

**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): **March 16, 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 8.01. Other Events.

On March 16, 2022, Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for SON-1010, a proprietary version of Interleukin 12 (IL-12) configured using Sonnet's Fully Human Albumin Binding (FHAB™) technology. This will allow Sonnet to initiate its First-in-Human Phase 1 trial in adult oncology patients in the second quarter of 2022.

The planned Phase 1 trial will be a multiple ascending dose study designed to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of SON-1010 in adult patients with advanced solid tumors. The study, utilizing a standard 3+3 oncology design in at least 5 cohorts, will establish the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) using monthly subcutaneous injections of SON-1010. The primary endpoint will assess the safety and tolerability of SON-1010, with key secondary endpoints planned to measure PK, PD, immunogenicity, and anti-tumor activity.

Forward-Looking Statements

This report 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 the Company operates 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 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Exhibit</u>
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: March 16, 2022

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