement to advance the development of SON-1210 (see Note 1). An IIOC that is funded by the SOC will conduct an investigator-initiated Phase 1b/2a study of SON-1210 in pancreatic cancer. The Company will provide the study drug and provide support services for the study. If the Company establishes a partnership with a third party prior to the initiation of the initial efficacy combination trial under this collaboration, the Company will incur, payable to the SOC, a one-time fee equal to the greater of 5% or $1.5 million from the first upfront payment received from such third party partnership.

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. 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, of which $0.3 million of evaluation milestones have been previously recognized. No milestones were achieved and no license fees were incurred during the years ended September 30, 2025 and 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.

6. Collaboration Revenue

New Life Agreement

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 DPN in humans (the "DPN Field") in Malaysia, Singapore, Indonesia, Thailand, Philippines, Vietnam, Brunei, Myanmar, Lao PDR and Cambodia (the "Exclusive Territory"). New Life paid the Company an aggregate of $1.0 million in non-refundable upfront cash payments in connection with the execution of the New Life Agreement. The related collaboration revenue was fully recognized by December 31, 2023, as the Company had completed its performance obligations under the New Life Agreement. In December 2024, New Life informed the Company that it has elected to move its business in a different direction and provided the Company with written notice of its intention to exercise its Give Back Option, which is the right to give back the rights with respect to Products in the DPN Field in one or more countries in the Exclusive Territory. The exercise of the Give Back Option is subject to the negotiation and mutual agreement of terms between the Company and New Life.

Alkem Agreement

Under the Alkem Agreement entered into on October 8, 2024 (see Note 1), the Company granted Alkem an exclusive license (with the right to sublicense) to research, develop, manufacture, import, export, market, use and commercialize pharmaceutical products containing its IL-6 (SON-080) asset (or any derivatives, fragments or conjugates thereof) (the "Compounds") (such products, the "Products") for the treatment of DPN (the "DPN Field") and to manufacture, import, export, market, use and commercialize Products for the treatment of CIPN and autonomic neuropathy (together with the DPN Field, the "Fields") in India. Except as provided for in the Alkem Agreement, the Company agreed not to develop, use, sell, offer or otherwise commercialize any Compounds or Products for use in the DPN Field in India during the term of the Alkem Agreement. The Company retains all rights to manufacture Compounds and Products anywhere in the world. The Company and Alkem will enter into a follow-on supply agreement pursuant to which the Company will manufacture for Alkem Compounds and Products for post-Phase 2 clinical development and commercialization 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 India. Alkem will own and maintain all regulatory filings and approvals for Products in India. Upon payment of a Clinical Data Access Fee (as defined in the Alkem Agreement), the Company will have rights to access and use the data generated by the clinical trials conducted in connection with the Alkem Agreement. Under the terms of the Alkem Agreement, Alkem paid the Company $1.0 million in upfront payments and will pay up to an additional $1.0 million in milestone payments. Additionally, the Company is entitled to receive a royalty equal to a percentage in the low double digits of the net sales of the Product upon commercialization of SON-080 in India, less certain expenses as set forth in the Alkem Agreement.

Revenue recognition

The Company first assessed the Alkem Agreement under ASC 808, *Collaborative Arrangements* ("ASC 808"), to determine whether the Alkem Agreement or units of accounts within the Alkem 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 Alkem.

In accordance with this guidance, the Company identified the following obligations under the Alkem arrangement: (i) License to research, develop, market, import, use and commercialize the Product in the DPN field in India (the "License"); and (ii) supply of Compound for a Phase 2 clinical trial ("Supply"). The future supply agreement for post-Phase 2 clinical development represents an optional purchase, which will be accounted for as a separate contract, and the Company did not identify any material right to be present. The Company determined that the License and Supply 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 related to the Alkem Agreement was recognized at the point-in-time at which the Company transferred the License and Supply to Alkem. Collaboration revenue from the single performance obligation related to the New Life Agreement was recognized over the estimated performance of the research and development activities. The Company recognized $1.0 million and $18,626 of collaboration revenue for the years ended September 30, 2025 and 2024, respectively.

7. Stockholders' Equity (Deficit)

October 2023 underwritten public offering

On October 26, 2023, the Company 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 its 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 710,931 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 $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 offer, 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 $0.0008 per share of common stock. All of the pre-funded warrants have been exercised as of September 30, 2025. 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 $16.00 per share and expire five years from the date of issuance.

Committed equity facility

On May 2, 2024, the Company entered into the Purchase Agreement and a Registration Rights Agreement (the "Registration Rights Agreement"), each with Chardan, related to a "ChEF," Chardan's committed equity facility, or the Facility (see Note 1). Pursuant to the Purchase Agreement, the Company has the right from time to time at its option to sell to Chardan up to $25.0 million in aggregate gross purchase price of newly issued shares of the Company's common stock, of which $24.7 million is available to be sold as of September 30, 2025. 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. Due to certain pricing and settlement provisions, the Purchase Agreement qualifies as a standby equity purchase agreement and includes an embedded put option and an embedded forward contract. The Company accounts for the embedded features in the Purchase Agreement as derivatives measured at fair value, with changes in fair value recognized in the consolidated statement of operations. The derivatives associated with the Purchase Agreement have been deemed de minimis. The Company sold 153,020 and 4,706 shares of common stock, respectively, pursuant to the Purchase Agreement for net proceeds of approximately $0.2 million and $0.1 million, respectively, during the years ended September 30, 2025 and 2024. The Company incurred $0.5 million and $0.4 million, respectively, of costs in connection with the Purchase Agreement during the years ended September 30, 2025 and 2024, which are included in general and administrative expenses in the consolidated statement of operations.

November 2024 underwritten public offering

On November 7, 2024, the Company closed a public offering of common stock and certain warrants through Chardan, as underwriter, for net proceeds of $4.2 million through the issuance and sale of 155,000 shares of its common stock, pre-funded warrants to purchase up to 956,111 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 2,222,222 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 $4.50 and the public offering price of each pre-funded warrant and accompanying common warrant was $4.4999. The common warrants were immediately exercisable at a price of $4.50 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision. 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. All of the pre-funded warrants and 1,611,112 of the common warrants have been exercised as of September 30, 2025.

December 2024 registered direct and PIPE offering

On December 10, 2024, the Company closed a registered direct offering with institutional investors for the issuance and sale of 768,000 shares of its common stock, pre-funded warrants to purchase up to 317,325 shares of common stock, and accompanying warrants to purchase up to an aggregate of 1,085,325 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 offering price of each share of common stock and accompanying common warrant was $2.23 and the offering price of each pre-funded warrant and accompanying common warrant was $2.2299, priced at-the-market under the rules of the Nasdaq Stock Market. The registered direct warrants were immediately exercisable at a price of $2.10 per share, expire five years from the date of issuance and contain an alternative cashless exercise provision. 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. All of the pre-funded and common warrants have been exercised as of September 30, 2025.

