

**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 June 30, 2024

OR

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

For the transition period from ____ to ____

Commission file number: 001-35570

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

20-2932652

(I.R.S. Employer
Identification No.)

100 Overlook Center, Suite 102, Princeton, NJ

(Address of Principal Executive Offices)

08540

(Zip Code)

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 5,202,505 shares of common stock, par value \$0.0001 per share, of Sonnet BioTherapeutics Holdings, Inc. issued and outstanding as of August 14, 2024.

Sonnet BioTherapeutics Holdings, Inc. and Subsidiaries

	<u>Page No.</u>
Part I	Financial Information 3
Item 1:	Financial Statements (unaudited) 3
	Consolidated Balance Sheets 4
	Consolidated Statements of Operations 5
	Consolidated Statements of Changes in Stockholders' Equity (Deficit) 6
	Consolidated Statements of Cash Flows 7
	Notes to Interim Consolidated Financial Statements 8
Item 2:	Management's Discussion and Analysis of Financial Condition and Results of Operations 23
Item 3:	Quantitative and Qualitative Disclosures about Market Risk 37
Item 4:	Controls and Procedures 37
Part II	Other Information 38
Item 1:	Legal Proceedings 38
Item 1A:	Risk Factors 38
Item 2:	Unregistered Sales of Equity Securities and Use of Proceeds 38
Item 3:	Defaults Upon Senior Securities 38
Item 4:	Mine Safety Disclosures 38
Item 5:	Other Information 38
Item 6:	Exhibits 39
	Signatures 40

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

INDEX TO THE UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

PART I - FINANCIAL INFORMATION

Item 1: Financial Statements.

	Page
Consolidated Balance Sheets	4
Consolidated Statements of Operations	5
Consolidated Statements of Changes in Stockholders' Equity (Deficit)	6
Consolidated Statements of Cash Flows	7
Notes to Interim Consolidated Financial Statements	8

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

Assets	June 30, 2024	September 30, 2023
Current assets:		
Cash	\$ 3,554,331	\$ 2,274,259
Prepaid expenses and other current assets	1,053,830	1,677,396
Incentive tax receivable	519,610	786,574
Total current assets	5,127,771	4,738,229
Property and equipment, net	23,733	33,366
Operating lease right-of-use asset	141,813	193,689
Deferred offering costs	15,000	49,988
Other assets	488,480	414,206
Total assets	<u>\$ 5,796,797</u>	<u>\$ 5,429,478</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,879,013	\$ 2,201,999
Accrued expenses and other current liabilities	1,149,492	3,230,922
Current portion of operating lease liability	81,349	73,048
Deferred income	—	18,626
Total current liabilities	3,109,854	5,524,595
Operating lease liability, net of current portion	68,837	130,863
Total liabilities	<u>3,178,691</u>	<u>5,655,458</u>
Commitments and contingencies (Note 4)		
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value: 125,000,000 shares authorized; 5,218,505 and 1,750,426 issued and outstanding at June 30, 2024 and September 30, 2023, respectively	522	175
Additional paid-in capital	117,169,976	110,017,598
Accumulated deficit	(114,552,392)	(110,243,753)
Total stockholders' equity (deficit)	<u>2,618,106</u>	<u>(225,980)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 5,796,797</u>	<u>\$ 5,429,478</u>

