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): **May 10, 2023**

SONNET BIOTHERAPEUTICS HOLDINGS, INC.
(Exact Name of Registrant as Specified in 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)

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 or to be 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 Stock 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 May 10, 2023, Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") issued a press release regarding financial results for the three months ended March 31, 2023. 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, 2022. 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 May 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: May 10, 2023

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

Exhibit 99.1

Sonnet BioTherapeutics Provides Fiscal Year 2023 Second Quarter and Year-to-Date Business and Earnings Update

- ***Additional data presented from two clinical trials of SON-1010 in both healthy volunteers and patients with advanced solid tumors. Cytokine data reveal extended PK profile for SON-1010:***
  - ***Induces prolonged and controlled IFNγ response***
  - ***No evidence of cytokine release syndrome***
  - ***Clinical benefit was seen in 36% of patients (5/14) with advanced solid tumors***
- ***Entered into a collaboration with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®) in ovarian cancer with study initiation currently underway***
- ***Announced data from two IND-enabling toxicology studies with SON-1210 in non-human primates***
  - ***Doses were well tolerated at over 50 times the anticipated human dose***
- ***Successfully completed a $15.0 million underwritten public offering***

PRINCETON, NJ / ACCESSWIRE / May 10, 2023 / Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) ("Sonnet" or the "Company"), a biopharmaceutical company developing innovative targeted biologic drugs, announced today its financial results for the three months and six months ended March 31, 2023 and provided a business update.

"We believe this quarter marked another noteworthy period of execution for Sonnet, where we made important progress with our pipeline, entered into a product development collaboration with Roche, and furthered our cost-cutting plan to extend our cash runway into the 2024 calendar year," said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "We remain incredibly enthusiastic about the best-in-class potential of our proprietary IL-12 therapeutic candidate, SON-1010, where our recent presentation at the 2023 American Association for Cancer Research Annual Meeting supported the consistency of the compound's data and reiterated the robustness of its overall profile. Additionally, we are very excited about the non-human primate data that we have generated with SON-1210, our proprietary bifunctional version of human Interleukins 12 (IL-12) and 15 (IL-15), that we believe will help propel the compound into clinical development. We are looking forward to continuing this forward momentum over the balance of 2023."

FY 2023 Second Quarter and Recent Corporate Updates

Sonnet provided the following corporate updates:

- On January 9, 2023, announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab. The companies have entered into a Master Clinical Trial and Supply Agreement (MCSA), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer (PROC) patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). The SB221 study has been formally submitted for final approval in Australia and preparations are on track to initiate the study during the second calendar quarter of 2023.

