

**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): **December 17, 2020**

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 2.02. Results of Operations and Financial Condition.

On December 17, 2020, Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") issued a press release regarding financial results for the fiscal year ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Forward-Looking Statements

This report, including Exhibit 99.1 furnished herewith, contains forward-looking statements within the meaning of the federal securities laws. Forward-looking statements typically are identified by use of terms such as "may," "will," "should," "plan," "expect," "anticipate," "estimate" and similar words, and the opposites of such words, although some forward-looking statements are expressed differently. Forward-looking statements involve known and unknown risks and uncertainties that exist in the Registrant's operations and business environment, which may be beyond the Registrant's control, and which may cause actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. For example, forward-looking statements include, without limitation: statements regarding prospects for additional customers; market forecasts; projections of earnings, revenues, synergies, accretion or other financial information; and plans, strategies and objectives of management for future operations. The risks and uncertainties referred to above include, but are not limited to, risks detailed from time to time in the Registrant's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended September 30, 2020. These risks could cause actual results to differ materially from those expressed in any forward-looking statements made by, or on behalf of, the Registrant. Forward-looking statements represent the judgment of management of the Registrant regarding future events. Although the Registrant believes that the expectations reflected in such forward-looking statements are reasonable at the time that they are made, the Registrant can give no assurance that such expectations will prove to be correct. Unless otherwise required by applicable law, the Registrant assumes no obligation to update any forward-looking statements, and expressly disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

Exhibit

99.1

[Press Release, dated December 17, 2020](#)

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: December 17, 2020

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

Name: Pankaj Mohan, Ph.D.

Title: Chief Executive Officer

Sonnet BioTherapeutics Provides Fiscal Year 2020 Business and Earnings Update

PRINCETON, NJ / ACCESSWIRE / December 17, 2020 / Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) (“Sonnet” or the “Company”), a biopharmaceutical company developing innovative targeted biologic drugs, announced today its financial results for the fiscal year ended September 30th, 2020 and provided a business update.

Pankaj Mohan, Ph.D., Founder and CEO commented, “This year has been incredibly exciting for Sonnet. We successfully executed our public listing, generated compelling new data to support our therapeutic pipeline and are working to finalize our first out-licensing deal. We believe this positions us well for continued growth and our IND submissions in 2021.”

Fiscal Year 2020 and Recent Corporate Updates

Warrant Repricing and Exchange: On August 4th, Sonnet announced a warrant repricing and exchange that provided the company with approximately \$10.5 million of gross proceeds. This restructuring simplified the Company’s capital structure and significantly reduced potential future dilution, while providing capital for ongoing operations.

Formation of Scientific Advisory Board: On April 6th, Sonnet announced the formation of its Scientific Advisory Board, including experts from MD Anderson, Fox Chase and Robert Wood Johnson.

Public Listing: On April 1st, Sonnet successfully completed its reverse merger public listing transaction and on April 2, 2020, the Company’s common stock began trading on The Nasdaq Capital Market under the symbol “SONN.”

Sonnet is pleased to provide the following updates on its pipeline assets:

SON-1010 (IL12-F_HAB): On November 30th, Sonnet reported the completion of a successful non-human primate (NHP) dose range-finding study, which showed SON-1010 to be well tolerated at dosage levels greater than 50 times the anticipated exposure in human clinical trials. Pharmacokinetic analysis of serum samples from the study animals indicated a mean half-life of 40.0 (±6.9) hours for the subcutaneous route of administration and 27.45 (±2.8) hours for intravenous dosing. These data follow the SCID mouse results reported September 1st. The Company expects to release data from its repeat dose NHP study in early 2021 and remains on-track to file an IND during the second half of 2021.

In virology, we are continuing work on viral challenge studies in mice using an influenza model to study SON-1010 as a potential adjuvant paired with a vaccine. We have determined from our initial review of the mouse data that further study of the compound’s activity is warranted in enhancing the immune response. If these studies are successful, we intend to seek a collaboration with an influenza vaccine manufacturer in 2021 to advance the development of a potentially more robust vaccine candidate.

SON-1210 (IL12-F_HAB-IL15): Cell line and manufacturing development of SON-1210, our first bispecific candidate, is underway and final clone selection is expected by the end of 2020. Early development material will be used in a xenograft mouse model study designed to evaluate PK/PD, dose response and efficacy. This work will inform our decision about dosing in a forthcoming nonhuman primate study, expected to be initiated by mid-2021, with an IND submission targeted around year-end.

SON-080 and SON-081 (low-dose IL-6): On August 4th, Sonnet announced the execution of a letter of intent (LOI) to negotiate an agreement with New Life therapeutics to license both SON-080 and SON-081 in ten ASEAN countries. Terms of the LOI agreement included a payment to Sonnet of \$500,000, up to \$40 million in upfront and milestone payments and a royalty on commercial sales. Sonnet continues to negotiate a definitive agreement, which it expects to reach in the first calendar quarter of 2021. With the agreement in place, the companies will work to initiate a Phase Ib/IIa study in Diabetic Peripheral Neuropathy (DPN). Additionally, the SON-080 development program in CIPN is progressing with an IND submission for the Phase Ib/IIa study expected in 2021.

