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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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	**20-2932652**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
100 Overlook Center, Suite 102, Princeton, NJ	**08540**
(Address of Principal Executive Offices)	(Zip Code)

(609) 375-2227
(Registrant's Telephone Number, Including Area Code)

Not applicable
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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, par value $0.0001 per share	SONN	The Nasdaq Capital Market LLC

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act).
☐ Yes ☒ No

There were 3,165,810 shares of common stock, par value $0.0001 per share, of Sonnet BioTherapeutics Holdings, Inc. issued and outstanding as of May 12, 2025.

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

INDEX TO THE UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

PART I - FINANCIAL INFORMATION

Item 1: Financial Statements.

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

	March 31, 2025	September 30, 2024
Assets		
Current assets:		
Cash	$ 2,059,284	$ 149,456
Accounts receivable	500,000	—
Prepaid expenses and other current assets	420,688	1,206,409
Incentive tax receivable	278,194	762,078
Total current assets	3,258,166	2,117,943
Property and equipment, net	14,802	20,523
Operating lease right-of-use asset	84,851	123,417
Deferred offering costs	—	15,000
Other assets	478,615	494,147
Total assets	$ 3,836,434	$ 2,771,030
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,745,174	$ 2,183,416
Accrued expenses and other current liabilities	1,338,552	942,489
Current portion of operating lease liability	90,446	84,291
Total current liabilities	3,174,172	3,210,196
Operating lease liability, net of current portion	—	46,573
Total liabilities	3,174,172	3,256,769
Commitments and contingencies (Note 4)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value: 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.0001 par value: 125,000,000 shares authorized; 3,123,429 and 650,284 issued and outstanding at March 31, 2025 and September 30, 2024, respectively	312	65
Additional paid-in capital	124,994,763	117,195,181
Accumulated deficit	(124,332,813)	(117,680,985)
Total stockholders' equity (deficit)	662,262	(485,739)
Total liabilities and stockholders' equity (deficit)	$ 3,836,434	$ 2,771,030

See accompanying notes to unaudited interim consolidated financial statements

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2025	**2024**	**2025**	**2024**
Collaboration revenue	$ —	$ —	$ 1,000,000	$ 18,626
Operating expenses:				
Research and development	1,884,907	2,167,288	3,770,983	2,811,330
General and administrative	2,344,513	1,701,273	4,307,859	2,354,728
Total operating expenses	4,229,420	3,868,561	8,078,842	5,166,058
Loss from operations	(4,229,420)	(3,868,561)	(7,078,842)	(5,147,432)
Other income	720,102	4,327,946	720,102	4,327,946
Foreign exchange gain (loss)	18,196	(93,960)	(134,688)	16,402
(Loss) income before provision for income taxes	(3,491,122)	365,425	(6,493,428)	(803,084)
Provision for income taxes	—	—	(158,400)	—
Net (loss) income	$ (3,491,122)	$ 365,425	$ (6,651,828)	$ (803,084)
Per share information:				
Net (loss) income per share, basic	$ (0.89)	$ 0.63	$ (2.25)	$ (1.53)
Weighted average shares outstanding, basic	3,921,641	577,374	2,961,796	525,756
Per share information:				
Net (loss) income per share, diluted	$ (0.89)	$ 0.60	$ (2.25)	$ (1.53)
Weighted average shares outstanding, diluted	3,921,641	610,891	2,961,796	525,756

See accompanying notes to unaudited interim consolidated financial statements

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

	Common stock		Additional paid-in	Accumulated	
	Shares	Amount	capital	deficit	Total
Balance at October 1, 2024	650,284	$ 65	$ 117,195,181	$ (117,680,985)	$ (485,739)
Sale of common stock, net of issuance costs	1,050,500	105	7,622,514	—	7,622,619
Retirement of shares in connection with reverse stock split	(373)	—	—	—	—
Shares released from abeyance	32,375	3	(3)	—	—
Net share settlement of warrants	1,209	—	—	—	—
Exercise of warrants	1,273,436	127	(127)	—	—
Share-based compensation	—	—	60,395	—	60,395
Net loss	—	—	—	(3,160,706)	(3,160,706)
Balance at December 31, 2024	3,007,431	300	$ 124,877,960	(120,841,691)	4,036,569
Sale of common stock, net of issuance costs	98,846	10	116,805	—	116,815
Issuance of common stock on vesting of restricted stock units and awards	17,152	2	(2)	—	—
Net loss	—	—	—	(3,491,122)	(3,491,122)
Balance at March 31, 2025	3,123,429	$ 312	$ 124,994,763	$ (124,332,813)	$ 662,262

