

**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): **August 30, 2021**

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 August 30, 2021, Sonnet BioTherapeutics Holdings, Inc. (the "Company") announced that it has selected a novel development candidate after completing comparative studies in a mouse melanoma model. The candidate represents Sonnet's second bispecific compound integrating Interleukin 12 (IL-12) with the company's Fully Human Albumin Binding (F_HAB) platform. Sonnet will analyze SON-1410 for potential use in treating melanoma and renal cancers.

IL18-F_HAB-IL12 showed statistically significant tumor size reduction in a mouse melanoma study compared with the placebo, as well as a dose response. The data demonstrated:

| Test Article | Day 0, Single Dose Tumor @ 100 mm ³ | Day 8 Tumor Volume (mm ³ +/- SEM), N=8 | Day 8 Percentage Tumor Shrinkage |
|-----------------------------|---|--|----------------------------------|
| Placebo | NA | 1747 +/- 301 | - |
| IL18-F _H AB-IL12 | 1 µg | 918 +/- 130 | 47% |
| IL18-F _H AB-IL12 | 5 µg | 619 +/- 141 | 65% |

Another mouse study compared the selected version of IL18-F_HAB-IL12 with two other candidates, GMCSF-F_HAB-IL18 and GMCSF-F_HAB-IL12. The comparison data indicated significantly greater reduction in tumor volume, along with higher Interferon Gamma levels and immune cell responses (NK, NKT, Th1, and cytotoxic CD8 T cells) using IL18-F_HAB-IL12, compared with GMCSF-F_HAB-IL12 or GMCSF-F_HAB-IL18. Based on this study, SON-1410 (IL18-F_HAB-IL12) will replace SON-2014 (GMCSF-F_HAB-IL18) as a development program.

Sonnet is initiating the manufacturing process for SON-1410 with cell line and process development, which will be followed by manufacturing for a toxicology study,

with the intention of filing an IND during the second half of 2022.

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.

| Exhibit No. | Exhibit |
|-------------|--|
| 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: August 31, 2021

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