

**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): **November 1, 2022**

**SONNET BIOTHERAPEUTICS HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**001-35570**

(Commission  
File Number)

**20-2932652**

(IRS Employer  
Identification No.)

**100 Overlook Center, Suite 102  
Princeton, New Jersey 08540**  
(Address of principal executive offices)

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 Stock 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 November 1, 2022, Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") issued a press release announcing that the company will host a webcast to share initial clinical data from its SB101 clinical study with SON-1010 in oncology patients ([NCT05352750](#)) and its SB102 clinical study with SON-1010 in healthy volunteers ([NCT05408572](#)) on Wednesday, November 2, 2022 at 8:30 am ET. A copy of the press release is attached hereto as Exhibit 99.1.

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, 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 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

**Exhibit No.      Exhibit**

99.1	<a href="#">Press Release dated November 1, 2022</a>
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.  
a Delaware corporation  
(Registrant)

Date: November 1, 2022

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

Name: Pankaj Mohan, Ph.D.

Title: Chief Executive Officer

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**Sonnet BioTherapeutics Announces Webcast to Discuss Interim Data from the Company's Phase 1 Dose-Escalation Trials of SON-1010 on November 2, 2022**

**PRINCETON, NJ / ACCESSWIRE / November 1, 2022/** Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN), a clinical-stage company developing targeted immunotherapeutic drugs, announced today that the company will host a webcast to share initial clinical data from its SB101 clinical study with SON-1010 in oncology patients (NCT05352750) and its SB102 clinical study with SON-1010 in healthy volunteers (NCT05408572) on Wednesday, November 2, 2022 at 8:30 am ET.

Webcast presenters will include:

Richard Kenney, M.D., Chief Medical Officer  
Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Office

The webcast at 8:30 am ET, with an accompanying presentation, will be accessible under News & Events, IR Calendar in the Investors section of the company's website. The archived audio webcast will be available on Sonnet's website following the call.

To participate in the webcast, please see the following details:

- Webcast Link: [https://event.webcasts.com/starthere.jsp?ei=1578849&tp\\_key=e61e9de382](https://event.webcasts.com/starthere.jsp?ei=1578849&tp_key=e61e9de382)
- Toll Free: 1-877-869-3847
- International: 201-689-8261
- Conference ID: 13733966

**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 will be 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 maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) using monthly subcutaneous injections of SON-1010. 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 FHAB platform.

**About the SB102 Phase 1 Trial**

The SB102 study is designed to robustly evaluate the safety, PK and PD of single ascending doses of SON-1010, using larger groups of healthy volunteers, and is being conducted at a single site in Australia. The study is done in a blinded fashion, comparing a single dose of SON-1010 to placebo utilizing five cohorts. Both PK and PD will be closely followed during dose escalation in this double-blind, placebo-controlled study, along with an assessment of the cellular immune responses at each dose using sophisticated fluorescence activated cell sorting (FACS) analysis. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure PK, PD and immunogenicity.

**About Sonnet BioTherapeutics Holdings, Inc.**

Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of single or bispecific 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 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.

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**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 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.

**Sonnet BioTherapeutics Investor Contact**

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**SOURCE:** Sonnet BioTherapeutics, Inc.

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