See accompanying notes to unaudited interim consolidated financial statements

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

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

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 capital	Accumulated deficit	Total
	Shares	Amount			
Balance at October 1, 2023	1,750,426	\$ 175	\$ 110,017,598	\$ (110,243,753)	\$ (225,980)
Sale of common stock, net of issuance costs	1,306,250	131	3,916,812	—	3,916,943
Retirement of shares in connection with reverse stock split	(1,522)	—	—	—	—
Net share settlement of warrants	14,362	1	(1)	—	—
Share-based compensation	—	—	50,005	—	50,005
Net loss	—	—	—	(1,168,509)	(1,168,509)
Balance at December 31, 2023	<u>3,069,516</u>	<u>307</u>	<u>113,984,414</u>	<u>(111,412,262)</u>	<u>2,572,459</u>
Issuance of common stock on vesting of restricted stock units and restricted stock awards	7,885	—	—	—	—
Exercise of warrants	35,000	4	55,996	—	56,000
Share-based compensation	—	—	60,395	—	60,395
Net income	—	—	—	365,425	365,425
Balance at March 31, 2024	<u>3,112,401</u>	<u>311</u>	<u>114,100,805</u>	<u>(111,046,837)</u>	<u>3,054,279</u>
Sale of common stock	37,654	4	62,015	—	62,019
Net share settlement of warrants	739,950	74	(74)	—	—
Exercise and modification of warrants, net of issuance costs	1,328,500	133	2,946,835	—	2,946,968
Share-based compensation	—	—	60,395	—	60,395
Net loss	—	—	—	(3,505,555)	(3,505,555)
Balance at June 30, 2024	<u><u>5,218,505</u></u>	<u><u>\$ 522</u></u>	<u><u>\$ 117,169,976</u></u>	<u><u>\$ (114,552,392)</u></u>	<u><u>\$ 2,618,106</u></u>

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

See accompanying notes to unaudited interim consolidated financial statements

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

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

See accompanying notes to unaudited interim consolidated financial statements

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

1. Organization and Description of Business

Description of business

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

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

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

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

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

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

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

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

Liquidity

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

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

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

2. Summary of Significant Accounting Policies

a. Basis of presentation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (ASUs”) of the Financial Accounting Standards Board (“FASB”). In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Company’s financial position as of June 30, 2024 and its results of operations and cash flows for the three and nine months ended June 30, 2024 and 2023. The unaudited interim consolidated financial statements presented herein do not contain all of the required disclosures under U.S. GAAP for annual financial statements and should be read in conjunction with the annual audited consolidated financial statements and related notes of Sonnet as of and for the year ended September 30, 2023 included in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2023. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

b. Consolidation

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

c. Use of estimates

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

d. Incentive tax receivable

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

e. Property and equipment

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

f. Collaboration revenue

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

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

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

g. Research and development expense

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

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

h. Other income

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

i. Reverse stock split

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

j. Net loss per share

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

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

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

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

k. Recent accounting pronouncements

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

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

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	September 30, 2023
Compensation and benefits	\$ 189,095	\$ 2,091,196
Research and development	753,497	913,145
Professional fees	204,344	224,031
Other	2,556	2,550
	<u>\$ 1,149,492</u>	<u>\$ 3,230,922</u>

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

4. Commitments and Contingencies

Legal proceedings

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

License agreements

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

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

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

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

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

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

Research and development agreement

In December 2021, the Company entered into a Research and Development Agreement (the “Navigo Agreement”), as subsequently amended, with Navigo Proteins GmbH (“Navigo”), pursuant to which Navigo will perform specified evaluation and development procedures to evaluate certain materials to determine their commercial potential. Under the terms of the Navigo Agreement, the Company has granted Navigo a royalty-free, non-exclusive, worldwide, non-sublicensable, non-transferable right and license to use certain technology to perform the evaluation and development activities, and Navigo has granted the Company (i) an exclusive, worldwide, perpetual, irrevocable, sublicensable, transferable, royalty-free right and license to research, develop, use, sell, have sold, distribute, import or otherwise commercially exploit certain materials, and (ii) a non-exclusive, worldwide, perpetual, sublicensable, non-transferable right and license to make or have made such materials. The Company incurred a \$0.1 million technology access fee upon execution of the Navigo Agreement, at which time it was recorded as acquired in-process research and development. The Company is obligated to make contingent milestone payments to Navigo, totaling up to \$1.0 million upon the achievement of certain evaluation and development milestones as outlined in the Navigo Agreement. Certain evaluation milestones were achieved in 2023, including \$0.2 million and \$0.3 million, respectively, in license fees which were recorded as acquired in-process research and development and included as research and development expenses in the unaudited interim consolidated statement of operations for the three and nine months ended June 30, 2023. No milestones were achieved and no license fees were incurred during the three and nine months ended June 30, 2024.

Employment agreements

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the contract. In addition, in the event of termination of employment following a change in control, as defined, either by the Company without cause or by the employee for good reason, any unvested portion of the employee’s initial stock option grant becomes immediately vested.

