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): January 21, 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 office)	(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 January 21, 2025, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing an expansion of its Phase 1 SB101 trial to evaluate the combination of SON-1010 with trabectedin in certain sarcomas.

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 January 21, 2025 the Company announced an expansion of its Phase 1 SB101 clinical study of SON-1010 (IL12-F_cAB) in adult patients with advanced solid tumors to add a new cohort to evaluate the effect of SON-1010 in combination with trabectedin (Yondelis®), following the successful completion of monotherapy dose escalation. This expansion will explore the immune-oncology impact of SON-1010 at the maximum tolerated (MTD) dose of 1200 ng/kg in combination with trabectedin, which is an approved chemotherapeutic drug for certain advanced soft-tissue sarcomas (STS). Patients with STS could potentially benefit from an enhanced local immune response in the tumor microenvironment (TME). Enrollment in this cohort is underway and is expected to be completed in H1 calendar year 2025. Topline safety data of the combination of SON-1010 with trabectedin is expected in H2 calendar year 2025; no new safety concerns have been reported to date.

SON-1010, after receipt of data suggesting clinical benefit when administered as a monotherapy in patients with advanced solid tumors, has entered into combination evaluation with trabectedin (Yondelis®) with the potential to improve trabectedin's therapeutic window in soft-tissue sarcoma patients. The combined mechanisms have the potential to enhance progression-free survival (PFS) in some of the largest cohorts of patients with soft-tissue sarcoma.

The Company expects to enroll up to 18 patients with unresectable, metastatic liposarcoma or leiomyosarcoma in this open-label, single-arm expansion cohort. The patients will be treated with SON-1010 in combination with the standard 21-day trabectedin cycles, alternating the dosing of the two drugs. This number of subjects may be needed to see a statistical benefit in the response using the standard RECIST paradigm. 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, which has been set at 1200 ng/kg. The Company believes the results of this expansion cohort could position SON-1010 for a larger Phase 2 study that could establish the combination of SON-1010 and trabectedin as a new and potentially improved treatment for STS.

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 ($F_HAB^{®}$) platform, which extends the half-life and bioactivity of the IL-12 component due to binding native albumin in the serum. Albumin naturally targets the TME by strong binding to gp60 and Secreted Protein Acidic and Rich in Cysteine (SPARC). The majority of patients enrolled to date in the Phase 1 SB101 trial have STS, which has a known potential for an enhanced response to immunotherapy.

Trabectedin is an alkylating DNA-binding agent that was approved as a second-line treatment in early 2024 for patients with unresectable, metastatic liposarcoma or leiomyosarcoma who have received a prior anthracycline-containing regimen. It is also known to activate tumor macrophages into a pro-inflammatory phenotype. The Company believes that SON-1010 has the potential to complement that activity by activating the NK and T cells in the TME to secrete more interferon-gamma (IFNγ) which is considered to be important for anti-tumor control.

For more information about the Phase 1 SB101 trial in adult patients with advanced solid tumors visit www.clinicaltrials.com and reference identifier 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 (Tecentriq®) (in collaboration with Genentech, a member of the Roche Group), which is focused on platinum-resistant ovarian cancer (PROC) (NCT05756907). Enrollment remains ongoing and an update on safety at the MTD in that trial is expected in Q1 calendar year 2025.

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 January 21, 2025.
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: January 21, 2025

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

Exhibit 99.1

Sonnet BioTherapeutics Expands Phase 1 SB101 Trial to Evaluate Combination of SON-1010 with Trabectedin in Certain Sarcomas

SON-1010, after receipt of data suggesting clinical benefit when administered as a monotherapy in patients with advanced solid tumors, enters combination evaluation with trabectedin (Yondelis®) with the potential to improve trabectedin's therapeutic window in soft-tissue sarcoma patients

Combined mechanisms have the potential to enhance progression-free survival (PFS) in some of the largest cohorts of patients with soft-tissue sarcoma

Topline safety data of the combination of SON-1010 with trabectedin is expected in H2 calendar year 2025

Sonnet management discusses what this expansion means in a Virtual Investor "What This Means" segment; Access here