The Company closed a concurrent private placement with an existing investor for the issuance and sale of 127,500 shares of its common stock, pre-funded warrants to purchase up to 545,500 shares of common stock, and accompanying warrants to purchase up to an aggregate 673,000 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold in the private placement ("PIPE") together with a common warrant to purchase one share of common stock. The PIPE offering price of each share of common stock and accompanying common warrant was $2.23 and the PIPE offering price of each pre-funded warrant and accompanying common warrant was $2.2299, priced at-the-market under the rules of the Nasdaq Stock Market. The PIPE warrants were immediately exercisable at a price of $2.10 per share, expire five years from the date of issuance and contain an alternative cashless exercise provision. 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. All of the pre-funded warrants and 323,000 of the common warrants have been exercised as of September 30, 2025.

The Company raised net proceeds of $3.4 million from the registered direct and PIPE offerings.

Convertible note and warrant private placements

In July 2025, the Company completed a private placement of zero-interest convertible notes, raising an aggregate of $2.0 million in principal. The notes were scheduled to mature on June 30, 2026, and were convertible at any time into an aggregate of up to 1,730,104 shares of common stock at a fixed price of $1.156 per share. If, at any time while the convertible notes remained outstanding, the Company issued shares of common stock or common stock equivalents in an offering for gross proceeds of at least $5.0 million (a "Subsequent Issuance"), the entire unpaid principal amount of the convertible notes would convert automatically into the same securities issued pursuant to the Subsequent Issuance. In connection with the notes, investors also received five-year warrants to purchase an aggregate of 865,052 shares of common stock at the same $1.156 exercise price, providing $0.1 million in additional cash proceeds.

The Company raised $2.0 million in net cash proceeds from the convertible note and warrant private placements. The Company analyzed the convertible notes and identified certain features that require bifurcation from the host and accounting as derivatives measured at fair value, with changes in fair value recognized in the consolidated statement of operations. The derivatives associated with the convertible notes have been deemed de minimis. However, as the convertible notes were issued with warrants, the net proceeds from the issuance were allocated to the convertible notes and the warrants based on their relative fair values, resulting in an allocation of $1.4 million to the convertible notes and $0.6 million to the warrants. The Company recorded a debt discount of approximately $0.6 million for the difference between the face value of the convertible notes and the amount allocated to the debt at the issuance date. These notes were subsequently converted into shares of non-voting convertible preferred stock and warrants in connection with the preferred stock private placement described below, and the remaining unamortized debt discount was expensed in full.

The fair value of the warrants at the issuance date was determined using a Black-Scholes option pricing model, which includes the use of Level 3 inputs. The Company estimates its stock price volatility using the historical volatility of publicly traded peer companies. The term is equal to the contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for the time period equal to the term of the warrants. The expected dividend yield is zero based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. Assumptions used in calculating the fair value of the warrants at the issuance date include the following:

Stock price per share	$	1.21
Term (years)		5.00
Expected volatility		99.84%
Dividend yield		—%
Risk-free interest rate		3.84%

The Company's Chief Medical Officer, Dr. Richard Kenney, participated in the private placement and purchased notes for a principal amount of $0.2 million and warrants to purchase up to an aggregate of 86,505 shares of common stock. As described below, Dr. Kenney's notes converted into shares of non-voting convertible preferred stock, which are convertible into an aggregate of 160,000 shares of common stock and warrants to purchase up to an aggregate of 320,000 shares of common stock.

Preferred stock and warrant private placements

Concurrently with the signing of the BCA, the Company raised an aggregate of $5.5 million in a private placement to accredited investors through the issuance and sale of an aggregate of 5,500 shares of non-voting Series 5 convertible preferred stock, convertible into up to an aggregate of 4,400,000 shares of common stock, and five-year warrants to purchase up to an aggregate of 8,800,000 shares of common stock at an exercise price of $1.25 per share. At the closing of the PIPE, the $2.0 million principal amount of convertible notes issued in July 2025 automatically converted into 2,000 shares of convertible preferred stock and the investors received additional warrants to purchase up to an aggregate of 3,200,000 shares of common stock on the same terms as the PIPE investors.

The significant rights and preferences of the Company's Series 5 convertible preferred stock are as follows:

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series 5 convertible preferred stock are entitled to receive, prior and in preference to any distribution to holders of junior securities (including common stock) and pari passu with any designated parity preferred, an amount per share equal to the stated value of $1,000 plus all unpaid, accrued and accumulated preferential dividends (whether or not declared). If the assets available for distribution are insufficient to pay the full amounts due, distributions to Series 5 holders will be made ratably based on the aggregate amounts otherwise payable.

Conversion

Each share of Series 5 preferred stock is convertible, at the option of the holder at any time, into a number of shares of common stock equal to (i) the stated value plus all unpaid, accrued and accumulated preferential dividends, divided by (ii) the conversion price. The initial conversion price is $1.25 per share, subject to adjustment for standard structural events (e.g., stock splits, stock dividends, combinations, and reclassifications), but there is no price-based anti-dilution adjustment. Conversions are subject to a beneficial ownership limitation (generally 4.99%, or 9.99% if elected, subject to notice-based increases up to but not exceeding applicable exchange limits) and to an exchange cap until required stockholder approval is obtained. Immediately prior to the closing of the transactions contemplated by the BCA, each outstanding share of Series 5 convertible preferred stock will automatically convert at the then-applicable conversion rate. No fractional shares will be issued upon conversion; the Company will round or make a customary cash adjustment consistent with the Certificate of Designation.

Voting

Holders of Series 5 convertible preferred stock have no general voting rights. A separate class vote of the holders of a majority of the outstanding Series 5 convertible preferred stock is required to approve specified actions, including (among others) altering or changing the powers, preferences, or rights of the Series 5 convertible preferred stock; authorizing or issuing any class or series ranking senior to or pari passu with the Series 5 convertible preferred stock as to dividends, redemption, or liquidation; increasing authorized shares of preferred stock; or certain distributions and redemptions.

Redemption rights

The Series 5 convertible preferred stock is not mandatorily redeemable at a fixed date, is not redeemable at the option of the holders, and is not redeemable upon events outside the Company’s control. The instrument provides only a liquidation preference payable upon an actual liquidation, dissolution, or winding up, and addresses mergers and similar transactions through conversion and Fundamental Transaction provisions rather than redemption.

Dividends

Dividends on the Series 5 convertible preferred stock are cumulative at 6.0% per annum of the stated value, payable quarterly in arrears. At the Company’s election and subject to applicable limitations, dividends may be paid in cash, in shares of common stock, or by accruing and compounding into the stated value. Unpaid, accrued and accumulated dividends are included in the conversion and liquidation preference calculations as described above.