5. Collaboration Revenue

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

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

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

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

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

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

Revenue recognition

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

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

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

6. Stockholders' Equity (Deficit)

On May 2, 2024, the Company entered into a ChEF Purchase Agreement (the “Purchase Agreement”) and a Registration Rights Agreement (the “Registration Rights Agreement”), each with Chardan Capital Markets LLC (“Chardan”) related to a “ChEF,” Chardan’s committed equity facility (the “Facility”). Pursuant to the Purchase Agreement, the Company has the right from time to time at its option to sell to Chardan up to the lesser of (i) \$25.0 million in aggregate gross purchase price of newly issued shares of the Company’s common stock and (ii) 622,168 shares of the Company’s common stock, which is equal to 19.99% of the shares of common stock outstanding immediately prior to the execution of the Purchase Agreement (the “Exchange Cap”), unless (i) the average price of such shares sold to Chardan under the Facility equals or exceeds the base price set forth in the Purchase Agreement, so that the Exchange Cap limitation would not apply to such issuances and sales pursuant to the Purchase Agreement under the rules of the Nasdaq Stock Market or (ii) the Company’s stockholders approve the issuance of common stock pursuant to the Purchase Agreement in excess of the Exchange Cap. The Facility will allow the Company to raise primary equity on a periodic basis at its sole discretion depending on a variety of factors including, among other things, market conditions, the trading price of the common stock, and determinations by the Company regarding the use of proceeds of such common stock. The purchase price of the shares of common stock will be determined by reference to the Volume Weighted Average Price (“VWAP”) of the common stock during the applicable purchase period, less a fixed 4% discount to such VWAP, and the total shares to be purchased on any day may not exceed 20% of the trading volume of the Company’s common stock during the applicable purchase period. The Purchase Agreement will be effective for a 36-month period ending May 16, 2027. During the three and nine months ended June 30, 2024, the Company sold 37,654 shares of common stock pursuant to the Purchase Agreement for net proceeds of \$0.1 million. The Company incurred \$0.4 million of costs in connection with the Purchase Agreement during the three and nine months ended June 30, 2024, which are included in general and administrative expenses in the unaudited interim consolidated statements of operations.

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

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

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

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

Common stock warrants

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

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

On June 19, 2024, the Company entered into inducement offer letter agreements with holders of certain existing warrants issued in October 2023 having an original exercise price of \$1.60 per share to purchase up to an aggregate of 2,828,500 shares of the Company’s common stock at a reduced exercise price of \$1.20 per share. The transaction closed on June 21, 2024, resulting in gross proceeds to the Company of \$3.4 million and net proceeds of \$2.9 million. Due to beneficial ownership limitations, 1,500,000 shares of common stock related to the exercise of warrants in this transaction are being held in abeyance as of June 30, 2024. Also in connection with this inducement offer, the Company (i) issued to holders who participated in the transaction new common stock warrants to purchase an aggregate of 5,625,000 shares of common stock, (ii) reduced the exercise price of existing warrants to purchase 2,840,000 shares of common stock for those holders who did not exercise warrants in the transaction from \$1.60 per share to \$1.20 per share for the remaining term of the warrants, and (iii) reduced the exercise price of certain existing warrants issued in June 2023 to purchase 227,272 shares of common stock from \$14.8478 per share to \$1.55 per share and extended the expiration date of these warrants from December 30, 2026 to June 21, 2029. The new common stock warrants are immediately exercisable at a price of \$1.55 per share and expire five years from the date of issuance. Warrants to purchase 113,140 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants are immediately exercisable at a price of \$1.86 per share and expire five years from the date of issuance. The incremental fair value associated with the modification of certain existing June and October 2023 warrants to purchase common stock has been accounted for in additional paid-in capital as an equity cost because the modification was done in order to raise equity by inducing the exercise of warrants.

