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): **March 26, 2025**

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 8.01. Other Events.

On March 26, 2025, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing the positive findings from the first safety review of the expansion cohort in its Phase 1 SB101 clinical trial evaluating SON-1010, the Company's proprietary version of recombinant human interleukin-12 ("rhIL-12") configured using genetic fusion to the Company's Fully Human Albumin Binding ("F_HAB®") platform, in combination with trabectedin ("Yondelis®") in adult patients with advanced leiomyosarcoma ("LMS") or liposarcoma ("LPS").The expansion cohort builds on the successful completion of monotherapy dose escalation and assignment of the SON-1010 maximum tolerated ("MTD") dose of 1200 ng/kg.

The SB101 Safety Review Committee ("SRC") met to evaluate the initial status of the patients in the expansion cohort, all of whom are receiving the SON-1010/trabectedin combination, as enrollment continues. After an average treatment of slightly over two months, one patient progressed and the other six are tolerating treatment. Adverse events ("AEs") considered to be related to either drug have all been mild or moderate, suggesting that the two drugs do not appear to be adversely impacting each other. The annual review including all 30 patients dosed to date showed that common AEs considered related to SON-1010 monotherapy or in combination included fatigue, fever, chills, and myalgia in 15% or more; moderate fatigue was the only related AE in 2 or more of the patients treated with trabectedin to date. Full enrollment of the combination cohort will provide an opportunity to evaluate statistical evidence of benefit in the response using the standard RECIST paradigm, which may also confirm synergy. Meanwhile, five of the six patients in the SON-1010 high-dose monotherapy group (83%) showed stable disease at 4 months and four continue on trial at 6 months with no new safety concerns. The partial response ("PR") in one of those patients persists, confirming the potential for benefit of SON-1010 monotherapy at the MTD in this small cohort. Overall, 13 of the 24 patients studied during SON-1010 dose escalation (54%) had evidence of monotherapy clinical benefit.

The primary outcome measures for the Phase 1 SB101 trial are the safety, tolerability, pharmacokinetics ("PK") and pharmacodynamics ("PD") of SON-1010 and to establish the MTD. The Company has treated 7 patients over 2 months on average and expects to enroll up to 18 patients with unresectable, metastatic LMS or LPS in this open-label, single-arm expansion cohort. Patients are being treated with SON-1010 in combination with the standard 21-day trabectedin cycles, alternating the dosing of the two drugs. Trabectedin, the first approved chemotherapeutic drug for advanced soft-tissue sarcomas ("STS") after failure of primary therapy, works by preventing tumor cells from

proliferating but has also been shown to have pro-inflammatory immune effects in the tumor microenvironment ("TME") that may be enhanced by the IL-12 activity in SON-1010. Trabectedin is approved in 76 countries globally for the treatment of advanced STS as a single-agent, and in 69 countries for relapsed ovarian cancer in combination with doxorubicin HCl liposome injection.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and Private Securities Litigation Reform Act, as amended, including those relating to the outcome of the Company's clinical trials, including the expansion cohort in its Phase 1 SB101 clinical trial which combines SON-1010 with trabectedin, 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, including potential partnerships, 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 the Company's 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 SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this Current Report. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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.

Date: March 26, 2025

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