Common stock warrants

As of September 30, 2025, the following equity-classified warrants and related terms were outstanding:

	Warrants Outstanding	Exercise Price	Expiration Date
Common stock warrants August 2021	14,031	$ 2,094.40	August 24, 2026
Underwriter warrants August 2021	284	$ 2,618	August 19, 2026
Chanticleer warrants	6	$ 144,144.00 - $224,224.00	April 30, 2027 - December 17, 2028
Series C warrants	2,297	$ 7,860.16	October 16, 2025
Series 3 warrants	1,566	$ 717.024	August 15, 2027
Common stock warrants February 2023	31,563	$ 190.08	February 10, 2028
Underwriter warrants February 2023	1,933	$ 237.60	February 8, 2028
Common stock private placement warrants June 2023	28,409	$ 12.4000	June 21, 2029
Placement agent warrants June 2023	852	$ 118.7824	December 30, 2026
Common stock warrants October 2023	354,994	$ 9.6000	October 27, 2028
Underwriter warrants October 2023	10,664	$ 16.0000	October 24, 2028
Placement agent warrants June 2024	14,142	$ 14.8800	June 19, 2029
Common stock warrants June 2024	623,125	$ 12.4000	June 21, 2029
Common stock warrants November 2024	611,110	$ 4.5000	November 7, 2029
Common stock PIPE warrants December 2024	350,000	$ 2.1000	December 9, 2029
Common stock warrants July 2025	865,052	$ 1.1560	June 30, 2030
Common stock PIPE warrants July 2025	8,800,000	$ 1.2500	July 14, 2030
Common stock warrants July 2025	3,200,000	$ 1.2500	July 14, 2030
Total	14,910,028		

During the year ended September 30, 2025, 2,419 warrants were net share settled, resulting in the issuance of 1,209 shares of common stock, and 5,018,060 warrants were exercised on a cash basis, resulting in proceeds of $11.2 million. In accordance with the BCA, any cash proceeds in excess of $3.0 million received from the exercise of warrants may not be spent by the Company without the prior written consent of Rorschach.

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 $12.80 per share to purchase up to an aggregate of 353,562 shares of the Company's common stock at a reduced exercise price of $9.60 per share. The transaction closed on June 21, 2024, resulting in net proceeds of the Company of $2.9 million. Due to beneficial ownership limitations, 187,500 shares of common stock related to the exercise of warrants in this transaction were initially held in abeyance. All 187,500 shares of common stock were released from abeyance during the year ended September 30, 2025. 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 703,125 shares of common stock, (ii) reduced the exercise price of existing warrants to purchase 354.994 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 $118.78 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 were 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 were immediately exercisable at a price of $14.88 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 was 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 year ended September 30, 2024, an aggregate of 96,090 warrants were net share settled, resulting in the issuance of 94,288 shares of common stock, 355,937 warrants were exercised on a cash basis (including 187,500 warrants for which the related shares were held in abeyance as of September 30, 2024 due to beneficial ownership limitations), resulting in proceeds of $3.0 million, and 4,302 warrants were abandoned by the warrant holder.

8. Share-Based Compensation

In April 2020, the Company adopted the 2020 Omnibus Equity Incentive Plan (the "Plan"). There were 302 shares available for issuance under the Plan as of September 30, 2025. 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 July 9, 2025, 120,000 restricted stock units ("RSUs") were granted, 100% of which vest on January 8, 2026. On January 1, 2024, 9,175 RSUs and 7,977 restricted stock awards ("RSAs") were granted, 100% of which vested 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 consolidated statements of operations as follows:

	Years ended September 30,	
	2025	**2024**
Research and development	$ 66,896	$ 109,356
General and administrative	132,699	121,834
	$ 199,595	$ 231,190

The following table summarizes RSU activity under the Plan:

	RSU	Weighted Average Grant Date Fair Value
Unvested balance at October 1, 2023	288	$ 174.26
Granted	9,175	$ 14.08
Vested	(288)	$ 174.26
Forfeited	—	$ —
Unvested balance at September 30, 2024	9,175	$ 14.08
Granted	120,000	$ 4.64
Vested	(9,175)	$ 14.08
Forfeited	—	$ —
Unvested balance at September 30, 2025	120,000	$ 4.64

As of September 30, 2025, total unrecognized compensation expense relating to unvested RSUs granted was $0.4 million, which is expected to be recognized over a weighted-average period of 0.3 years.

The following table summarizes RSA activity under the Plan:

	RSA	Weighted Average Grant Date Fair Value
Unvested balance at October 1, 2023	688	$ 226.16
Granted	7,977	$ 14.08
Vested	(688)	$ 226.16
Unvested balance at September 30, 2024	7,977	$ 14.08
Granted	—	$ —
Vested	(7,977)	$ 14.08
Unvested balance at September 30, 2025	—	$ —

During the years ended September 30, 2025 and 2024, there were no RSAs forfeited. As of September 30, 2025, there was no unrecognized compensation expense relating to unvested RSAs granted.

9. Income Taxes

As of September 30, 2025, the Company had $117.9 million, $26.7 million and $16.0 million of federal, state and foreign net operating losses, respectively. The federal net operating losses will begin to expire in 2030, the state net operating losses will begin to expire in 2039 and the foreign net operating losses begin to expire in 2027. As of September 30, 2025, the Company has federal and state research and development tax credit carryforwards of $2.4 million and $0.4 million available to reduce future tax liabilities which will begin to expire in 2035 and 2032, 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, 2025 and 2024. The valuation allowance increased $3.2 million during the year ended September 30, 2025 and decreased $0.6 million during the year ended September 30, 2024.

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,	
	2025	**2024**
Deferred tax assets:		
Net operating loss carryforwards	$ 29,195,207	$ 26,754,767
Research and development credit carryforwards	2,789,965	3,129,222
Amortization	6,620,882	5,791,883
Share-based compensation	39,130	19,357
Operating lease liability	13,092	36,786
Accrued expenses and other	24,327	26,977
Section 163(j) disallowed interest expense	758,351	761,450
Foreign tax credits	218,400	—
Gross deferred tax assets	39,659,354	36,520,442
Less: valuation allowance	(39,644,696)	(36,480,967)
	14,658	39,475
Deferred tax liabilities:		
Property and equipment	(2,353)	(4,782)
Operating lease right-of-use asset	(12,305)	(34,693)
Net deferred tax assets	$ —	$ —

During the year ended September 30, 2025, the Company sold New Jersey state net operating losses in the amount of $8.1 million and unused New Jersey state research and development tax credits in the amount of $0.1 million, resulting in the recognition of other income of $0.7 million in the consolidated statement of operations. During the year ended September 30, 2024, the Company sold New Jersey state net operating losses in the amount of $49.4 million and unused New Jersey state research and development tax credits in the amount of $0.3 million, resulting in the recognition of other income of $4.4 million in the consolidated statement of operations.

The Company recorded foreign income tax expense of $0.2 million for the year ended September 30, 2025 and no income tax expense for the year ended September 30, 2024. A reconciliation of income tax expense at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements is as follows:

	Years ended September 30,	
	2025	2024
U.S. federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(6.0)	(5.8)
Permanent differences	2.7	2.7
Foreign tax rate differential	—	0.1
Foreign tax credits	(1.4)	—
Foreign withholding taxes	1.4	—
Research and development credit	1.8	(4.6)
Change in valuation allowance	20.0	(8.3)
Sale of state net operating losses and research and development credits	4.1	51.5
Other	(0.2)	(14.6)
Effective income tax rate	1.4%	—%

In August 2022, the U.S. enacted the Inflation Reduction Act of 2022 ("IRA"). The IRA contains a number of tax-related provisions that were 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 various provisions of the IRA did not result in a material impact on the consolidated financial statements.