SON-2014 (GMcSF-F_HAB-IL18): On July 20th, Sonnet reported that it had completed initial preclinical proof-of-concept work with both GMcSF and IL-18 and with GMcSF and IL-12 in a xenograft mouse model of melanoma. This study was designed to evaluate preclinical activity of the concomitantly administered cytokines as F_HAB-conjugated molecules, in several groups of tumor-bearing mice. Sonnet’s proprietary candidates all showed statistically significant reduction in tumor growth when compared to placebo and when compared to their wild-type, naked cytokine counterparts. Further animal studies are planned to optimize combinations for CMC development of bispecific combinations with GMcSF.

Fiscal Year Ended September 30, 2020 Financial Results

Jay Cross, CFO, elaborated on Sonnet’s 2020 fiscal year results, saying, “The Company has made important progress since our public listing in April and we expect to continue to deliver on our stated objectives of furthering the therapeutic pipeline. We believe we are in good position to maintain our forward momentum through 2021.”

- As of September 30, 2020, Sonnet had approximately \$7.3 million cash on hand, an increase from last quarter after the warrant exchange from Aug 25, 2020 and the cash associated with the signing of the LOI with New Life Therapeutics.
- The Company currently has 17,175,729 shares of common stock outstanding, 42,373 Series B Warrants outstanding and 11,329,461 Series C Warrants outstanding. In the event all the Series C Warrants were exercised for cash, the Company could receive up to an additional \$36.1 million.
- Research and development expenses were \$9.9 million for the year ended September 30, 2020, compared to \$2.2 million for the year ended September 30, 2019. The increase of was primarily driven by our expansion of R&D activities including studies of IL12-F_HAB and IL12- F_HAB-IL15, along with associated manufacturing and increased costs for research and development activities due to the acquisition of Relief.
- General and administrative expenses were \$7.5 million for the year ended September 30, 2020, compared to \$2.5 million for the year ended September 30, 2019. The increase was primarily due to one-time, transaction related fees associated with the closing of the Merger and an increase in insurance expenses related to directors and officer’s insurance. The remainder of the increase is due to scaling up of operations including those related to Relief.
- A \$20 million share subscription facility remains in place, access to which is subject to certain conditions. The Company has \$20 million remaining in this facility.

About Sonnet BioTherapeutics Holdings, Inc.

Founded in 2011, 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 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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Sonnet BioTherapeutics Holdings, Inc. Consolidated Balance Sheets

	September 30,	
	2020	2019
Assets		
Current assets:		
Cash	\$ 7,349,903	\$ 35,653
Prepaid expenses and other current assets	287,738	4,101
Total current assets	7,637,641	39,754
Property and equipment, net	67,889	—
Operating lease right-of-use asset	205,919	—
Other assets	82,959	—
Total assets	\$ 7,994,408	\$ 39,754
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Related-party notes	\$ 21,184	\$ 217,380
Accounts payable	2,057,559	1,842,996
Accrued expenses	2,063,678	824,865
Operating lease liability	82,060	—
Deferred income	500,000	—
Total current liabilities	4,724,481	2,885,241
Note payable	124,878	—
Operating lease liability	125,132	—
Total liabilities	4,974,491	2,885,241
Commitments and contingencies (note 8)		
Stockholders' equity (deficit):		
Preferred stock; \$0.0001 par value: 5,000,000 shares authorized. No shares issued or outstanding	—	—
Common stock; \$0.0001 par value: 125,000,000 shares authorized; 14,724,105 and 5,547,643 issued and outstanding at September 30, 2020 and 2019, respectively	1,472	555
Additional paid-in capital	39,723,702	9,594,100
Accumulated deficit	(36,705,257)	(12,440,142)
Total stockholders' equity (deficit)	3,019,917	(2,845,487)
Total liabilities and stockholders' equity (deficit)	\$ 7,994,408	\$ 39,754

See 10k filed today for notes to the consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc. Consolidated Statements of Operations

	Year ended September 30,	
	2020	2019
Operating expenses:		
Research and development	\$ 9,877,555	\$ 2,199,297
Acquired in-process research and development	6,826,495	—
General and administrative	7,533,722	2,509,041
Loss from operations	(24,237,772)	(4,708,338)

Interest income (expense)	20,677	(162,873)
Foreign exchange loss	(48,020)	—
Net loss	\$ (24,265,115)	\$ (4,871,211)
Deemed dividend arising from warrant amendment	(41,338,934)	—
Net loss attributable to common stockholders	\$ (65,604,049)	\$ (4,871,211)
Per share information:		
Net loss per share, basic and diluted	\$ (6.96)	\$ (0.91)
Weighted average shares outstanding, basic and diluted	9,420,484	5,348,195

See 10k filed today for notes to the consolidated financial statements