	Common stock		Additional paid-in	Accumulated	
	Shares	Amount	capital	deficit	Total
Balance at October 1, 2023	218,786	$ 22	$ 110,017,751	$ (110,243,753)	$ (225,980)
Sale of common stock, net of issuance costs	163,281	16	3,916,927	—	3,916,943
Retirement of shares in connection with reverse stock split	(190)	—	—	—	—
Net share settlement of warrants	1,795	—	—	—	—
Share-based compensation	—	—	50,005	—	50,005
Net loss	—	—	—	(1,168,509)	(1,168,509)
Balance at December 31, 2023	383,672	38	113,984,683	(111,412,262)	2,572,459
Issuance of common stock on vesting of restricted stock units and awards	976	—	—	—	—
Exercise of warrants	4,375	—	56,000	—	56,000
Share-based compensation	—	—	60,395	—	60,395
Net income	—	—	—	365,425	365,425
Balance at March 31, 2024	389,023	$ 38	$ 114,101,078	$ (111,046,837)	$ 3,054,279

See accompanying notes to unaudited interim consolidated financial statements

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

	Six Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (6,651,828)	$ (803,084)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,721	6,422
Acquired in-process research and development	12,000	12,000
Amortization of operating lease right-of-use asset	38,566	34,048
Share-based compensation	60,395	110,400
Financing costs related to ChEF Purchase Agreement	480,200	—
Non-cash financing costs	7,122	—
Changes in operating assets and liabilities:		
Accounts receivable	(500,000)	—
Prepaid expenses and other current assets	785,721	618,560
Incentive tax receivable	483,884	408,612
Other assets	15,532	(70,636)
Accounts payable	(454,465)	(368,681)
Accrued expenses and other current liabilities	376,063	(2,261,988)
Operating lease liability	(40,418)	(34,972)
Deferred income	—	(18,626)
Net cash used in operating activities	(5,381,507)	(2,367,945)
Cash flows from investing activities:		
Purchases of in-process research and development	(12,000)	—
Net cash used in investing activities	(12,000)	—
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	7,762,403	3,838,870
Payment of deferred offering costs	—	(15,000)
Proceeds from exercise of warrants, net of issuance costs	(13,868)	56,000
Payment of financing costs related to ChEF Purchase Agreement	(445,200)	—
Net cash provided by financing activities	7,303,335	3,879,870
Net increase in cash	1,909,828	1,511,925
Cash, beginning of period	149,456	2,274,259
Cash, end of period	$ 2,059,284	$ 3,786,184
Supplemental disclosure of non-cash operating, investing and financing activities:		
ChEF Purchase Agreement financing costs in accrued expenses	$ 20,000	$ —
In-process research and development in accrued expenses	$ —	$ 12,000
Deferred offering costs expensed as ChEF Purchase Agreement financing costs	$ 15,000	$ —
Common stock issuance costs in accounts payable	$ 30,091	$ —

See accompanying notes to unaudited interim consolidated financial statements

1. Organization and Description of Business

Description of business

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

Sonnet's lead proprietary asset, SON-1010, is a fully human version of Interleukin 12 ("IL-12"), covalently linked to the F_HAB construct, for which Sonnet is pursuing clinical development in solid tumor indications, including ovarian cancer, soft tissue sarcoma, non-small cell lung cancer and head and neck 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 will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and proof-of-concept study (SB221). Part 1 of this 2-part study was approved in June 2023 by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. In August 2023, the FDA accepted the IND for SB221. The trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose ("MTD") of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose ("RP2D"). Part 2 of the study will then investigate SON-1010 in combination with atezolizumab, or the standard of care ("SOC") for PROC in a randomized comparison to show proof-of-concept ("POC"). Interim safety, tolerability, and efficacy data from the SB221 study was most recently reported in April 2025 following completion of dose escalation.

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 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 activate tumor macrophages into 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.

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. 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. 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 interaction with the IL-18 inhibitor binding protein, and single-chain human IL-12 for solid tumor cancers. Cell line development and titer/bioactivity assessments are underway. The Company has elected to place the SON-1411 development program on hold for expense reduction purposes.

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

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and it expects to 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 at March 31, 2025 of $2.1 million will fund the Company's projected operations into July 2025. 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 unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, substantial doubt about the Company's ability to continue as a going concern exists. The unaudited interim consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company plans to secure additional capital in the future through equity 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. If additional capital is not available when required, the Company may need to delay or curtail its operations until such funding is received. Various internal and external factors will affect whether and when the Company's product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company's product candidates, length of time and cost of developing and commercializing these product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations.

