

**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): September 18, 2024

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35570</u> (Commission File Number)	<u>20-2932652</u> (IRS Employer Identification No.)
<u>100 Overlook Center, Suite 102 Princeton, New Jersey</u> (Address of principal executive office)		<u>08540</u> (Zip Code)

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

Not Applicable

(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 per share	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 7.01 Regulation FD.

On September 18, 2024, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing the completion of enrollment and initiation of dosing in its Phase 1 SB101 clinical trial of SON-1010 (IL12-FHAB) in adult patients with advanced solid tumors.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission (the "SEC"), and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On September 18, 2024, the Company announced the completion of enrollment and initiation of dosing in its Phase 1 SB101 clinical trial of SON-1010 in adult patients with advanced solid tumors. The Company expects to report topline data from this study in Q4 2024.

SB101 is the Company's open-label, adaptive-design dose-escalation study to assess the safety, tolerability, and PK/PD of SON-1010 administered to patients with advanced solid tumors. The study enrolled 24 subjects. Primary outcome measures for the study are to evaluate the safety and tolerability of SON-1010 and establish the maximum tolerated dose (MTD) of SON-1010.

SON-1010 is the Company's proprietary version of recombinant human interleukin-12 (rhIL-12), configured using the Company's Fully Human Albumin Binding (FHAB®) platform, which extends the half-life and activity of the IL-12 component due to binding native albumin in the serum and targets the tumor microenvironment (TME) by strongly binding gp60 and Secreted Protein Acidic and Rich in Cysteine (SPARC).

As previously announced, the safety of SON-1010 was reviewed by the Safety Review Committee at each step during dose escalation. The trial uses a ‘desensitizing’ first dose to take advantage of the known tachyphylaxis with rhIL-12, which minimizes toxicity and allows higher maintenance doses. No dose-limiting toxicities have occurred to date. 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. All have been transient, with no evidence of cytokine release syndrome.

As previously announced, one patient with progressive endometrial sarcoma receiving SON-1010 monotherapy in SB101 had stable disease (SD) for almost 2 years before progressing - her ascites had resolved and tumors had shrunk at one point but she never reached a partial response (PR) by Response Evaluation Criteria in Solid Tumors (RECIST) rules. Cytokine analysis following each dose in that study revealed controlled and prolonged induction of interferon gamma (IFN γ) that peaked at 24 to 48 hours and returned to baseline within 2 to 4 weeks. A small increase in IL-10 was observed with each dose as expected in response to IFN γ . There was either a minimal or no signal for IL-1 β , IL-6, IL-8, and TNF α , and there was no indication of any potential for cytokine release syndrome (CRS) at these doses.

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 and Section 21E of the Exchange Act and Private Securities Litigation Reform Act, as amended, including those relating to the outcome of the Company’s clinical trials, 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 18, 2024.
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.

Date: September 18, 2024

By: /s/ Pankaj Mohan, Ph.D.

Name: Pankaj Mohan, Ph.D.

Title: Chief Executive Officer



CONFIDENTIAL DRAFT NOT FOR IMMEDIATE RELEASE

Sonnet BioTherapeutics Completes Enrollment in Phase 1 Study of SON-1010 (IL12-F_HAB) as a Monotherapy (SB101) for the Treatment of Solid Tumors

SON-1010 is a targeted immune activation cancer therapy designed to turn 'cold' tumors 'hot'

Topline safety data of SB101 Phase 1 study expected by Q4 2024

PRINCETON, NJ / GlobeNewswire / September 18, 2024/ Sonnet BioTherapeutics Holdings, Inc. (the “Company” or “Sonnet”) (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today announced the completion of enrollment and initiation of dosing in its Phase 1 SB101 clinical trial of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors. The Company expects to report topline data from this study in Q4 2024.

Pankaj Mohan, Founder and Chief Executive Officer of Sonnet commented, “This milestone is an important step forward in our development program for SON-1010 as a monotherapy. We are encouraged by the data seen to date demonstrating safety and tolerability being well within expected levels. We are hopeful that we will continue to see extended PK/PD, tumor targeting and clinical activity during treatment. We remain committed to bringing this trial to completion and we expect to report topline safety data in Q4 2024.”

SB101 is the Company’s open-label, adaptive-design dose-escalation study to assess the safety, tolerability, and PK/PD of SON-1010 administered to patients with advanced solid tumors. The study enrolled 24 subjects. Primary outcome measures for the study are to evaluate the safety and tolerability of SON-1010 and establish the maximum tolerated dose (MTD) of SON-1010.