On July 4, 2025, the U.S. enacted the One Big Beautiful Bill Act (the "Act"), which contains a broad range of tax reform provisions affecting businesses, including extending or reinstating certain provisions of the 2017 Tax Cuts and Jobs Act, tax relief measures, modifications of certain energy tax credits granted under the IRA and limits on various tax deductions, among other key provisions. The Company is currently evaluating the full effects of the Act and does not anticipate a material impact on its consolidated financial statements.

10. Segment Information

The Company has a single reportable segment and allocates resources based on cash resources and operating expense projections. The table below summarizes the significant expense categories regularly reviewed by the CODM:

	Years ended September 30,	
	2025	2024
Research and development:		
Clinical	$ 5,632,217	$ 2,613,188
Non-clinical	2,260,300	3,888,787
Other[(1)]	462,787	(764,723)
Total research and development	8,355,304	5,737,252
General and administrative:		
Payroll and related	1,716,552	715,846
Professional fees	3,695,790	1,922,292
Consulting	1,314,698	1,532,601
Other[(2)]	1,761,771	1,960,106
Total general and administrative	8,488,811	6,130,845
Operating expenses	$ 16,844,115	$ 11,868,097

(1) Other research and development consists primarily of payroll and related expenses and dues, licenses and subscriptions. The balance is negative for the year ended September 30, 2024 due to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023.
(2) Other general and administrative consists primarily of facilities, insurance, filing fees, travel expenses and franchise taxes.

11. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through December 16, 2025, the date at which the consolidated financial statements were available to be issued.

As discussed in Note 1, on December 2, 2025 (the "Closing Date"), the Company completed the business combination (the "Closing") contemplated by the BCA. The common stock of HSI, par value $0.01 per share ("HSI Common Stock") began trading on the Nasdaq Capital Market under the symbol "PURR" on December 3, 2025. The BCA, among other things, provided for (i) the merger of Rorschach Merger Sub with and into Rorschach (the "Rorschach Merger"), with Rorschach surviving the Rorschach Merger as a direct wholly owned subsidiary of HSI, and (ii) immediately following the Rorschach Merger, the merger of Sonnet Merger Sub with and into Sonnet (the "Sonnet Merger" and, together with the Rorschach Merger, the "Mergers" or "Business Combination"), with Sonnet surviving the Sonnet Merger as a direct wholly owned subsidiary of HSI.

In addition, concurrently with the execution of the BCA, certain accredited investors (the "Subscribers") entered into subscription agreements with the Company and HSI (the "Subscription Agreements"), pursuant to which the Company agreed to issue, and the Subscribers agreed to purchase, immediately prior to the Closing, an aggregate of 239,921,355 shares of the Company's common stock at a purchase price of $1.25 per share, pursuant to a private placement in accordance with Section 4(a)(2) of the Securities Act (the "Closing PIPE"). The Closing PIPE was consummated on the Closing Date immediately prior to the Closing and the Company issued 239,921,355 shares of its common stock to the Subscribers pursuant to the Subscription Agreements.

As a result of the Closing, Nasdaq filed a notification of removal from listing and deregistration of the Company's common stock on Form 25 with the SEC on December 2, 2025. After the Form 25 becomes effective, the Company intends to file with the SEC a Form 15 to request deregistration of its common stock under Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and suspension of its reporting obligations under Sections 13 and 15(d) of the Exchange Act.

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

None.

Item 9A. Controls and Procedures.

Conclusions Regarding the Evaluation of Our Disclosure Controls

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure. We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13(a)-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2025, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on tis financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of September 30, 2025.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm because we are a "non-accelerated filer," and may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are accelerated filers, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

Changes in Internal Controls over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) under the Exchange Act) that occurred during the fourth quarter ended September 30, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) None.

(b) During the three months ended September 30, 2025, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

The following table sets forth certain information about our officers and our members of the Board of Directors as of September 30, 2025. Directors are elected to hold office until the next annual meeting of stockholders and until their successors are elected and qualified. As described above, Donald Giffith, Nailesh Bhatt, Albert Dyrness and Lori McNeill resigned and ceased to serve as directors of Sonnet as of the Closing Date.

Directors	Age	Year First Became Director
Raghu Rao	63	2020
Donald Griffith	76	2020
Nailesh Bhatt (1)(2)(3)	53	2020
Albert Dyrness (1)(2)(3)	62	2020
Lori McNeill (1)(3)	53	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 serving as our directors as of September 30, 2025, based on information furnished to the Company by such individuals.

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.

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 served as our Controller, until February 2025 when he became our Chief Financial Officer. 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.

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 of VGYAAN Pharmaceuticals LLC ("VGYAAN"), a company focused on developing and commercializing clinically critical drugs. Mr. Bhatt was also a Board Member of VGYAAN until June 2023. 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 a Board Member of Azurity Pharmaceuticals, Inc., CoreRx Pharma and Spectra Medical Devices. 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.

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 executive officers of the Company as of September 30, 2025:

Executive Officers	Age	Position and Office
Raghu Rao	63	Interim Chief Executive Officer and Director
Donald Griffith	76	Chief Financial Officer and Director
John K. Cini, Ph.D.	73	Chief Scientific Officer
Susan Dexter	69	Chief Technical Officer
Richard Kenney, M.D.	67	Chief Medical Officer
Stephen J, McAndrew, Ph.D.	71	President and Chief Business Officer

Set forth below are brief biographical descriptions of the individuals serving as the Company's executive officers as of September 30, 2025, based on information furnished to the Company by such individuals.

Raghu Rao

See description under Directors.

Donald Griffith, CPA

See description under Directors.

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 audit committee member since 2022. In February 2023, Ms. Dexter 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. In October 2024, Ms. Dexter was appointed to the board of directors of Virica, a Canadian provider of Viral Sensitizer Enhancers for improved productivity of viral vectors used in gene therapy.

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. Dr. Kenney 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.

Stephen J. McAndrew, Ph.D.

Stephen J. McAndrew, Ph.D. has served as the Company's Chief Business Officer since February 2025 and its President since April 2025, and previously its Senior Vice President of Business Development since the Company's Merger in 2020. Prior to the Merger, Dr. McAndrew served as the Senior Vice President of Business Development of Sonnet BioTherapeutics, Inc. ("Prior Sonnet") from February 2020. Before joining Prior Sonnet, Dr. McAndrew served as the Senior Vice President of Business Strategy & Development at Oncobiologics, Inc. from March 2014 to October 2019 and as the Vice President of Business Development from February 2012 to March 2014. Prior to Oncobiologics, Inc., Dr. McAndrew served in various business development roles at several biopharmaceutical companies from 2001 to 2011. From March 1993 to December 2001, Dr. McAndrew also served in various positions of increasing responsibility at Bristol-Myers Squibb Company, including as the Director of Biotechnology Licensing within the External Science and Technology Department. Dr. McAndrew earned his Ph.D. in Molecular and Cellular Biology from Ohio University, an M.S in Molecular Genetics from the State University of New York at Albany and a B.S from the State University of New York at Oswego.