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

2. Summary of Significant Accounting Policies

a. Basis of presentation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates (ASUs") of the Financial Accounting Standards Board ("FASB"). In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2025 and its results of operations and cash flows for the three and six months ended March 31, 2025 and 2024. The unaudited interim consolidated financial statements presented herein do not contain all of the required disclosures under U.S. GAAP for annual financial statements and should be read in conjunction with the annual audited consolidated financial statements and related notes of Sonnet as of and for the year ended September 30, 2024 included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2024. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

b. Consolidation

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

c. Use of estimates

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

d. Incentive tax receivable

Subsidiary is eligible to participate in an Australian research and development tax incentive program. As part of this program, Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by Subsidiary in Australia. The cash refund is available to eligible companies with annual aggregate revenues of less than $20.0 million (Australian) during the reimbursable period. The Company estimates the amount of cash refund it expects to receive related to the Australian research and development tax incentive program and records the incentive when it is probable (i) the Company will comply with relevant conditions of the program and (ii) the incentive will be received. As of March 31, 2025, 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 $0.3 million. For the three months ended March 31, 2025 and 2024, $0.1 million and $0.2 million for the expected net cash refund related to the tax incentive program was included as a reduction in research and development expenses. For the six months ended March 31, 2025 and 2024, $0.3 million and $0.4 million, respectively, for the expected net cash refund related to the tax incentive program was included as a reduction in research and development expenses. In November 2024, the Company received $0.7 million from the Australian government related to eligible research and development expenses for the year ended September 30, 2024. In December 2023, the Company received $0.8 million from the Australian government related to eligible research and development expenses for the year ended September 30, 2023.

e. Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets. Expenditures for repairs and maintenance that do not extend the estimated useful life or improve an asset are expensed as incurred. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts, and any resulting gain or loss is included in the consolidated statement of operations.

f. 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.

g. 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 Purchase Agreement (see Note 6) qualified as embedded derivatives. The derivative liability is accounted for separately from the Purchase Agreement at fair value, which has been deemed de minimis.

h. 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 12 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 Therapeutics Pte, Ltd. ("New Life"). In October 2024, the Company entered into the Alkem Agreement. See Note 5 for further discussion of these agreements.

i. 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.

j. 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 during the three and six months ended March 31, 2025 and $4.3 million during the three and six months ended March 31, 2024 from the sale of New Jersey state net operating losses through the Program, which is included in other income in the unaudited interim consolidated statements of operations.

k. 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 gain (loss) line item in the consolidated statement of operations.

l. Reverse stock split

On September 30, 2024, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware, which effected a 1-for-8 reverse stock split of the Company's issued and outstanding shares of common stock. As a result of the reverse stock split, every eight shares of common stock issued and outstanding was converted into one share of common stock. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity. No fractional shares were issued in connection with the reverse stock split. Stockholders who would otherwise be entitled to a fractional share of common stock were instead entitled to receive a proportional cash payment. The reverse stock split did not change the par value or authorized number of shares of common stock. All common share and per share amounts presented in the unaudited interim consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

m. Net income (loss) per share

Basic net income (loss) per share of common stock is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during each period (and potential shares of common stock that are exercisable for little or no consideration). Included in basic weighted-average number of shares of common stock outstanding during the three and six months ended March 31, 2025 are pre-funded October 2023 warrants to purchase 99,687 shares of common stock with an exercise price of $0.0008 per share, warrants exercised through the June 2024 inducement offer for 155,125 shares of common stock that are being held in abeyance as of March 31, 2025 due to beneficial ownership limitations, and pre-funded December 2024 warrants to purchase 545,500 shares of common stock with an exercise price of $0.0001 per share. Included in basic weighted-average number of shares of common stock outstanding during the three and six months ended March 31, 2024 are pre-funded October 2023 warrants to purchase 192,187 shares of common stock with an exercise price of $0.0008 per share.

Diluted income (loss) per share includes the effect, if any, from the potential exercise or conversion of securities such as common stock warrants and restricted stock units or awards which would result in the issuance of incremental shares of common stock. For diluted net loss per share in periods where the Company has a net loss, 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. For the three months ended March 31, 2024, the Company was in a net income position and calculated the diluted net income per share by dividing the Company's net income by the diluted weighted-average number of shares of common stock outstanding during the period, determined using the treasury stock method and the average stock price during the period. The following table summarizes the computation of basic and diluted net income (loss) per share:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2025	2024	2025	2024
Numerator:				
Net (loss) income	$ (3,491,122)	$ 365,425	$ (6,651,828)	$ (803,084)
Denominator:				
Weighted average shares outstanding, basic	3,921,641	577,374	2,961,796	525,756
Restricted stock units and awards	—	1,389	—	—
Warrants	—	32,128	—	—
Weighted average shares outstanding, diluted	3,921,641	610,891	2,961,796	525,756
Net (loss) income per share, basic	$ (0.89)	$ 0.63	$ (2.25)	$ (1.53)
Net (loss) income per share, diluted	$ (0.89)	$ 0.60	$ (2.25)	$ (1.53)