PRINCETON, NJ, January 21, 2025 (GLOBE NEWSWIRE) — Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) (the "Company" or "Sonnet"), a clinical-stage company developing targeted immunotherapeutic drugs, announced today an expansion of its Phase 1 SB101 clinical study of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors to add a new cohort to evaluate the effect of SON-1010 in combination with trabectedin (Yondelis®), following the successful completion of monotherapy dose escalation. This expansion will explore the immune-oncology impact of SON-1010 at the maximum tolerated (MTD) dose of 1200 ng/kg in combination with trabectedin, which is an approved chemotherapeutic drug for certain advanced soft-tissue sarcomas (STS). Patients with STS could potentially benefit from an enhanced local immune response in the tumor microenvironment (TME). Enrollment in this cohort is underway and is expected to be completed in H1 calendar year 2025. Topline safety data of the combination with trabectedin is expected in H2 calendar year 2025; no new safety concerns have been reported to date. Additionally, the Company announced the release of a "What This Means" segment to discuss the expansion of the Phase 1 clinical study which is now available here.

"The Sarcoma Oncology Center is pleased to have been able to enroll most of the patients in Sonnet's Phase1 SB101 study to date, with the majority of the patients having STS," commented Dr. Sant Chawla, Principal Investigator at the Sarcoma Oncology Center in Santa Monica, California. "Additionally, as we have contributed to the development of trabectedin over the years, we were excited to see its approval in early 2024 as a monotherapy in the second-line treatment for two of the most common types of sarcoma — liposarcoma and leiomyosarcoma. While the trabectedin approval was based on several clinical trials in sarcoma, we believe a large unmet need remains for the treatment of STS. We believe that combining trabectedin with SON-1010 has the potential for a natural synergistic effect of the two mechanisms of action."

The Company expects to enroll up to 18 patients with unresectable, metastatic liposarcoma or leiomyosarcoma in this open-label, single-arm expansion cohort. The patients will be treated with SON-1010 in combination with the standard 21-day trabectedin cycles, alternating the dosing of the two drugs. This number of subjects may be needed to see a statistical benefit in the response using the standard RECIST paradigm. 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, which has been set at 1200 ng/kg. The Company believes the results of this expansion cohort could position SON-1010 for a larger Phase 2 study that could establish the combination of SON-1010 and trabectedin as a new and potentially improved treatment for STS.

"The ability to assess earlier-stage patients is an exciting opportunity to evaluate the potential for SON-1010 to turn 'cold' tumors 'hot'," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "Most Phase 1 studies in the oncology space are done in patients with advanced disease, whose immune systems may not respond optimally after multiple types of chemotherapy. Trabectedin's approval as a single agent second-line therapy in STS provides access to patients at an earlier stage with an underlying immune response that may be more robust."

"The Sonnet team has been studying the efficacy and safety of SON-1010 as a single agent, which has thus far suggested clinical benefit when administered as a monotherapy in patients with advanced solid tumors," said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "Further, we believe this synergy could improve the response in a serious type of cancer at an earlier stage of disease, which could open up another potential opportunity for partnering."

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. Albumin naturally targets the TME by strong binding to gp60 and Secreted Protein Acidic and Rich in Cysteine (SPARC). The majority of patients enrolled to date in the Phase 1 SB101 trial have STS, which has a known potential for an enhanced response to immunotherapy.

Trabectedin is an alkylating DNA-binding agent that was approved as a second-line treatment in early 2024 for patients with unresectable, metastatic liposarcoma or leiomyosarcoma who have received a prior anthracycline-containing regimen. It is also known to activate tumor macrophages into a pro-inflammatory phenotype. The Company believes that SON-1010 has the potential to complement that activity by activating the NK and T cells in the TME to secrete more interferon-gamma (IFNγ) which is considered to be important for anti-tumor control.

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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 single-chain antibody fragment 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 to this approach. SON-1010 is designed to deliver IL-12 to local tumor tissue, turning 'cold' tumors 'hot' by stimulating IFN□, which activates innate and adaptive immune cell responses and increases the production of Programed 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 the 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, established the MTD at 1200 ng/kg 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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