Delinquent Section 16(a) Reports

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 review of copies of Forms 3, 4 and 5 furnished to us, we believe that all of our 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, 2025, except for the following: we filed a Form 4 for Rick Kenney on August 21, 2025 to report the acquisition of (i) warrants on June 30, 2025 and (ii) Series 5 Preferred Stock and warrants on July 14, 2025.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our directors, officers and employees. The purpose of the Code of Business Conduct and Ethics is to deter wrongdoing and to provide guidance to our 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. Our Code of Business Conduct and Ethics is publicly available on our website at https://www.sonnetbio.com/. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver, including any implicit waiver from a provision of the Code of Business Conduct and Ethics to its directors or executive officers, we intend to disclose the nature of such amendments or waiver on our website or in a current report on a Current Report on Form 8-K.

Insider Trading Policy

The Board has adopted an Insider Trading Policy governing the purchase, sale and other dispositions of our securities that applies to each of our directors, officers, employees, and other covered persons. The Board has adopted the Insider Trading Policy to ensure, among other things: (i) that persons to whom the policy applies understand their obligations to preserve the confidentiality of undisclosed "Material Information" (as defined in the Insider Trading Policy); (ii) strict compliance by all insiders with all requirements relating to the reporting of insider trading and with respect to trading when in possession of undisclosed "Material Information"; and (iii) that individuals subject to scheduled and unscheduled blackout periods adhere to the restrictions on trading as set out in the policy. We seek to discourage our employees from frequent buying and selling of securities for the purpose of realizing short term profits and to acquire securities as long term investments only. We believe that our Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us.

Under our Insider Trading Policy, among other things, short sales and certain forms of hedging or monetization transactions involving our securities are prohibited, including zero-cost collars and forward sale contracts. In addition, persons subject to the policy are generally prohibited under our Insider Trading Policy from pledging our securities in a margin account or as collateral for a loan, except in circumstances that are pre-approved by our Chief Financial Officer. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Policies and Practices Related to the Timing of Grants of Certain Equity Awards

At a regularly scheduled meeting of our Board and Compensation Committee held in December of each year, our Board and Compensation Committee has a long-standing practice to review our results for the most recently completed fiscal year, review our financial plan and strategy for the upcoming fiscal year. This timing coincides with our calendar-year-based performance management cycle, allowing managers to deliver the equity awards close in time to performance appraisals. Our Board and Compensation Committee believe that maintaining a consistent grant practice, based on a date that is generally set three months in advance, is in the best interests of the Company as is strengthens the link between pay and performance while also minimizing the risk that awards are granted opportunistically for the benefit of employees.

During these annual meetings, the Compensation Committee and our Board reviews market data on how much equity similarly situated officers are receiving at companies as well as how much equity and the mix of equity awards that should be granted to each executive officer in order to be competitive with equity awards provided to comparable officers at companies. Among the types of equity awards often granted to our executive officers are restricted stock units and restricted stock awards. These grants provide a certain amount of equity to officers that will vest as long as the officer continues to serve, aligning the officers' interests with those of our stockholders because the grants will only have value to the extent the market value of equity increases from the price per share on the date of grant.

Board Committees

Audit Committee

The Audit Committee of the Board as of September 30, 2025 consisted of Messrs. Bhatt (Chairman) and Dyrness and Ms. McNeill. 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. Our Board has determined that each Audit Committee member has sufficient knowledge in financial and auditing matters to serve on the Committee. Our Board determined that Mr. Bhatt 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 as of September 30, 2025 consisted of the following two non-employee directors: Mr. Dyrness (Chairman) and Mr. Bhatt. None of these Compensation Committee members was an officer or employee of the Company during the year ended September 30, 2025. 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 as of September 30, 2025 consisted of Messrs. Bhatt and Dyrness (Chairman) and Ms. McNeill. None of these members was an officer or employee of the Company during the year ended September 30, 2025. 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 our 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.

Item 11. Executive Compensation.

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 2025, our two most highly compensated executive officers who were serving as executive officers as of September 30, 2025, 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, 2025. 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 ($)	Total ($)
Raghu Rao	2025	155,769	100,000	92,800	—	—	348,569
Interim Chief Executive Officer (2)	2024	—	—	5,254	—	—	5,254
Pankaj Mohan, Ph.D.	2025	407,414	—	—	—	122,718	530,132
Former President and Chief Executive Officer(3)	2024	538,998	—	87,628	—	—	626,626
John K. Cini, Ph.D.	2025	397,750	—	55,680	—	19,584	473,014
Chief Scientific Officer	2024	397,750	—	21,907	—	—	419,657
Susan Dexter	2025	330,150	—	37,120	—	7,201	374,471
Chief Technical Officer	2024	330,150	—	16,852	—	—	347,002

(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) Mr. Rao became the interim Chief Executive Officer on March 31, 2025 as a result of the passing of Dr. Mohan.

(3) 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. On March 31, 2025, Dr. Mohan ceased serving as our President and Chief Executive Officer as a result of his passing.

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 Raghu Rao on July 31, 2025 (the "Rao Agreement"), setting forth the terms of his employment as interim Chief Executive Officer. Pursuant to the Rao Agreement, Mr. Rao is entitled to, among other things, (i) an annual gross base salary of $400,000, (ii) eligibility for a bonus equal to 5.0% of gross revenue received by the Company from a strategic transaction (subject to certain exceptions and not including the Business Combination) and (iii) at the sole discretion of the Company's board of directors, a cash or equity/options/restricted stock units bonus for achieving or progressing Company stated goals. The Rao Agreement shall terminate in accordance with its terms. Pursuant to the Agreement, if Mr. Rao is terminated without "Cause" (as defined in the Rao Agreement), he is entitled to his base salary for six months, payable in accordance with the Company's then-current payroll practices and subject to all required withholdings. In the event Mr. Rao resigns for any reason, Mr. Rao will not receive any severance benefits, provided that, pursuant to the Company's standard payroll policies, the Company shall pay Mr. Rao any accrued obligations.

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 was 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 Mohan Agreement terminated in accordance with its terms on March 31, 2025 in connection with Dr. Mohan's passing. Pursuant to Dr. Mohan's employment agreement, if he was terminated without "Cause" or for "Good Reason" within 2 months prior to or within 12 months following a "Change in Control", he was 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 was terminated without "Cause" or for "Good Reason" not coincident with a "Change in Control", he was 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 Cini Agreement, Dr. Cini was 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 Cini Agreement terminated in accordance with its terms on December 2, 2025 in connection with his resignation as a result of the Business Combination. Pursuant to Dr. Cini's employment agreement, if he was terminated without "Cause" or for "Good Reason" within 2 months prior to or within 12 months following a "Change in Control", he was 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 was terminated without "Cause" or for "Good Reason" not coincident with a "Change in Control", he was 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.