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2025	**2024**	**2025**	**2024**
Common stock warrants August 2021	14,031	14,031	14,031	14,031
Underwriter warrants August 2021	284	284	284	284
Chanticleer warrants	6	6	6	6
Series C warrants	2,297	2,297	2,297	2,297
Series 3 warrants	1,566	1,566	1,566	1,566
Unvested restricted stock units and awards	—	—	—	17,152
Common stock warrants February 2023	31,563	33,982	31,563	33,982
Underwriter warrants February 2023	1,933	1,933	1,933	1,933
Common stock private placement warrants June 2023	28,409	28,409	28,409	28,409
Placement agent warrants June 2023	852	852	852	852
Common stock warrants October 2023	354,994	—	354,994	706,556
Underwriter warrants October 2023	10,664	10,664	10,664	10,664
Placement agent warrants June 2024	14,142	—	14,142	—
Common stock warrants June 2024	703,125	—	703,125	—
Common stock warrants November 2024	2,222,222	—	2,222,222	—
Common stock registered direct warrants December 2024	1,085,325	—	1,085,325	—
Common stock PIPE warrants December 2024	673,000	—	673,000	—
	5,144,413	94,024	5,144,413	817,732

n. Recent accounting pronouncements

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

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

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*, as subsequently amended by ASU 2025-01 to clarify the effective date, 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 in the consolidated statement of operations. The guidance in this ASU is effective for annual reporting periods in fiscal years beginning after December 15, 2026, and interim periods in 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:

	March 31, 2025	September 30, 2024
Compensation and benefits	$ 138,121	$ 149,802
Research and development	956,083	617,545
Professional fees	242,687	173,319
Other	1,661	1,823
	$ 1,338,552	$ 942,489

4. Commitments and Contingencies

Legal proceedings

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

License agreements

In July 2012, the Company entered into a Discovery Collaboration Agreement (the "Collaboration Agreement") with XOMA (US) LLC ("XOMA"), pursuant to which XOMA granted to the Company a non-exclusive, non-transferable license and/or right to use certain materials, technologies and related information related to discovery, optimization and development of antibodies and related proteins and to develop and commercialize products thereunder. The Company is obligated to make contingent milestone payments to XOMA totaling $3.8 million on a product-by-product basis upon the achievement of certain development and approval milestones related to a product. The Company has also agreed to pay XOMA low single-digit royalties on net sales of products sold by the Company. Royalties on each product are payable on a country-by-country basis until the later of (i) a specified period of time after the first commercial sale, and (ii) the date of expiration of the last valid claim in the last-to-expire of the issued patents covered by the Collaboration Agreement. The first milestone was achieved in April 2022, at which time the Company incurred a $0.5 million license fee which was recorded as acquired in-process research and development. No license fees were incurred during the three and six months ended March 31, 2025 and 2024.

In August 2015, the Company entered into a License Agreement (the "ARES License Agreement") with Ares Trading ("ARES"), a wholly-owned subsidiary of Merck KGaA. Under the terms of the ARES License Agreement, as subsequently amended in October 2021, 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 5) 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 5), which is included in research and development expenses in the unaudited interim consolidated statement of operations for the six months ended March 31, 2025. No license fees were incurred during the three months ended March 31, 2025 and the three and six months ended March 31, 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 fee which was recorded as acquired in-process research and development. No license fees were incurred during the three and six months ended March 31, 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 the six months ended March 31, 2025 and 2024, which were recorded as acquired in-process research and development and included in research and development expenses in the unaudited interim consolidated statements of operations. No license fees were incurred during the three months ended March 31, 2025 and 2024.

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 March 31, 2025). No license fees were incurred during the three and six months ended March 31, 2025 and 2024.

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 three and six months ended March 31, 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.

5. 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 six months ended March 31, 2025 and 2024, respectively. No collaboration revenue was recognized for the three months ended March 31, 2025 and 2024. As of March 31, 2025, the Company has an outstanding balance of $0.5 million related to the single performance obligation under the Alkem Agreement, which is included in accounts receivable in the unaudited interim consolidated balance sheet.

6. 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. 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 $24.8 million is available to be sold as of March 31, 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 98,846 shares of common stock pursuant to the Purchase Agreement for net proceeds of approximately $0.1 million during the six months ended March 31, 2025. The Company incurred $0.5 million of costs in connection with the Purchase Agreement during the six months ended March 31, 2025, which are included in general and administrative expenses in the unaudited interim 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 have been exercised as of March 31, 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 warrants have been exercised as of March 31, 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 are immediately exercisable at any time, until exercised in full, at a price of $0.0001 per share of common stock.

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

Common stock warrants

As of March 31, 2025, the following equity-classified warrants and related terms were outstanding:

	Warrants Outstanding	Exercise Price	Expiration Date
Common stock warrants August 2021	14,031	$ 2,094.4000	August 24, 2026
Underwriter warrants August 2021	284	$ 2,618.0000	August 19, 2026
Chanticleer warrants	6	$144,144.0000 - $224,224.0000	April 30, 2027 - December 17, 2028
Series C warrants	2,297	$ 7,860.1600	October 16, 2025
Series 3 warrants	1,566	$ 717.0240	August 15, 2027
Common stock warrants February 2023	31,563	$ 190.0800	February 10, 2028
Underwriter warrants February 2023	1,933	$ 237.6000	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
Pre-funded warrants October 2023	99,687	$ 0.0008	—
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	703,125	$ 12.4000	June 21, 2029
Common stock warrants November 2024	2,222,222	$ 4.5000	November 7, 2029
Common stock registered direct warrants December 2024	1,085,325	$ 2.1000	December 9, 2029
Common stock PIPE warrants December 2024	673,000	$ 2.1000	December 9, 2029
Pre-funded warrants December 2024	545,500	$ 0.0001	—
Total	5,789,600		

