

**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): December 9, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 December 9, 2024, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing topline safety data following successful completion of SON-1010 monotherapy dose escalation in Phase 1 SB101 trial.

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 December 9, 2024, the Company announced topline safety data following successful completion of SON-1010 monotherapy dose escalation in Phase 1 SB101 trial. The maximum tolerated dose (MTD) of SON-1010 was set at 1200 ng/kg, without dose-limiting toxicity or evidence of cytokine release syndrome at any dose level. Stable disease (SD) at four months post-initiation of dosing was seen in 10 of 21 (48%) evaluable monotherapy patients, and importantly included one patient dosed at the MTD who had a partial response (PR) by RESIST criteria (a 45% decrease from baseline). Together, these data suggest clinical benefit when SON-1010 is administered as a monotherapy.

The results of SON-1010 at the highest dose have been formally evaluated by the Safety Review Committee in the Phase 1 SB101 clinical trial of SON-1010 (IL12-FHAB) in adult patients with advanced solid tumors. SB101 is the Company's open-label, adaptive-design dose-escalation study to assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of SON-1010 administered to patients with advanced solid tumors. The study has enrolled 24 subjects to date. Primary outcome measures for the study were to evaluate the safety and tolerability of SON-1010 and establish the MTD.

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

All enrolled patients have had advanced solid tumors. The final 1200 ng/kg dose-escalation cohort was increased in size to 6 patients to enhance the assessment of PK and PD at the MTD. The SB101 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 and allowing for higher maintenance doses. No dose-limiting toxicities or related serious adverse events (SAE) 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 AEs seen to date have been transient, with no evidence of cytokine release syndrome. Of the 24 patients dosed to date, 17 (71%) had SD at the first follow-up CT, 12 of whom were progressing at study entry. 10 of 21 patients (48%) remained stable at four months, suggesting SON-1010 clinical benefit, and one of those patients, who has clear cell sarcoma, had a PR with a 45% reduction in tumor size by RESIST criteria. As previously disclosed, one patient with endometrial sarcoma who was progressing at study entry had evidence of improvement after 11 months, with smaller tumors and complete resolution of ascites. This patient later progressed at 23 months and started chemotherapy.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated December 9, 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: December 9, 2024

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



Sonnet BioTherapeutics Announces Topline Safety Data Following Successful Completion of SON-1010 Monotherapy Dose Escalation in Phase 1 SB101 Trial

The maximum tolerated dose (MTD) of SON-1010 was set at 1200 ng/kg, without dose-limiting toxicity or evidence of cytokine release syndrome at any dose level

Stable disease (SD) at four months post-initiation of dosing was seen in 10 of 21 (48%) evaluable monotherapy patients, and importantly included one patient dosed at the MTD who had a partial response (PR) by RESIST criteria (a 45% decrease from baseline)

Together, these data suggest clinical benefit when SON-1010 is administered as a monotherapy

Sonnet management discusses what this data means in a Virtual Investor "What This Means" segment, [access here](#)

PRINCETON, NJ, December 9, 2024 (GLOBE NEWSWIRE) — Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) (the "Company" or "Sonnet"), a clinical-stage company developing targeted immunotherapeutic drugs, announced today that the results of SON-1010 at the highest dose have been formally evaluated by the Safety Review Committee in the Phase 1 SB101 clinical trial of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors. SB101 is the Company's open-label, adaptive-design dose-escalation study to assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of SON-1010 administered to patients with advanced solid tumors. The study has enrolled 24 subjects to date. Primary outcome measures for the study were to evaluate the safety and tolerability of SON-1010 and establish the MTD. Additionally, the Company announced the release of a "What This Means" segment to discuss the data which is now available [here](#).

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

"We are encouraged by this topline safety data generated to date in our Phase 1 study. Given the history of safety concerns with rhIL-12 in its first human trials over 25 years ago, it is exciting to see higher doses of SON-1010 demonstrating minimal toxicity, which is likely due to its unique biodistribution and albumin binding profile, with delivery to and retention in the tumor microenvironment," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "We may finally be able to realize the promising antitumor effect that has been associated with this cytokine in preclinical models for decades. The IFN γ response, which is considered to be important for anti-tumor control, has been robust but controlled with a much longer return to baseline. While the clinical benefit we have been seeing during dose escalation has been reassuring, the PR at the highest dose is particularly important, as this suggests that there may be a synergistic effect in combination with checkpoint inhibitors and/or chemotherapy."

All enrolled patients have had advanced solid tumors. The final 1200 ng/kg dose-escalation cohort was increased in size to 6 patients to enhance the assessment of PK and PD at the MTD. The SB101 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 and allowing for higher maintenance doses. No dose-limiting toxicities or related serious adverse events (SAE) 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 AEs seen to date have been transient, with no evidence of cytokine release syndrome. Of the 24 patients dosed to date, 17 (71%) had SD at the first follow-up CT, 12 of whom were progressing at study entry. 10 of the 21 evaluable patients (48%) remained stable at four months, suggesting SON-1010 clinical benefit, and one of those patients in the highest dose cohort, who has clear cell sarcoma, had a PR with a 45% reduction in tumor size by RESIST criteria. As previously disclosed, one patient in the first dose cohort with endometrial sarcoma who was progressing at study entry had evidence of improvement after 11 months, with smaller tumors and complete resolution of ascites. This patient later progressed at 23 months and started chemotherapy.

"This topline safety data release on our lead program is a significant milestone for Sonnet's clinical development. We have now successfully completed dose escalation in our first trial with SON-1010 and are pleased to see a partial response in one patient at the highest dose, in addition to clinical benefit in almost half of the evaluable patients," said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "Safety of this extended PK version of IL-12 has been within expected levels and the comparison with dosing in healthy volunteers provided strong evidence of tumor targeting in humans. We have used this trial to establish the MTD and will continue to follow the patients currently being treated to assess longer-term safety and tumor responses. Sonnet is currently seeking partnership opportunities to help support later stage development of SON-1010."

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

SON-1010 is also being evaluated in a Phase 1b/2a dose-escalation and proof-of-concept study (SB221) in combination with SON-1010 and atezolizumab (in collaboration with Genentech, a member of the Roche Group), which is focused on platinum-resistant ovarian cancer (PROC) ([NCT05756907](https://clinicaltrials.gov/ct2/show/study/NCT05756907)). Enrollment remains ongoing and an update on safety at the MTD in that trial is expected in Q1 2025.

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 Programmed Death Ligand 1 (PD-L1) on tumor cells.

About the Phase 1 SB101 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 PK, 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 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 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. In October 2024, Sonnet announced an India license agreement with Alkem Laboratories, Inc. who will assume responsibility for advancing development of the SON-080 program into a Phase 2 study in DPN.

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