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

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

7. Share-Based Compensation

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

Restricted stock units and awards

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

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

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

The following table summarizes RSU activity under the Plan:

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

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

The following table summarizes RSA activity under the Plan:

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

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

8. Income Taxes

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

9. Subsequent Events

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 passages of future laws;
- acceptance of our business model by investors;
- the emergence and effect of competing or complementary products, including the ability of our future products to compete effectively;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

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 1A - 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 improve drug accumulation in solid tumors, as well as to extend the duration of activity in the body. F_HAB development candidates can be produced in mammalian cell culture, which enables glycosylation of the interleukins, thereby reducing the risk of immunogenicity, as well as E. coli. We believe our F_HAB technology, for which we received an initial U.S. patent in June 2021 and a continuation of such patent in June 2024, is a distinguishing feature of our biopharmaceutical platform. The approach is well suited for future drug development across a range of human disease areas, including in oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

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

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

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

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

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

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

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.

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

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

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

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

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, including sales pursuant to our 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): Solid Tumors (Monotherapy)

This first-in-human study is primarily designed to evaluate the safety of multiple ascending doses of SON-1010 in cancer patients and is being conducted at several sites across the United States.

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 efficacy of SON-1010 administered subcutaneously (SC), either alone or in combination with atezolizumab given intravenously (IV).

Program Highlights:

- PK data reveals about 10-fold extended half-life for SON-1010 compared with rhIL-12 and suggests tumor targeting by the F_HAB.
- Dose-related IFN γ response.
- The SB101 trial and the SB221 trial have collectively enrolled 61 subjects, with 8 of 23 patients (35%) with cancer suggesting clinical benefit of SON-1010 (Stable Disease at 4 months).
- Patients have received up to 25 cycles of SON-1010 as monotherapy and up to 10 cycles of SON-1010 with atezolizumab (Tecentriq[®]) without dose-limiting toxicity at any dose level.
- Toxicity is minimized in both trials with the use of a ‘desensitizing’ first dose that takes advantage of the known tachyphylaxis with rhIL-12, which allows higher maintenance doses and potential improvements in efficacy.
- Favorable safety profile.

Upcoming Milestones:

- Phase 1: Solid Tumors (Monotherapy)
 - 2H 2024: Safety Data
 - 1H 2025: Topline Efficacy Data
- Phase 1b/2a: PROC (Combo with Atezolizumab)
 - 2H 2024: Additional Safety Data
 - 2H 2025: RP2D & Topline Efficacy Data

SON-080

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

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

Phase 1b Data Highlights:

- SON-080 demonstrated to be well-tolerated at both 20 μ g and 60 μ g/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:

- Seeking partnership to support initiation of a Phase 2 clinical trial in DPN, a mechanistically synergistic and larger, high-value indication with unmet medical need.

Recent Developments

Patent Update

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

Nasdaq Letter

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

We have timely requested a hearing before the Panel, at which hearing we will request an extension within which to evidence compliance with the Bid Price Requirement. Our request for a hearing automatically stayed any suspension or delisting action by the Staff pending the hearing and the expiration of any additional extension period that may be granted by the Panel following the hearing. We intend to continue to take definitive steps in an effort to evidence compliance with the Bid Price Requirement, including by effecting a reverse stock split. However, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the Bid Price Requirement within any extension period that may be granted by the Panel or maintain compliance with the other Nasdaq listing requirements.

Components of Results of Operations

Collaboration Revenue

Collaboration revenue is currently earned from the license arrangement entered into with New Life in May 2021, which granted New Life rights to an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the “Compound”) (such preparations, the “Products”) for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the “DPN Field”) in the Exclusive Territory. We identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the “License”); and (ii) transfer of know-how and clinical development and regulatory activities (“R&D Activities”). We determined that the License and the R&D Activities are not distinct from each other and, therefore, combined these material promises into a single performance obligation. Under this agreement, we received upfront cash payments totaling \$1.0 million, which were fully allocated to the single performance obligation and are being recognized over the estimated performance period of R&D Activities.

Operating Expenses

Research and Development Expenses

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

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

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

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

We will continue to incur research and development expenses for the foreseeable future as we attempt to advance development of our product candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our current pipeline or any future product candidates we may develop due to the numerous risks and uncertainties associated with clinical development, including risk and uncertainties related to:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs that we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with investigational new drug-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;

- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of product candidates, if approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- the potential impact of the widespread outbreak of any communicable disease on operations which may affect among other things, the timing of clinical trials, availability of raw materials, and the ability to access and secure testing facilities.