Due to beneficial ownership limitations, 187,500 shares of common stock related to warrants that were exercised in June 2024 through the inducement offer were being held in abeyance. During the six months ended March 31, 2025, 32,375 of these shares of common stock were released from abeyance, resulting in 155,125 shares of common stock held in abeyance as of March 31, 2025.

During the six months ended March 31, 2025, 2,419 warrants were net share settled, resulting in the issuance of 1,209 shares of common stock, and 1,273,436 pre-funded warrants were exercised on a cash basis for de minimis proceeds.

During the six months ended March 31, 2024, 3,590 warrants were net share settled, resulting in the issuance of 1,795 shares of common stock, 4,375 warrants were exercised on a cash basis, resulting in proceeds of $0.1 million, and 4,302 warrants were abandoned by the warrant holder.

7. Share-Based Compensation

In April 2020, the Company adopted the 2020 Omnibus Equity Incentive Plan (the "Plan"). There were 120,302 shares available for issuance under the Plan as of March 31, 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 January 1, 2024, 9,175 restricted stock units ("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 unaudited interim consolidated statements of operations as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2025	2024	2025	2024
Research and development	$ —	$ 28,268	$ 28,268	$ 52,821
General and administrative	—	32,127	32,127	57,579
	$ —	$ 60,395	$ 60,395	$ 110,400

The following table summarizes RSU activity under the Plan:

	RSU	Weighted Average Grant Date Fair Value
Unvested balance at October 1, 2024	9,175	$ 14.08
Vested	(9,175)	$ 14.08
Unvested balance at March 31, 2025	—	$ —

During the six months ended March 31, 2025, there were no RSUs granted or forfeited. As of March 31, 2025, there was no unrecognized compensation expense relating to unvested RSUs granted.

The following table summarizes RSA activity under the Plan:

	RSA	Weighted Average Grant Date Fair Value
Unvested balance at October 1, 2024	7,977	$ 14.08
Vested	(7,977)	$ 14.08
Unvested balance at March 31, 2025	—	$ —

During the six months ended March 31, 2025, there were no RSAs granted or forfeited. As of March 31, 2025, there was no unrecognized compensation expense relating to unvested RSAs granted.

8. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through May 13, 2025, the date at which the unaudited interim consolidated financial statements were available to be issued. Subsequent to March 31, 2025, the Company sold 42,381 shares of common stock pursuant to the Purchase Agreement for net proceeds of $0.1 million.

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history and history of operating losses;
- our need for significant additional capital and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our products and obtain approval from the U.S. Food and Drug Administration (the "FDA") or other regulatory agents 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 passage 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.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see "*Part II - Item IA - Risk Factors*" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Overview

Sonnet BioTherapeutics Holdings, Inc. ("Sonnet," "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 variable fragment (scFv) that binds to and "hitchhikes" on 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 accumulation in solid tumors, which extends the duration of cytokine activity. F_HAB development candidates can be produced in mammalian cell culture, which enables glycosylation of the interleukins, thereby reducing the risk of immunogenicity. Production can also be performed in *E. coli*. We believe our F_HAB technology, for which we received an initial U.S. patent in June 2021 and a continuation of such patent in June 2024, is a distinguishing feature of our biopharmaceutical platform. The approach is well suited for future drug development across a range of human disease areas, including in oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

Our current internal pipeline development activities are focused on cytokines, which are a class of cell signaling molecules that serve as potent immunomodulatory agents, 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 and certain types of sarcoma. 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, following successful completion of dose escalation in December 2024.

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 efficacy study (SB221). Part 1 of this 2-part study was approved in June 2023 by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. In August 2023, the FDA accepted the IND for the use of SON-1010 in ovarian cancer. The SB221 trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose ("MTD") of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose ("RP2D"). Part 2 of the study will then investigate SON-1010 in combination with atezolizumab versus the standard of care ("SOC") for PROC in a randomized comparison to show proof-of-concept ("POC"). Interim safety, tolerability, and efficacy data from the SB221 study was most recently reported in April 2025 following completion of dose escalation.

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 completion of monotherapy dose escalation. 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 activate 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.

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) in July 2022. Enrollment of the first portion of the SB211 study in CIPN has been completed, and the Data Safety Monitoring Board ("DSMB") completed its review of the preliminary safety data during the first calendar quarter of 2024, clearing 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 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 is has elected to move its business in a different direction. 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, the Give Back Option will expire unexercised, New Life will retain the rights granted subject to the terms and conditions of the New Life Agreement and 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. 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. In November 2024, the IIOC submitted a pre-IND package to the FDA. 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 interaction with the IL-18 inhibitor 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 place the SON-1411 development program on hold for expense reduction purposes.

