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): **April 4, 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 April 4. 2025, Sonnet BioTherapeutics Holdings, Inc. (the "Company") announced positive safety results of SON-1010 at the highest dose combined with atezolizumab (Tecentriq®) in the Phase 1b/2a clinical trial in adult patients with advanced solid tumors or platinum-resistant ovarian cancer (PROC) (the "SB221 study"). Based on positive feedback from a formal evaluation by the Safety Review Committee (SRC) for the SB221 study, the study can now advance to the expansion phase, which will study the preliminary effect of the combination at the maximum tolerated dose (MTD), before proceeding to a Phase 2a randomized comparison with the standard of care in patients with PROC.

The SB221 study was designed to assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of increasing doses of SON-1010 administered with atezolizumab. The primary goal for the first part of the study was to establish the MTD in combination with the immune checkpoint inhibitor (ICI). A total of 19 subjects were treated during dose escalation and one patient with PROC had a partial response at the highest dose.

The SB221 SRC review at the completion of dose expansion in combination with atezolizumab concluded that fatigue, fevers, and gastrointestinal symptoms were the most common adverse effects; no dose-limiting toxicity or cytokine release syndrome were seen. The only related serious adverse event (SAE) during dose escalation was Grade 2 pneumonitis, which is a known adverse event with atezolizumab. One patient with PROC had a 44% tumor size reduction, indicating a partial response (PR), along with a more than 2-fold reduction in the CA 125 ovarian cancer biomarker. SON-1010 monotherapy in the SB101 study led to a PR at the same MTD in a patient with sarcoma.

All enrolled patients have advanced solid tumors and all patients at the higher doses have PROC, including those enrolled in a final 1200 ng/kg dose-escalation cohort. The SB221 trial employed a 'desensitizing' first dose of 300 ng/kg to take advantage of the known tachyphylaxis with rhIL-12, with the intention of minimizing toxicity while allowing for higher maintenance doses. The safety and toxicity profile that has developed is typical for a Phase 1 oncology trial, with the majority of adverse events (AEs) being reported as mild and transient and there has been no evidence of cytokine release syndrome. Of the 19 patients dosed to date, 8 of the 15 evaluable patients (53%) had SD at the first follow-up CT scan and 5 of the 15 evaluable patients (33%) remained stable at four months, suggesting SON-1010 is showing clinical benefit. While the follow-up is still

early, four of those 15 patients were still on trial at 6 months, including 3 with SD and one with an unconfirmed PD. As noted, one of the PROC patients in the highest SON-1010 dose cohort had a PR at 2 months.

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: April 4, 2025

By: */s/ Donald Griffith*
Name: Donald Griffith
Title: Chief Financial Officer
