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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **August 14, 2024**

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

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

100 Overlook Center, Suite 102 Princeton, New Jersey	**08540**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

Item 2.02. Results of Operations and Financial Condition.

On August 14, 2024, Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") issued a press release regarding its financial results for the three months ended June 30, 2024. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Forward-Looking Statements

This report, including Exhibit 99.1 furnished herewith, contains forward-looking statements within the meaning of the federal securities laws. Forward-looking statements typically are identified by use of terms such as "may," "will," "should," "plan," "expect," "anticipate," "estimate" and similar words, and the opposites of such words, although some forward-looking statements are expressed differently. Forward-looking statements involve known and unknown risks and uncertainties that exist in the Registrant's operations and business environment, which may be beyond the Registrant's control, and which may cause actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. For example, forward-looking statements include, without limitation: statements regarding prospects for additional customers; market forecasts; projections of earnings, revenues, synergies, accretion or other financial information; and plans, strategies and objectives of management for future operations. The risks and uncertainties referred to above include, but are not limited to, risks detailed from time to time in the Registrant's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended September 30, 2023. These risks could cause actual results to differ materially from those expressed in any forward-looking statements made by, or on behalf of, the Registrant. Forward-looking statements represent the judgment of management of the Registrant regarding future events. Although the Registrant believes that the expectations reflected in such forward-looking statements are reasonable at the time that they are made, the Registrant can give no assurance that such expectations will prove to be correct. Unless otherwise required by applicable law, the Registrant assumes no obligation to update any forward-looking statements, and expressly disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit
99.1	Press Release, dated August 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

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

Date: August 14, 2024

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

Exhibit 99.1

Sonnet BioTherapeutics Reports Third Quarter Fiscal Year 2024 Financial Results and Provides Corporate Update

Ongoing progress with both clinical trials of lead program, SON-1010, for solid tumors and Platinum-Resistant Ovarian Cancer (PROC)

Partnership efforts to support initiation of a Phase 2 clinical trial of SON-080 in Diabetic Peripheral Neuropathy (DPN) underway

Granted composition of matter patent in key territory – the United States – covering SON-1210 and its application in high-value solid tumor indications with significant unmet need, including pancreatic cancer

Multiple value-driving milestones expected in 2024 and throughout 2025 as well as pipeline expansion opportunities throughout high-value solid tumor market

PRINCETON, NJ / ACCESSWIRE / August 14, 2024 / Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today reported financial results for the three and nine months ended June 30, 2024 and provided a corporate update.

"We continue to be encouraged with the data generated by our lead program SON-1010. While preliminary, demonstrating evidence of clinical benefit at 4 months in 35% of evaluable patients in both of our ongoing studies of SON-1010 represents a significant opportunity to help patients with PROC and address an indication in desperate need of innovative therapies," commented Pankaj Mohan, Ph.D., Founder and CEO of Sonnet. "Additionally, we are actively working to identify a partner to help advance our SON-080 program through the next phases of development and potentially address a significant unmet need in diabetic peripheral neuropathy."

Recent Highlights

- Reported encouraging data from Phase 1b/2a clinical trial of SON-080 in Chemotherapy-Induced Peripheral Neuropathy (CIPN) that support advancement into Phase 2 study;
- Announced the exercise of warrants for $3.4 million in gross proceeds;
- Announced the generation and *in vitro* characterization of two novel drug candidates, SON-1411 (IL18-F_HAB-IL12) and SON-1400 (IL18-F_HAB), each containing a modified version of recombinant human interleukin-18 (IL-18);
- Presented the SB221 study of SON-1010 (recombinant human Interleukin-12 linked to Sonnet's fully-human albumin binding domain or IL12-F_HAB) dosed in combination with atezolizumab (Tecentriq®) in a 'Trial in Progress' poster at the ASCO Annual Meeting in June 2024; and
- Announced updated clinical data for SON-1010 as monotherapy or combined with atezolizumab, an anti-PD-L1 antibody, along with an increase in the dose-escalation target.

Patent Update

- On June 11, 2024, the U.S. Patent and Trademark Office (USPTO) granted patent No. 12,006,361, titled, "*Albumin Binding Domain Fusion Proteins*," covering composition of matter for product candidate SON-1210, the Company's proprietary, bifunctional version of human Interleukins 12 (IL-12) and 15 (IL-15), configured using Sonnet's Fully Human Albumin Binding (F_HAB®) platform. The granted patent is a Continuation of Patent No. 11,028,166 issued in June 2021.

"We remain committed to strengthening the intellectual property portfolio for our F_HAB enabling technology platform and are pleased to further expand our patent estate in this key territory for Sonnet with this granted U.S. patent for SON-1210, our dual-targeting cytokine. We believe that including SON-1210 in our unique platform may create a next generation cancer treatment that can enhance patients' own immune systems to fight cancer. We look forward to identifying a development pathway through a collaboration for the continued advancement of SON-1210 and offering patients with cancer a much needed therapeutic option," added Pankaj Mohan, Ph.D., Founder and CEO of Sonnet.

Lead Clinical Programs Update

SON-1010*: Targeted Immune Activation Cancer Therapy, Turning 'Cold' Tumors 'Hot' Initially Targeting Solid Tumors and Platinum-Resistant Ovarian Cancer (PROC)*

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.

For more information about the SB101 clinical trial, visit clinicaltrials.gov and reference identifier NCT05352750.

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) in combination with atezolizumab given intravenously (IV).

For more information about the SB221 clinical trial, visit clinicaltrials.gov and reference identifier NCT05756907.

SON-1010 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 IFNγ 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.

SON-1010 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: *Low dose of rhIL-6 for Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN)*

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 µg and 60 µg/dose, which was about 10-fold lower than the maximum tolerated dose (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.

For more information about the SB211 study, visit clinicaltrials.gov and reference identifierNCT05435742.

SON-080 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.

Summary of Financial Results for the Third Quarter 2024

As of June 30, 2024, Sonnet had $3.6 million cash on hand, which the Company believes is sufficient to fund operations into November 2024.

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 the Company is managing expenses for liquidity purposes and is tightening its focus on the research and development projects it has assessed to have the greatest near-term potential. In addition to transitioning product development activities to cost advantaged locations such as India and Australia, the Company has 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 it seeks potential partnering opportunities.

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 May 2024 ChEF Purchase Agreement entered into with Chardan Capital Markets LLC and an increase in legal and professional expenses and franchise taxes, partially offset by a decrease in consulting expenses related to licensing.

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of single or bifunctional action. Known as F_HAB (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. Sonnet's F_HAB was designed to specifically target tumor and lymphatic tissue, with an improved therapeutic window for optimizing the safety and efficacy of immune modulating biologic drugs. F_HAB is the foundation of a modular, plug-and-play construct for potentiating a range of large molecule therapeutic classes, including cytokines, peptides, antibodies, and vaccines.

Forward-Looking Statements

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

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

Investor Relations Contact:

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

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

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

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