- On January 19, 2023, announced that the interim pharmacokinetic (PK) profile simulation of SON-1010 dosing had been completed in the randomized, placebo-controlled Phase 1 clinical trial (SB102) of healthy volunteers. Study SB102 is a single-ascending dose trial that was initiated in July 2022, to address the safety, PK, and PD of SON-1010 in subjects without interference from prior chemotherapy. Data from the first 24 of a total of 31 patients enrolled have been presented to date, most recently at the 2023 American Association for Cancer Research (AACR) Annual Meeting. As an update, the 5th dose cohort was removed, as enough data have now been collected to support the dosing strategy in the cancer trials moving forward. Typical dose-related increases were seen with SON-1010, drug levels peaked at about 11 hours with a geometric mean maximum concentration (C_{max}) of 29, 68, and 125 pg/mL for the 50, 100, and 150 ng/kg dose groups, respectively. The mean elimination half-life ($t_{½}$) after a 150 ng/kg dose of SON-1010 was 112 hours, compared to the published value of 12 hours for rhIL-12. Observed increases in interferon gamma (IFNγ) were most pronounced and were dose-related, controlled, and prolonged. SON-1010 induced IFNγ in all active-drug subjects, which peaked at 24 to 48 hours then returned to baseline after 2 weeks. Low amounts of IL-10 were induced in a dose-dependent manner, which could also be due to the increase in IFNγ. There were small transient increases in IL-6, IL-8, and TNFα after dosing but no consistent pattern was seen with IL-1β, IL-2, or IL-4 and there was no evidence of cytokine release syndrome (CRS). Safety was consistent with what has been reported previously; adverse events have generally been mild/moderate, transient in nature, and have all been tolerable.
- On February 1, 2023, announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. SON-1210 is a proprietary, bispecific version of human Interleukins 12 (IL-12) and 15 (IL-15), configured using Sonnet's Fully Human Albumin Binding (F_HAB) platform. The first of two studies, a non-GLP toxicology study, was designed to elucidate the maximum tolerated dose (MTD) of SON-1210 in a dose-escalation format in four cohorts of NHPs. The second study was a GLP repeat-dose toxicology study that employed three dose levels of SON-1210 or a vehicle control, each dosed three times every two weeks. There were no SON-1210-related increases in toxicity, including liver enzymes, in the GLP study apart from the expected, and mild, on-target changes in hematology and clinical chemistry parameters that resolved completely within 14 to 21 days post-dosing. A significant increase in IFNγ, which was transient in nature, was noted as early as one day following administration, with no apparent increase in other proinflammatory cytokines. Sonnet remains on track to initiate the regulatory authorization process for SON-1210 in the first half of calendar 2023.
- On February 8, 2023, announced the pricing of an underwritten public offering of 13,888,888 shares of common stock or common stock equivalents (which includes pre-funded warrants to purchase shares of common stock in lieu of shares of common stock) and investor warrants to purchase up to an aggregate of 27,777,776 shares of common stock. Each share of common stock (or pre-funded warrant in lieu thereof) were sold together with one investor warrant to purchase two shares of common stock at a combined offering price of $1.08, for total gross proceeds of $15.0 million, before underwriting discounts and commissions and offering expenses payable by Sonnet. The investor warrants have an exercise price of $1.08 per share, are exercisable for a period of five years and contain an alternative cashless exercise provision whereby, subject to certain conditions, a warrant may be exercised in a cashless transaction for shares of common stock at the rate of half a share of common stock per full share otherwise issuable upon a cash exercise.
- On April 18, 2023, presented additional data from the SB101 study of SON-1010 at the 2023 AACR Annual Meeting. SB101 is a single-ascending dose (SAD) trial in adult patients with advanced solid tumors that commenced in the second quarter of 2022 and is currently enrolling the final dose cohort. Of the 15 patients from the first five cohorts of SB101 evaluable for follow-up at this latest cutoff, 9 had stable disease at the first follow-up scan, 4 of which were already progressing at study entry. At the four-month follow-up, 5 of 14 patients remained stable at the second scan, suggesting clinical benefit of SON-1010 in 36% of patients. As an example, the very first patient dosed, with an aggressive endometrial sarcoma, had target tumor shrinkage with complete resolution of ascites at one point and has been clinically stable for nearly a year. SON-1010 has been safe and tolerable at all doses tested to date. Adverse events have generally been mild/moderate and transient in nature, with no study discontinuations for safety reasons. In addition, adverse effects have been less numerous and less intense with subsequent doses. The geomean half-life ($t_{½}$) of SON-1010 was 113 hours in SB101 and 122 hours in SB102, compared to the published value of 12 hours for recombinant IL-12 observed in prior studies. Comparison of the PK curves between the two studies suggests that SON-1010 may be targeting tumors, as it was designed to do. Cytokine analysis following each dose revealed controlled and prolonged induction of IFNγ that peaked at 24 to 48 hours and returned to baseline after 2 to 4 weeks. A small increase in IL-10 was observed with each dose as expected in response to IFNγ. There was either a minimal or no signal for IL-1β, IL-6, IL-8, and TNFα and no indication of any potential for cytokine release syndrome (CRS) at these doses.

- Sonnet has initiated an ex-U.S. Phase 1b/2a study with SON-080 in CIPN. This study is on track to yield initial clinical safety data during the first half of calendar 2023. Pursuant to a license agreement the Company entered 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 evaluate the data and potentially initiate a Phase 2 study in the second half of calendar 2023, once the CIPN safety data has been evaluated.
- Preclinical development continues for SON-1410 (IL18-F_HAB-IL12), Sonnet's proprietary bispecific combination of Interleukins 18 (IL-18) and 12 (IL-12), with early experimental drug supply suitable for formulation and analytical method development activities, in addition to small quantities for use in early development proof-of-concept *in vitro* studies. Process development activities will continue through 2023, with the potential to generate a drug suitable for initial *in vivo* mouse studies by the end of the 2023 calendar year.
- As part of the ongoing cost-cutting evaluations, all antiviral development with SON-1010 has been suspended.