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) 12 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, 2025.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END - 2025

	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 ($)
Raghu Rao	20,000(1)	$ 92,800
John K. Cini, Ph.D.	12,000(1)	$ 55,680
Susan Dexter	8,000(1)	$ 37,120

(1) Scheduled to vest in full on January 8, 2026.

Director Compensation

Non-Employee Director Compensation Policy

In connection with the Merger, our Board approved a compensation policy for our 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.

The following table sets forth director compensation for the fiscal year ended September 30 2025, paid by us (excluding compensation to our executive officer set forth in the summary compensation table above). Except as set forth in the table below, the non-employee directors did not receive any cash or equity compensation during fiscal year 2025.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Nailesh Bhatt(2)	54,000	46,400	—	—	100,400
Albert Dyrness(3)	55,500	18,560	—	—	74,060
Donald Griffith (4)	—	46,400	—	169,301	215,701
Raghu Rao(5)	97,375	92,800	—	255,769	445,944
Lori McNeill(6)	60,000	18,560	—	—	78,560

(1) Represents the aggregate grant date fair value for grants made in 2025 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 10,000 restricted stock units, as of September 30, 2025.

(3) Mr. Dyrness holds an aggregate of 4,000 restricted stock units, as of September 30, 2025.

(4) Mr. Griffith served as Sonnet's Financial Controller since January 1, 2019, and since the Merger served as our Controller. In connection with Mr. Cross's resignation, on February 12, 2025, Mr. Griffith was appointed to succeed Mr. Cross as our Chief Financial Officer. The amounts in the table above under "All Other Compensation" represent salary and bonus earned by Mr. Griffith for the fiscal year 2025. See the description of the employment agreement with Mr. Griffith below. Mr. Griffith holds an aggregate of 10,000 restricted stock units, as of September 30, 2025.

(5) Mr. Rao became the interim Chief Executive Officer on March 31, 2025 as a result of the passing of Dr. Mohan. The amounts in the table above under "All Other Compensation" represent salary and bonus earned by Mr. Rao for the fiscal year 2025. See the description of the employment agreement with Mr. Rao in the "Employment Agreements" section above. Mr. Rao holds an aggregate of 20,000 restricted stock units, as of September 30, 2025.

(6) Ms. McNeill holds an aggregate of 4,000 restricted stock units, as of September 30, 2025.

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 (the "Griffith Offer Letter"). Pursuant to the Griffith Offer Letter, 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 Griffith Offer Letter has no specific term and constitutes an at-will employment. The terms of the Griffith Offer Letter continue to govern Mr. Griffith's employment with us as Chief Financial Officer.

Item 12. 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 December 12, 2025 with respect to the beneficial ownership of our common stock by the following: (i) each of our current directors; (ii) each of our Named Executive Officers; (iii) all of the current executive officers and directors as a group; and (iv) each person known by us to own beneficially more than five percent (5%) of the outstanding shares of the our 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, we believe that each person or entity named in the table has sole voting and investment power with respect to all shares of our 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 our common stock issuable under options that are exercisable on or within 60 days after December 12, 2025 ("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 no shares of common stock issued and outstanding as of the Closing Date.

Name And Address of Beneficial Owner*	Amount And Nature of Beneficial Ownership	Percent Of Class
Named Executive Officers and Directors:		
Nailesh Bhatt	—	**
Albert Dyrness	—	**
Donald Griffith	—	**
Raghu Rao	—	**
Lori McNeill	—	**
John K. Cini, Ph.D.	—	**
Susan Dexter	—	**
Richard Kenney	—	**
All current executive officers and directors as a group (8 persons)	—	**

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

** Less than 1%.

Equity Compensation Plan Information

The following table provides information as of September 30, 2025 regarding shares of our common stock that may be issued under our existing equity compensation plans, including our 2020 Omnibus Equity Incentive Plan (the "2020 Plan").

	Equity Compensation Plan Information		
Plan Category	(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)	120,000	N/A	302
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	120,000	—	302

(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 September 30, 2025.

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

Other than compensation arrangements for our Named Executive Officers and directors, we describe below each transaction and series of similar transactions, since the beginning of fiscal year 2024, to which we were 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 our directors, nominees for director, executive officers or holders of more than 5% of our 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 our Named Executive Officers and directors are described in the section entitled "Executive Compensation."

Public Offering

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

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

Private Placement

Dr. Richard Kenney, our Chief Medical Officer, participated in a private placement that closed on June 30, 2025, and purchased convertible notes for a principal amount of $200,000 and warrants to purchase up to an aggregate of 86,505 shares of common stock. The notes converted into shares of convertible preferred stock, which are convertible into an aggregate of 160,000 shares of common stock and warrants to purchase up to an aggregate of 320,000 shares of common stock.

Indemnification Agreements

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

Director Independence

Our Board as of September 30, 2025 consisted of six directors. Our Board has determined that Messrs. Bhatt and Dyrness and Ms. McNeill were "independent" as that term is defined under the rules of The Nasdaq Stock Market.

Item 14. Principal Accountant Fees and Services.

The following table summarizes the fees for professional services rendered by KPMG LLP, our independent registered public accounting firm, for each of the respective last two fiscal years:

Fee Category	2025	2024
Audit Fees	$ 1,257,500	$ 668,000
Audit-Related Fees	—	—
Tax Fees	61,825	42,074
All Other Fees	—	—
Total Fees	$ 1,319,325	$ 710,074

Audit Fees

Represents fees for professional services provided in connection with the audit of our annual consolidated financial statements and reviews of our quarterly interim consolidated financial statements, as well as for fees associated with registration statements, comfort letters and consents.

Audit-Related Fees

We did not incur any audit-related fees from our independent auditors in 2025 or 2024.

Tax Fees

Tax fees are associated with tax compliance, tax advice, tax planning and tax preparation services.

All Other Fees

Fees related to products and services provided by the principal accountant, other than the services reported in the above sections.

The Audit Committee is responsible for appointing, setting compensation and overseeing the work of the independent auditors. The Audit Committee is required to review and approve the proposed retention of independent auditors to perform any proposed auditing and non-auditing services as outlined in its charter. The Audit Committee has not established policies and procedures separate from its charter concerning the pre-approval of auditing and non-auditing related services. As required by Section 10A of the Exchange Act, our Audit Committee has authorized all auditing and non-auditing services provided by KPMG LLP during 2025 and 2024 and the fees paid for such services. However, the pre-approval requirement may be waived with respect to the provision of non-audit services for the Company if the "de minimis" provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied.

The Audit Committee has considered whether the provision of Audit-Related Fees, Tax Fees, and all other fees as described above is compatible with maintaining KPMG LLP's independence and has determined that such services for fiscal years 2024 and 2023 were compatible. All such services were approved by the Audit Committee pursuant to Rule 2-01 of Regulation S-X under the Exchange Act to the extent that rule was applicable.