SON-1010 is the Company’s proprietary version of recombinant human interleukin-12 (rhIL-12), configured using Sonnet’s Fully Human Albumin Binding (F_HAB[®]) platform, which extends the half-life and activity of the IL-12 component due to binding native albumin in the serum and targets the tumor microenvironment (TME) by strongly binding gp60 and Secreted Protein Acidic and Rich in Cysteine (SPARC).

As previously announced, the safety of SON-1010 was reviewed by the Safety Review Committee at each step during dose escalation. The trial uses a ‘desensitizing’ first dose to take advantage of the known tachyphylaxis with rhIL-12, which minimizes toxicity and allows higher maintenance doses. No dose-limiting toxicities have occurred to date. 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. All have been transient, with no evidence of cytokine release syndrome.

As previously announced, one patient with progressive endometrial sarcoma receiving SON-1010 monotherapy in SB101 had stable disease (SD) for almost 2 years before progressing - her ascites had resolved and tumors had shrunk at one point but she never reached a partial response (PR) by Response Evaluation Criteria in Solid Tumors (RECIST) rules. Cytokine analysis following each dose in that study revealed controlled and prolonged induction of interferon gamma (IFN γ) that peaked at 24 to 48 hours and returned to baseline within 2 to 4 weeks. A small increase in IL-10 was observed with each dose as expected in response to IFN γ . There was either a minimal or no signal for IL-1 β , IL-6, IL-8, and TNF α , and there was no indication of any potential for cytokine release syndrome (CRS) at these doses.

For more information about the SB101 Phase 1 trial in adult patients with advanced solid tumors visit www.clinicaltrials.com and reference identifier [NCT05352750](https://clinicaltrials.gov/ct2/show/study/NCT05352750).

About SON-1010

SON-1010 is a candidate immunotherapeutic recombinant drug that links unmodified single-chain human IL-12 with the albumin-binding domain of the single-chain antibody fragment A10m3. This was selected to bind albumin both at normal pH, as well as at the acidic pH typically found in the TME. The F_HAB technology targets tumor and lymphatic tissue, providing a mechanism for dose sparing and an opportunity to improve the safety and efficacy profile of not only IL-12, but a variety of potent immunomodulators that can be linked using the platform. Interleukin-12 can orchestrate a robust immune response to many cancers and pathogens. Given the types of proteins induced in the TME, such as the Secreted Protein and Rich in Cysteine (SPARC) and glycoprotein 60 (GP60), several types of cancer such as non-small cell lung cancer, melanoma, head and neck cancer, sarcoma, and some gynecological cancers are particularly relevant for this approach. SON-1010 is designed to deliver IL-12 to local tumor tissue, turning ‘cold’ tumors ‘hot’ by stimulating IFN γ , which activates innate and adaptive immune cell responses and increases the production of Programed Death Ligand 1 (PD-L1) on tumor cells.

About the SB101 Phase 1 Trial

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. While the optimal dose is unknown at this stage, the potential to target tumors, the extended PK mechanism, and our preclinical data suggest the therapeutic dose may be lower compared to native human IL-12. The study, utilizing a standard 3+3 oncology design in at least five cohorts, should establish the MTD using subcutaneous injections of SON-1010 every 3 to 4 weeks. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, and anti-tumor activity. This study will form the basis for potential combinations with other types of immunotherapies and the future development of bispecific candidates using the F_HAB platform.

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet is an oncology-focused biotechnology company with a proprietary platform for developing targeted biologic drugs with single or bifunctional action. Known as FHAB (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 FHAB 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. FHAB platform 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.

Sonnet’s lead program, SON-1010, or IL-12-F_HAB, is in development for the treatment of solid tumors and ovarian cancer. SON-1010 is being evaluated in an ongoing Phase 1/2a study through a Master Clinical Trial and Supply Agreement, along with ancillary Quality and Safety Agreements, with Roche in combination with atezolizumab (Tecentriq[®]) for the treatment of Platinum-Resistant Ovarian Cancer (PROC). The Company is also evaluating its second program, SON-1210, an IL12-F_HAB-IL15 for solid

tumors, in collaboration with the Sarcoma Oncology Center to commence an investigator-initiated and funded Phase 1/2a study for the treatment of pancreatic cancer.

The Company's SON-080 program is a low dose of rhIL-6 in development for Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN). SON-080 demonstrated encouraging results in a Phase 1b/2a clinical trial, being well tolerated with no evidence of a pro-inflammatory cytokine response. Sonnet is currently seeking partnership opportunities to support a Phase 2 trial.

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 outcome of the Company's clinical trials, 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
Jenene Thomas
833-475-8247
SONN@jtcir.com

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