"After initiating human studies just over a year ago, the clinical development program is moving forward rapidly on several fronts with four active trials being conducted in collaboration with two external partners," said Richard Kenney, M.D., Sonnet Chief Medical Officer. "We are very pleased with the team's progress to date and are on track to meet our projected targets. The dose of SON-1010 was escalated safely in both cancer patients in SB101 and in healthy volunteers in SB102. Comparison of the data from the two trials shows intriguing pharmacokinetic profiles that suggest direct targeting of tumor tissue, as we presented at AACR last month. The combination of SON-1010 with atezolizumab in SB221 has the potential to induce a synergistic response in platinum-resistant ovarian cancer, and we are excited about the potential added benefit that SON-1010 can bring to these patients with this significant unmet medical need. While the SB211 trial with SON-080 in patients with chemotherapy-induced peripheral neuropathy is still blinded, no serious adverse events have been reported to date."

FY 2023 Second Quarter Ended March 31, 2023 Financial Results

- As of March 31, 2023, Sonnet had $11.4 million cash on hand and no debt. On February 10, 2023, the company closed a public offering for gross proceeds of $15.0 million (net proceeds of $13.6 million), issuing 11,664,888 shares of common stock, pre-funded warrants to purchase 2,224,000 shares of common stock, with an exercise of $0.0001 per share, and common warrants to purchase 27,777,776 shares of common stock, with an exercise price of $1.08 per share.
- Research and development expenses were $3.8 million for the three months ended March 31, 2023, compared to $6.4 million for the three months ended March 31, 2022. The decrease of $2.6 million was primarily due to the establishment of cost savings by transitioning product development activities to cost advantaged locations such as India and Australia and by reducing expenditures on tertiary programs such as SON-3015, which has been placed on a development hold, as well as a decrease in share-based compensation expense.

- General and administrative expenses were $1.9 million for each of the three months ended March 31, 2023 and 2022. There was no significant change in general and administrative expense as we are managing expenses for liquidity purposes.

"Following the successful completion of a $15.0 million financing in February and the cost-cutting objectives that we previewed during the first fiscal quarter of 2023, we have implemented constructive measures to extend our cash runway. These are important initiatives that we have undertaken to deliver on our stated objective of advancing our drug development pipeline, which has progressed considerably over the last 18 months" said Jay Cross, CFO.

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of single or bispecific, 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 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.

Sonnet BioTherapeutics Investor Contact:

Michael V. Morabito, Ph.D.
Solebury Strategic Communications
917-936-8430
mmorabito@soleburystrat.com

SOURCE: Sonnet BioTherapeutics, Inc.

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

	March 31, 2023	September 30, 2022
Assets		

Current assets:		
Cash	$ 11,390,177	$ 3,052,879
Incentive tax receivable	447,010	717,305
Prepaid expenses and other current assets	1,208,641	1,643,743
Total current assets	13,045,828	5,413,927
Property and equipment, net	39,789	46,211
Operating lease right-of-use asset	225,709	256,594
Deferred offering costs	—	113,280
Total assets	$ 13,311,326	$ 5,830,012
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Related-party notes	$ 748	$ 748
Accounts payable	4,500,043	4,752,340
Accrued expenses and other current liabilities	3,112,282	3,193,972
Operating lease liability	67,920	51,328
Deferred income	92,731	166,431
Total current liabilities	7,773,724	8,164,819
Operating lease liability	168,939	203,912
Total liabilities	7,942,663	8,368,731
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock; $0.0001 par value: 5,000,000 shares authorized. No shares issued or outstanding	—	—
Common stock; $0.0001 par value: 125,000,000 shares authorized; 20,498,370 and 5,544,528 shares issued and outstanding at March 31, 2023 and September 30, 2022, respectively	2,050	554
Additional paid-in capital	107,986,885	88,871,786
Accumulated deficit	(102,620,272)	(91,411,059)
Total stockholders' equity (deficit)	5,368,663	(2,538,719)
Total liabilities and stockholders' equity (deficit)	$ 13,311,326	$ 5,830,012

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 36,445	$ 95,320	$ 73,700	$ 225,119
Operating expenses:				
Research and development	3,816,644	6,405,273	7,562,584	10,671,138
General and administrative	1,884,569	1,900,263	3,788,278	3,979,149
Total operating expenses	5,701,213	8,305,536	11,350,862	14,650,287
Loss from operations	(5,664,768)	(8,210,216)	(11,277,162)	(14,425,168)
Foreign exchange (loss) gain	(2,303)	1,717	67,949	15,688
Net loss	$ (5,667,071)	$ (8,208,499)	$ (11,209,213)	$ (14,409,480)
Per share information:				
Net loss per share, basic and diluted	$ (0.34)	$ (1.91) (1.91)	$ (0.96)	$ (3.35)
Weighted average shares outstanding, basic and diluted	16,514,377	4,306,775	11,664,815	4,306,709