

**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 29, 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 7.01. Regulation FD Disclosure.

On March 29, 2021, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release regarding the Company's business update on its ongoing programs. The press release is attached hereto as Exhibit 99.1 and incorporated by reference in this Item 7.01.

The information presented in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 is being furnished and shall not be deemed to be "filed" for 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 March 29, 2021, the Company announced a business update on its ongoing programs, as summarized below:

- **SON -1010 (FH-AB-IL12):** The Company has completed nonhuman primate ("NHP") GLP toxicity studies with SON-1010 and is awaiting data to prepare an IND submission, while working in parallel to initiate clinical trials during the second half of this year. Prior to IND submission, the Company will initiate pre-IND interactions with the U.S. Food and Drug Administration, which are expected during the second quarter, and will work to finalize the first-in-human protocol, along with selecting a contract research organization ("CRO") to perform the studies. CMC activities are on schedule to deliver GMP material prior to the IND filing.
- **SON-080 (Fully Human IL-6) – Chemotherapy Induced Peripheral Neuropath ("CIPN"):** With successful GLP toxicity studies completed, the CMC manufacturing is well underway, and product is expected to be available for a clinical trial commencing during the second half of this year. Plans have been initiated to complete the study design protocol for a Phase 1b/2a study, as well as the completion of diligence and selection of a CRO.

- **SON-081 (Fully Human IL-6)** – Diabetic Peripheral Neuropathy (“DPN”): The Company anticipates completing the partnership deal in South East Asia during April 2021 that the Company expects will position New Life Therapeutics (“NLT”) to fund and progress the asset forward into a Phase 1b/2a clinical trial. NLT has elected to focus on the acceleration of the development of low dose IL-6 for DPN at this time, and to hold an option to the CIPN indication for several months following the execution of a definitive agreement. The Company anticipates that clinical trial initiation will occur during the second half of this year. The Company has recently obtained positive initial comparability data from the new batch being manufactured using an updated process and awaits final study completion and reports of product comparability, prior to IND filing.
- **SON-1210 (IL12-F_HAB-IL15)**: The Company’s first bispecific candidate is undergoing cell line and process development. The Company has engaged a novel intensified perfusion manufacturing process to generate clinical grade material and expects completion of NHP studies in the second half of this year with an IND submission during the first half of 2022.
- **SON-2014 (GMcSF-F_HAB-IL18)**: In addition to GMcSF-F_HAB-IL18, the Company has manufactured bi-specific preclinical constructs of IL18-F_HAB-IL12 and IL12-F_HAB-GMcSF that are being evaluated for *in vivo* efficacy, biomarker profiles and fluorescence-activated cell sorting (“FACS”) assessment in single dose and multi-dose preclinical studies.

Upon completion of the preclinical efficacy evaluation in the second quarter of this year, the Company intends to initiate commercial cell line development necessary for future clinical trials. An IND submission for SON-2014 is currently targeted for the second half of 2022.

- **SON-3015 (Anti-IL6-F_HAB-Anti-TGFβ)**: The Company is in the discovery phase of SON-3015 development and is currently panning the candidate for binding and stability, after which the preclinical bispecific product will be evaluated in a mice model, expected during the second half of 2021. The Company is planning to initiate commercial cell line development in the first quarter of 2022.
- **INTELLECTUAL PROPERTY**: The Company has received Notice of Allowance from the United States Patent and Trademark Office for its first issued patent on the F_HAB delivery technology. Formal issuance is expected during the balance of the first half of 2021.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit
99.1	Press Release, dated March 29, 2021

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 30, 2021

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

Sonnet BioTherapeutics Provides 2021 Business Update

PRINCETON, NJ / ACCESSWIRE / March 29, 2021 / Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) (“Sonnet” or the “Company”), a biopharmaceutical company developing innovative targeted biologic drugs, announced today a business update on its ongoing programs.

“Last year we continued execution across our pipeline, and I am excited to share an update on our ongoing activities,” commented Pankaj Mohan, Ph.D., Founder and CEO. “This year we expect to be in the clinic with multiple programs, which we believe is an important milestone for patients.”

SON-1010 (F_HAB-IL12): Sonnet has completed nonhuman primate (NHP) GLP toxicity studies with SON-1010 and is awaiting data to prepare an IND submission, while working in parallel to initiate clinical trials during the second half of this year. Prior to IND submission, the Company will initiate pre-IND interactions with FDA, which are expected during the second quarter, and will work to finalize the first-in-human protocol, along with selecting a CRO to perform the studies. CMC activities are on schedule to deliver GMP material prior to the IND filing.

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INTELLECTUAL PROPERTY: Sonnet has received Notice of Allowance from the USPTO for its first issued patent on the F_HAB delivery technology. Formal issuance is expected during the balance of 1H21.

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 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. F_HAB 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.

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 on-going negotiations with New Life Therapeutics and the execution of a definitive agreement with New Life Therapeutics, 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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