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

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 $6.7 million and $0.8 million for the six months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had cash of $2.1 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase 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 Capital Markets LLC ("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 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 MTD was established 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 underway and is expected to be completed in 3Q calendar year 2025. 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 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 after the MTD was established at 1200 ng/kg was released on April 4, 2025. One of the three patients with PROC who were enrolled at the MTD has had a PR.

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 80 subjects, with 13 of 24 evaluable patients (54%) with cancer suggesting clinical benefit of SON-1010 monotherapy (stable disease [SD] at four months). One patient had a PR by RECIST criteria (45% decrease from baseline) to SON-1010 at the highest dose.
- 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 with rhIL-12, which allows higher maintenance doses and potential improvements in efficacy.
- Favorable safety profile.
- Dose escalation has been completed and the SON-1010 MTD was established at 1200 ng/kg in both trials.
- The final 1200 ng/kg dose-escalation cohort in SB101 was increased in size to six patients to enhance the assessment of PK and PD at the MTD. 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)
    - H1 calendar year 2025: Topline Efficacy Data
- Phase 1b/2a: PROC (SON-1010 in Combination with Atezolizumab)
    - H2 calendar year 2025: RP2D Safety & Topline Efficacy
- Phase 1: Soft-tissue Sarcoma (SON-1010 with Trabectedin)
    - H2 calendar year 2025: Topline Efficacy Data

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 data and safety monitoring board reviewed the unblinded safety and tolerability of SON-080 in the first nine patients and concluded that the symptoms were tolerable in the initial patients and the study could proceed to Phase 2. 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_HAB 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. We expect the SOC to initiate SON-1210 dosing in study SOC-241 in H1 calendar year 2025.

Upcoming Milestones:

- H1 calendar year 2025: 1st Patient Dosed in Investigator-Initiated Phase 1b/2a Study

Recent Developments

Patent Update

On January 22, 2025, the European Patent Office granted our Patent No. EP3583125 B1, entitled "Albumin Binding Domain Fusion Proteins," which covers our F_HAB technology and includes therapeutic fusion proteins that utilize F_HAB for tumor targeting and retention, and provide extended pharmacokinetics (PK). The EU patent carries a term effective until February 20, 2038. In addition to the U.S. and EU, our global intellectual property coverage now extends to China, Japan, Russia and New Zealand.

Reverse Stock Split

On September 30, 2024, we effected a reverse stock split of our issued and outstanding common stock at a ratio of 1-for-8 (the "Reverse Stock Split"). Shares of common stock underlying outstanding stock options and other equity instruments convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities in connection with the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to a fractional share of common stock instead received a proportional cash payment. All of our historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock included in this Quarterly Report on Form 10-Q have been adjusted, on a retroactive basis, to reflect the Reverse Stock Split.

Management Updates

On February 10, 2025, Jay Cross submitted his resignation as our Chief Financial Officer, effective February 21, 2025. In connection with Mr. Cross's resignation, on February 12, 2025, our board of directors (the "Board") appointed Donald Griffith, our current Controller and a member of the Board, to succeed Mr. Cross as our Chief Financial Officer effective February 21, 2025.

On February 12, 2025, Stephen McAndrew, Ph.D., our Senior Vice President of Business Development, was appointed as our Chief Business Officer. In connection with his appointment, Dr. McAndrew entered into an employment agreement with the Company, dated February 12, 2025. Dr. McAndrew's employment as our Chief Business Officer commenced on February 17, 2025.

On March 31, 2025, as a result of the passing of Pankaj Mohan, President, Chief Executive Officer and Chairman of the Board, the Board unanimously appointed Raghu Rao, a current member of the Board, as interim Chief Executive Officer and promoted Dr. McAndrew to President and Chief Business Officer.

New Jersey Net Operating Loss Sale

In February 2025, we received net proceeds of $0.7 million from the sale of New Jersey state net operating losses ("NOLs") through the Technology Business Tax Certificate Transfer Program (the "Program").

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 New Life rights to an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in the Exclusive Territory. We identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the "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 into a single performance obligation. Under this agreement, we received upfront cash payments totaling $1.0 million, which were fully allocated to the single performance obligation and 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 Alkem rights to 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 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 into a single performance obligation. Under the Alkem Agreement, we are entitled to upfront cash payments totaling $1.0 million, which have been 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;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved;

- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of product candidates, if approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- the potential impact of 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 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.