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

General and Administrative Expenses

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

Our general and administrative expenses will increase in the future as we increase our headcount to support continued research activities and development of product candidates. We will continue to incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Other Income

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

Foreign Exchange Gain (Loss)

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

Results of Operations

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

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

	Three Months Ended June 30,		Change
	2024	2023	
Collaboration revenue	\$ —	\$ 36,850	\$ (36,850)
Operating expenses:			
Research and development	1,727,033	2,409,471	(682,438)
General and administrative	1,801,632	1,542,689	258,943
Total operating expenses	3,528,665	3,952,160	(423,495)
Loss from operations	(3,528,665)	(3,915,310)	386,645
Foreign exchange gain (loss)	23,110	(31,432)	54,542
Net loss	\$ (3,505,555)	\$ (3,946,742)	\$ 441,187

Collaboration Revenue

We did not recognize any revenue related to the New Life Agreement during the three months ended June 30, 2024, compared to \$36,850 during the three months ended June 30, 2023. The decrease of \$36,850 was due to our completion of R&D Activities during the first quarter of fiscal 2024.

Research and Development Expenses

Research and development expenses were \$1.7 million for the three months ended June 30, 2024, compared to \$2.4 million for the three months ended June 30, 2023. The decrease of \$0.7 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. In addition to transitioning product development activities to cost advantaged locations such as India and Australia, we have reduced expenditures on tertiary programs and suspended antiviral development related to SON-1010, as well as programs related to SON-080 and SON-1210 while we seek partnering opportunities.

General and Administrative Expenses

General and administrative expenses were \$1.8 million for the three months ended June 30, 2024, compared to \$1.5 million for the three months ended June 30, 2023. The increase of \$0.3 million related primarily to costs incurred in connection with the Purchase Agreement and an increase in legal and professional expenses and franchise taxes, partially offset by a decrease in consulting expenses related to licensing.

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

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

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

Collaboration Revenue

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

Research and Development Expenses

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

General and Administrative Expenses

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

Other Income

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

Liquidity and Capital Resources

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

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

We have evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We believe our cash of \$3.6 million at June 30, 2024 will fund our projected operations into November 2024. 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:

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

Operating Activities

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

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

Investing Activities

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

Financing Activities

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

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

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 the COVID-19 pandemic or the widespread outbreak of any other communicable disease on our clinical trials and operations.

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

October 2023 Offering

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

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 the lesser of (i) \$25.0 million in aggregate gross purchase price of newly issued shares of our common stock and (ii) 622,168 shares of our common stock, which is equal to 19.99% of the shares of common stock outstanding immediately prior to the execution of the Purchase Agreement (the “Exchange Cap”), unless (i) the average price of such shares sold to Chardan under the Facility equals or exceeds the base price set forth in the Purchase Agreement, so that the Exchange Cap limitation would not apply to such issuances and sales pursuant to the Purchase Agreement under the rules of the Nasdaq Stock Market or (ii) our stockholders approve the issuance of common stock pursuant to the Purchase Agreement in excess of the Exchange Cap. The Facility will allow us to raise primary equity on a periodic basis at our sole discretion depending on a variety of factors including, among other things, market conditions, the trading price of the common stock, and determinations by us regarding the use of proceeds of such common stock. The purchase price of the shares of common stock will be determined by reference to the Volume Weighted Average Price (“VWAP”) of the common stock during the applicable purchase period, less a fixed 4% discount to such VWAP, and the total shares to be purchased on any day may not exceed 20% of the trading volume of our common stock during the applicable purchase period. The Purchase Agreement will be effective for a 36-month period ending May 16, 2027, unless earlier terminated upon the terms and conditions therein. During the three and nine months ended June 30, 2024, we sold 37,654 shares of common stock pursuant to the Purchase Agreement for net proceeds of \$0.1 million.