The Audit Committee is responsible for reviewing and discussing the audited consolidated financial statements with management, discussing with the independent registered public accountants the matters required by Public Company Accounting Oversight Board Auditing Standard No. 1301 *Communications with Audit Committees*, receiving written disclosures from the independent registered public accountants required by the applicable requirements of the Public Company Accounting Oversight Board regarding the independent registered public accountants' communications with the Audit Committee concerning independence and discussing with the independent registered public accountants their independence, and recommending to the Board that the audited consolidated financial statements be included in our Annual Report on Form 10-K.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) *Financial Statements*. The financial statements filed as part of this report are listed on the Index to the Consolidated Financial Statements.

(a)(2) *Financial Statement Schedules*. Schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(a)(3) *Exhibits.* Reference is made to the Exhibit Index. The exhibits are included, or incorporated by reference, in this Annual Report on Form 10-K and are numbered in accordance with Item 601 of Regulation S-K.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Sonnet BioTherapeutics Holdings, Inc.
(Registrant)

Date: December 16, 2025

/s/ Raghu Rao
Raghu Rao
Chief Executive Officer
(Principal Executive Officer, Principal Financial and Accounting Officer and sole Director)

INDEX TO EXHIBITS

Exhibit No.	Description
2.1#	Agreement and Plan of Merger, dated October 10, 2019, by and among the Company, Sonnet Sub. and Merger Sub (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K as filed on October 11, 2019, and incorporated herein by reference).#
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated February 7, 2020, by and among the Company, Sonnet Sub and Merger Sub (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K as filed on February 7, 2020, and incorporated herein by reference).
2.3#	Share Exchange Agreement, between Sonnet BioTherapeutics, Inc. and Relief Therapeutics Holding SA, dated August 9, 2019 (incorporated by reference to Exhibit 2.10 to the Company's Registration Statement on Form S-4 filed with the SEC on November 27, 2019).#
2.4#	Business Combination Agreement, dated July 11, 2025, by and among the Company, Rorschach I LLC, Hyperliquid Strategies Inc, TBS Merger Sub Inc and Rorschach Merger Sub, LLC (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K as filed on July 14, 2025 and incorporated herein by reference).#
2.5	Amendment No. 1 to Business Combination Agreement, dated September 22, 2025, by and among the Company, Rorschach I LLC, Hyperliquid Strategies Inc, TBS Merger Sub Inc and Rorschach Merger Sub, LLC (filed as Exhibit 2.2 to the Company's Current Report on Form 8-K as filed on December 3, 2025 and incorporated herein by reference).
3.1	Certificate of Incorporation, as amended, of Sonnet BioTherapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2020).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series 3 Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 15, 2022).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series 4 Preferred Stock (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on August 15, 2022).
3.4	Certificate of Amendment of Certificate of Incorporation, as amended, of Sonnet BioTherapeutics Holdings, Inc., dated September 16, 2022 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 19, 2022).
3.5	Certificate of Amendment of Certificate of Incorporation, as amended, of Sonnet BioTherapeutics Holdings, Inc., dated August 31, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 1, 2023).
3.6	Certificate of Amendment of Certificate of Incorporation, as amended, of Sonnet BioTherapeutics Holdings, Inc., dated September 25, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 30, 2024).

3.7	Amended and Restated Bylaws, of Sonnet BioTherapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K, filed with the SEC on August 15, 2022).
3.8	Certificate Of Designation of Preferences, Rights and Limitations of Series 5 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 14, 2025).
3.9	Certificate of Amendment of Certificate of Incorporation, as amended, of Sonnet BioTherapeutics Holdings, Inc., dated December 2, 2025 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on December 3, 2025).
4.1	Form of Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (Registration No. 333-178307), filed with the SEC on December 2, 2011).
4.2	Form of Warrant dated May 4, 2017 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on May 5, 2017).
4.3	Spin-Off Entity Warrant, dated April 1, 2020 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 3, 2020).
4.4	Form of Sonnet BioTherapeutics, Inc. Converted Warrant (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2020).
4.5	Form of Series A/B Warrants (incorporated by reference to Exhibit 4.16 to the Company's Registration Statement on Form S-4/A filed with the SEC on February 7, 2020).
4.6	Form of Series C Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 4, 2020).
4.7	Registration Rights Agreement, dated February 7, 2020, by and between the Company and certain investors named therein (incorporated by reference to Exhibit 4.17 to the Company's Registration Statement on Form S-4/A filed with the SEC on February 7, 2020).
4.8	Description of Securities (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2024).
4.9	Form of Pre-Funded Warrant, dated August 24, 2021 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC August 25, 2021).
4.10	Form of Underwriter Warrant, dated August 24, 2021 (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1/A filed with the SEC on August 16, 2021).
4.11	Form of Common Warrant, dated August 24, 2021 (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC August 25, 2021).
4.12	Form of Pre-Funded Warrant dated February 10, 2023 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on February 13, 2023).
4.13	Form of Underwriter Warrant dated February 10, 2023 (incorporated by reference to Exhibit 4.3 to our Current Report on Form 8-K filed with the SEC on February 13, 2023).

4.14	Form of Common Warrant dated February 10, 2023 (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on February 13, 2023).
4.15	Form of Pre-Funded Warrant dated June 30, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 30, 2023).
4.16	Form of Warrant dated June 30, 2023 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 30, 2023).
4.17	Form of Placement Agent Warrant dated June 30, 2023 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the SEC on June 30, 2023).
4.18	Form of Pre-Funded Warrant (filed as Exhibit 4.14 to the Company's Registration Statement on Form S-1/A as filed on September 28, 2023, and incorporated herein by reference).
4.19	Form of Underwriter Warrant (filed as Exhibit 4.15 to the Company's Registration Statement on Form S-1/A as filed on September 28, 2023, and incorporated herein by reference).
4.20	Form of Common Warrant (filed as Exhibit 4.16 to the Company's Registration Statement on Form S-1/A as filed on September 28, 2023, and incorporated herein by reference).
4.21	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024).
4.22	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024).
4.23	Form of Common Warrant (incorporated by reference to Exhibit 4.22 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 6, 2024).
4.24	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.23 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 6, 2024).
4.25	Form of Registered Direct Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 10, 2024).
4.26	Form of Private Placement Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on December 10, 2024).
4.27	Form of Common Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on December 10, 2024).
4.28	Form of Convertible Note (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 2, 2025).
4.29	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on July 2, 2025).
4.30	Form of PIPE Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 14, 2025).