Provision for Income Taxes

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

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,		
	2025	**2024**	**Change**
Collaboration revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	1,884,907	2,167,288	(282,381)
General and administrative	2,344,513	1,701,273	643,240
Total operating expenses	4,229,420	3,868,561	360,859
Loss from operations	(4,229,420)	(3,868,561)	(360,859)
Other income	720,102	4,327,946	(3,607,844)
Foreign exchange gain (loss)	18,196	(93,960)	112,156
(Loss) income before provision for income taxes	(3,491,122)	365,425	(3,856,547)
Provision for income taxes	—	—	—
Net (loss) income	$ (3,491,122)	$ 365,425	$ (3,856,547)

Research and Development Expenses

Research and development expenses were $1.9 million for the three months ended March 31, 2025, compared to $2.2 million for the three months ended March 31, 2024. The decrease of $0.3 million was primarily due to cost saving initiatives, as we are managing expenses for liquidity purposes and are tightening our focus on the research and development projects we have assessed to have the greatest near-term potential. Certain development projects have been placed on hold while we seek partnering opportunities.

General and Administrative Expenses

General and administrative expenses were $2.3 million for the three months ended March 31, 2025, compared to $1.7 million for the three months ended March 31, 2024. The increase of $0.6 million was primarily due to costs incurred in connection with the Purchase Agreement and an increase in professional fees.

Other Income

Other income was $0.7 million for the three months ended March 31, 2025, compared to $4.3 million for the three months ended March 31, 2024. The decrease of $3.6 million was due to a reduction in unused New Jersey state NOLs available for sale under the Program.

Comparison of the Six Months Ended March 31, 2025 and 2024

The following table summarizes our results of operations for the six months ended March 31, 2025 and 2024:

	Six Months Ended March 31,		
	2025	**2024**	**Change**
Collaboration revenue	$ 1,000,000	$ 18,626	$ 981,374
Operating expenses:			
Research and development	3,770,983	2,811,330	959,653
General and administrative	4,307,859	2,354,728	1,953,131
Total operating expenses	8,078,842	5,166,058	2,912,784
Loss from operations	(7,078,842)	(5,147,432)	(1,931,410)
Other income	720,102	4,327,946	(3,607,844)
Foreign exchange (loss) gain	(134,688)	16,402	(151,090)
Loss before provision for income taxes	(6,493,428)	(803,084)	(5,690,344)
Provision for income taxes	(158,400)	—	(158,400)
Net loss	$ (6,651,828)	$ (803,084)	$ (5,848,744)

Collaboration Revenue

We recognized $1.0 million of revenue related to the Alkem Agreement during the six months ended March 31, 2025, compared to $18,626 of revenue related to the New Life Agreement during the six months ended March 31, 2024. Revenue of $1.0 million for the six months ended March 31, 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 six months ended March 31, 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 $3.8 million for the six months ended March 31, 2025, compared to $2.8 million for the six months ended March 31, 2024. The increase of $1.0 million was primarily due to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 in the amount of $1.0 million during the six months ended March 31, 2024.

General and Administrative Expenses

General and administrative expenses were $4.3 million for the six months ended March 31, 2025, compared to $2.4 million for the six months ended March 31, 2024. The increase of $2.0 million was primarily due to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 in the amount of $0.9 million during the six months ended March 31, 2024, $0.5 million of costs incurred in connection with the Purchase Agreement during the six months ended March 31, 2025, and a $0.6 million increase in professional fees, including those related to the Alkem Agreement executed during the six months ended March 31, 2025.

Other Income

Other income was $0.7 million for the six months ended March 31, 2025, compared to $4.3 million for the six months ended March 31, 2024. The decrease of $3.6 million was due to a reduction in unused New Jersey state NOLs available for sale under the Program.

Provision for Income Taxes

Provision for income taxes was $0.2 million for the six months ended March 31, 2025 as a result of collaboration revenue earned under the Alkem Agreement.

Liquidity and Capital Resources

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

We have incurred net losses of $6.7 million and $0.8 million for the six months ended March 31, 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 into which we may enter.

We have evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We believe our cash of $2.1 million at March 31, 2025 will fund our projected operations into July 2025. 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:

	Six Months Ended March 31,	
	2025	**2024**
Net cash used in operating activities	$ (5,381,507)	$ (2,367,945)
Net cash used in investing activities	(12,000)	—
Net cash provided by financing activities	7,303,335	3,879,870
Net increase in cash	$ 1,909,828	$ 1,511,925

Operating Activities

During the six months ended March 31, 2025, we used $5.4 million of cash in operating activities, which was primarily attributable to our net loss of $6.7 million, a $0.5 million increase in accounts receivable related to the Alkem Agreement, and a $0.5 million decrease in accounts payable due to payments made from proceeds of the sale of common stock; partially offset by a $0.8 million decrease in prepaid expenses and other current assets primarily related to research and development expenses, $0.5 million of financing costs related to the Purchase Agreement and a $0.5 million decrease in incentive tax receivable due to the collection of the incentive tax receivable for fiscal year 2024.