June 2024 Inducement Offer

On June 19, 2024, we entered into inducement offer letter agreements with holders of certain existing warrants issued in October 2023 having an original exercise price of \$1.60 per share to purchase up to an aggregate of 2,828,500 shares of our common stock at a reduced exercise price of \$1.20 per share. The transaction closed on June 21, 2024, resulting in gross proceeds of \$3.4 million and net proceeds of \$2.9 million. Due to beneficial ownership limitations, 1,500,000 shares of common stock related to the exercise of warrants in this transaction are being held in abeyance as of June 30, 2024. Also in connection with this inducement offer, we (i) issued to holders who participated in the transaction new common stock warrants to purchase an aggregate of 5,625,000 shares of common stock, (ii) reduced the exercise price of existing warrants to purchase 2,840,000 shares of common stock for those holders who did not exercise warrants in the transaction from \$1.60 per share to \$1.20 per share for the remaining term of the warrants, and (iii) reduced the exercise price of certain existing warrants issued in June 2023 to purchase 227,272 shares of common stock from \$14.8478 per share to \$1.55 per share and extended the expiration date of these warrants from December 30, 2026 to June 21, 2029. The new common stock warrants are immediately exercisable at a price of \$1.55 per share and expire five years from the date of issuance. Warrants to purchase 113,140 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants are immediately exercisable at a price of \$1.86 per share and expire five years from the date of issuance.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of June 30, 2024 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years	Total
Operating Lease (1)	\$ 95,014	\$ 72,324	\$ —	\$ —	\$ 167,338
Total	\$ 95,014	\$ 72,324	\$ —	\$ —	\$ 167,338

(1) Reflects obligations pursuant to our office lease in Princeton, New Jersey.

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

Critical Accounting Policies and Estimates

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

While our significant accounting policies are described in more detail in the notes to the unaudited interim consolidated financial statements included elsewhere in this 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 June 30, 2024, we did not make any material adjustments to our prior estimates of accrued research and development expenses.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to the 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 December 31, 2023, the end of the period covered by this report on Form 10-Q. Based on this evaluation, our Chairman, President and 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 June 30, 2024.

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 June 30, 2024 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 June 30, 2024 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, 2023 filed with the Securities and Exchange Commission on December 14, 2023.

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 June 30, 2024, 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	<u>ChEF Purchase Agreement, dated as of May 2, 2024, by and between Sonnet BioTherapeutics Holdings, Inc. and Chardan Capital Markets LLC (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on May 3, 2024).</u>
10.2	<u>Registration Rights Agreement, dated as of May 2, 2024, by and between Sonnet BioTherapeutics Holdings, Inc. and Chardan Capital Markets LLC (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on May 3, 2024).</u>
10.3	<u>Form of June 2024 Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024).</u>
10.4	<u>Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024).</u>
10.5	<u>Form of Inducement Letter (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024).</u>
31.1	<u>Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).</u>
31.2	<u>Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).</u>
32.1**	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).</u>
32.2**	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).</u>
101.INS*	Inline XBRL Instance 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).

* XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

** Furnished, not filed.

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: August 14, 2024

By: /s/ Pankaj Mohan

Pankaj Mohan
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Jay Cross

Jay Cross
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Pankaj Mohan, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2024 of Sonnet BioTherapeutics Holdings, Inc.;
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.

/s/ Pankaj Mohan

Pankaj Mohan
Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2024

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Jay Cross, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2024 of Sonnet BioTherapeutics Holdings, Inc.;
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.

/s/ Jay Cross

Jay Cross

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

Date: August 14, 2024

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

I, Pankaj Mohan, certify that:

1. I am the Chief Executive Officer of Sonnet BioTherapeutics Holdings, Inc. (the "Issuer").
2. Attached to this certification is the Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 (the "Report") filed by the Issuer with the Securities Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), which contains financial statements.
3. I hereby 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:
 - The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
 - The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Issuer.

August 14, 2024

/s/ Pankaj Mohan

Pankaj Mohan
Chief Executive Officer
(Principal Executive Officer)

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

I, Jay Cross, certify that:

1. I am the Chief Financial Officer of Sonnet BioTherapeutics Holdings, Inc. (the "Issuer").
2. Attached to this certification is the Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 (the "Report") filed by the Issuer with the Securities Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), which contains financial statements.
3. I hereby 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:
 - The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
 - The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Issuer.

August 14, 2024

/s/ Jay Cross

Jay Cross
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