10.1	Common Stock Purchase Agreement, between GEM Global Yield Fund LLC SCS and Sonnet BioTherapeutics, Inc., dated August 6, 2019 (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-4 filed with the SEC on November 27, 2019).
10.2	Amendment to Common Stock Purchase Agreement, between GEM Global Yield Fund LLC SCS and Sonnet BioTherapeutics, Inc., dated September 25, 2019 (incorporated by reference to Exhibit 10.55 to the Company's Registration Statement on Form S-4 filed with the SEC on November 27, 2019).
10.3	Side Letter and Amendment No. 2 to Common Stock Purchase Agreement, between GEM Global Yield Fund LLC SCS, Sonnet BioTherapeutics, Inc. and Chanticleer Holdings, Inc., dated February 7, 2020 (incorporated by reference to Exhibit 10.60 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020).
10.4†	Employment Agreement, between Pankaj Mohan and Sonnet BioTherapeutics, Inc., dated December 31, 2018 (incorporated by reference to Exhibit 10.56 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020). †
10.5†	Employment Agreement, between John Cini and Sonnet BioTherapeutics, Inc., dated January 10, 2020 (incorporated by reference to Exhibit 10.58 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020). †
10.6†	Employment Agreement, between Jay Cross and Sonnet BioTherapeutics, Inc., dated January 10, 2020 (incorporated by reference to Exhibit 10.57 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020). †
10.7†	Employment Agreement, between Susan Dexter and the Company, dated April 1, 2020 (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on April 3, 2020). †
10.8†	Offer Letter, between Donald Griffith and Sonnet BioTherapeutics, Inc., dated January 1, 2019 (incorporated by reference to Exhibit 10.59 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020). †
10.9†	Sonnet BioTherapeutics Holdings, Inc. 2020 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8 filed with the SEC on May 20, 2020). †
10.10†	Form of Restricted Stock Unit Award (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2020). †
10.11	License Agreement, between Ares Trading SA and Relief Therapeutics SA, dated August 28, 2015 (incorporated by reference to Exhibit 10.51 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020).***
10.12	Discovery Collaboration Agreement, between XOMA (US) LLC and Oncobiologics, Inc., dated July 23, 2012 (incorporated by reference to Exhibit 10.52 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020).***
10.13	Amendment of Discovery Collaboration Agreement, between XOMA (US) LLC and Sonnet BioTherapeutics, Inc., dated May 7, 2019 (incorporated by reference to Exhibit 10.53 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020).***
10.14	Securities Purchase Agreement, dated as of February 7, 2020, by and among Chanticleer Holdings, Inc., Sonnet BioTherapeutics, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.64 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020).

10.15	Form of Warrant Exercise and Omnibus Amendment Agreement, dated as of August 3, 2020, by and between Sonnet BioTherapeutics Holdings, Inc. and the Holders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 4, 2020).
10.16†	Assignment and Assumption Employment Agreements by Sonnet BioTherapeutics Holdings, Inc., effective April 1, 2020 (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2020).†
10.17†	Amendment No. 1 to Executive Employment Agreement, between Pankaj Mohan and the Company, dated November 23, 2020 (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2020).†
10.18†	Amendment No. 1 to Executive Employment Agreement, between John Cini and the Company, dated November 23, 2020 (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2020).†
10.19†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2020).†
10.20	At-The-Market Sales Agreement, dated February 5, 2020, between the Company and BTIG (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on February 5, 2021).
10.21	License Agreement, dated May 2, 2021, between Sonnet BioTherapeutics, Inc. and New Life Therapeutics PTE, LTD (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 17, 2021).
10.22	First Amendment to License Agreement, dated June 11, 2021, between Sonnet BioTherapeutics, Inc. and New Life Therapeutics PTE, LTD (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K, filed with the SEC on December 17, 2021).
10.23	Second Amendment to License Agreement, dated July 7, 2021, among Sonnet Biotherapeutics CH SA, Sonnet BioTherapeutics, Inc. and New Life Therapeutics PTE, Ltd. (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K, filed with the SEC on December 17, 2021).
10.24	Amendment to License Agreement and Settlement, dated November 1, 2021, between ARES TRADING SA and Sonnet BioTherapeutics CH SA (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed with the SEC on December 17, 2021).
10.25	At-The-Market Sales Agreement, dated August 15, 2022, between the Company and BTIG (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 15, 2022).
10.26	Underwriting Agreement, dated February 8, 2023, between the Company and Chardan Capital Markets, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on February 13, 2023).
10.27	Form of Securities Purchase Agreement, dated June 28, 2023, by and between the Company and the Purchaser (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 30, 2023).

10.28	ChEF Purchase Agreement, dated as of May 2, 2024, by and between Sonnet BioTherapeutics Holdings, Inc. and Chardan Capital Markets, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 3, 2024).
10.29	Registration Rights Agreement, dated as of May 2, 2024, by and between Sonnet BioTherapeutics Holdings, Inc. and Chardan Capital Markets, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 3, 2024).
10.30	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024).
10.31	License Agreement, dated October 8, 2024, between Sonnet BioTherapeutics, Inc., Sonnet BioTherapeutics CH SA and Alkem Laboratories Limited (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 9, 2024).
10.32	Underwriting Agreement, dated November 6, 2024, between the Company and Chardan Capital Markets, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on November 8, 2024).
10.33	Form of Registered Direct Securities Purchase Agreement, dated December 9, 2024, by and between the Company and the Purchasers (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 10, 2024).
10.34	Form of Private Placement Securities Purchase Agreement, dated December 9, 2024, by and between the Company and the Purchasers (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on December 10, 2024).
10.35†	Offer Letter, between Donald Griffith and Sonnet BioTherapeutics, Inc., dated January 1, 2019 (incorporated by reference to Exhibit 10.59 to the Company's Registration Statement on Form S-4 filed with the SEC on February 7, 2020).†
10.36†	Employment Agreement by and between the Company and Stephen McAndrew, Ph.D., dated February 12, 2025 (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed with the SEC on February 13, 2025). †
10.37	Form of Contribution Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 14, 2025).
10.38	Form of Subscription Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 14, 2025).
10.39	Form of PIPE Purchase Agreement (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 14, 2025).
10.40†	Employment Agreement by and between the Company and Raghu Rao, dated July 31, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2025)†
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed with the SEC on December 17, 2024).

21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the SEC on December 14, 2023).
23.1*	Consent of KPMG LLP.*
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended.*
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended.*
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
97.1	Clawback Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed with the SEC on December 14, 2023).
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101).*
*	Filed herewith.
**	Furnished herewith.
***	Filed herewith; portions of the exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K. A copy of any omitted portions will be furnished to the Securities and Exchange Commission upon request.
#	The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
†	Indicates a management contract or compensation plan, contract or arrangement.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-290034) on Form S-4, and (No. 333-291017) on Form S-1 of our report dated December 16, 2025, with respect to the consolidated financial statements of Sonnet BioTherapeutics Holdings, Inc. and subsidiaries.

/s/ KPMG LLP

Philadelphia, Pennsylvania
December 16, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Raghu Rao, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") for the period ended September 30, 2025;

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

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

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

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: December 16, 2025

/s/ Raghu Rao
Raghu Rao
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Raghu Rao, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") for the period ended September 30, 2025;

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

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

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

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: December 16, 2025

/s/ Raghu Rao
Raghu Rao
Chief Executive Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Sonnet BioTherapeutics Holdings, Inc. (the "Company") on Form 10-K for the year ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raghu Rao, Chief Executive Officer and Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 16, 2025

/s/ Raghu Rao
Raghu Rao
Chief Executive Officer
(*Principal Executive Officer)*

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Sonnet BioTherapeutics Holdings, Inc. (the "Company") on Form 10-K for the year ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raghu Rao, Chief Executive Officer and Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 16, 2025

/s/ Raghu Rao
Raghu Rao
Chief Executive Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.