During the six months ended March 31, 2024, we used $2.4 million of cash in operating activities, which was primarily attributable to a $2.6 million net decrease in accounts payable and accrued expenses and other current liabilities primarily due to the cancellation of accrued but unpaid bonuses that had been awarded for fiscal years 2022 and 2023 and the decrease in research and development expenses and our net loss of $0.8 million; offset by a $1.0 million net decrease in prepaid expenses and other current assets and incentive tax receivable, primarily related to the collection of the incentive tax receivable for fiscal year 2023.

Investing Activities

During the six months ended March 31, 2025, we used $12,000 of cash to purchase in-process research and development. During the six months ended March 31, 2024, we had no cash flows from investing activities.

Financing Activities

During the six months ended March 31, 2025, net cash provided by financing activities was $7.3 million, consisting of $7.8 million of net proceeds from the sale of common stock and pre-funded warrants through a combination of public, registered direct and PIPE offerings, partially offset by the payment of $0.4 million of financing costs related to the Purchase Agreement.

During the six months ended March 31, 2024, net cash provided by financing activities was $3.9 million, consisting primarily of net proceeds from the sale of common stock and pre-funded warrants in a public offering.

Funding Requirements

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we advance preclinical activities and clinical trials of product candidates in development. In addition, we expect to continue to incur costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the scope, number, initiation, progress, timing, costs, design, duration, any potential delays, and results of clinical trials and nonclinical studies for our current or future product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates and programs that we develop or may in-license;
- the outcome, timing and cost of regulatory reviews, approvals or other actions to meet regulatory requirements established by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies for our product candidates than those that we currently expect;
- our ability to obtain marketing approval for product candidates;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights covering our product candidates;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities with respect to product candidates;
- our ability to establish and maintain licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;

- the success of any other business, product or technology that we acquire or in which we invest;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our need and ability to hire additional management and scientific and medical personnel;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for our business;
- market acceptance of our product candidates, to the extent any are approved for commercial sale;
- the effect of competing technological and market developments; and
- the potential impact of a widespread outbreak of any communicable disease on our clinical trials and operations.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, 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.

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 $24.8 million is available to be sold as of March 31, 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 98,846 shares of common stock pursuant to the Purchase Agreement for net proceeds of approximately $0.1 million during the six months ended March 31, 2025.

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.

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.

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 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 are 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.

Contractual Obligations and Commitments

Our contractual obligations as of March 31, 2025 that will affect our future liquidity consist of an operating lease. As of March 31, 2025, we had a current operating lease liability of $0.1 million.

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 unaudited interim consolidated financial statements included elsewhere in this Form 10-Q, 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 March 31, 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 unaudited interim consolidated financial statements included elsewhere in this Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We evaluated, under the supervision and with the participation of the principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended ("Exchange Act")) as of March 31, 2025, the end of the period covered by this report on Form 10-Q. Based on this evaluation, our Interim Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial officer) have concluded that our disclosure controls and procedures were effective at the reasonable assurance level at March 31, 2025.

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) is accumulated and communicated to management, including the principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are subject to various legal proceedings from time to time in the ordinary course of business, which may not be required to be disclosed under this Item 1. For the three-month period ended March 31, 2025 covered by this Quarterly Report, there have been no reportable legal proceedings or material developments to previously reported legal proceedings.

Item 1A. Risk Factors.

As a smaller reporting company, we are not required to provide the information required by this item. However, we direct you to the risk factors included in the "*Risk Factors*" section in our Annual Report on Form 10-K for the year ended September 30, 2024 filed with the Securities and Exchange Commission on December 17, 2024. No material changes to such risk factors have occurred during the quarter ended March 31, 2025.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

a) None.

b) None.

c) During the three months ended March 31, 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 6: Exhibits.

Exhibit No.	Description
10.1†	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/A filed with the SEC on February 7, 2020).
10.2†	Employment Agreement by and between the Company and Stephen McAndrew, Ph.D., dated February 12, 2025 (incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q filed with the SEC on February 13, 2025).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
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 Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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, not filed.

† Indicates a management contract or compensation plan, contract or arrangement.

SIGNATURES

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

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

Date: May 13, 2025

By: */s/ Raghu Rao*
Raghu Rao
Interim Chief Executive Officer
(Principal Executive Officer)

By: */s/ Donald Griffith*
Donald Griffith
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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 Quarterly Report on Form 10-Q of Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") for the period ended March 31, 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: May 13, 2025

/s/ Raghu Rao
Raghu Rao
Interim 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, Donald Griffith certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") for the period ended March 31, 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: May 13, 2025

/s/ Donald Griffith
Donald Griffith
Chief Financial 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 Quarterly Report of Sonnet BioTherapeutics Holdings, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raghu Rao, Interim Chief 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: May 13, 2025

/s/ Raghu Rao
Raghu Rao
Interim 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 Quarterly Report of Sonnet BioTherapeutics Holdings, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Donald Griffith, Chief Financial 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: May 13, 2025

/s/ Donald Griffith
Donald Griffith
Chief Financial 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.