

**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 22, 2023**

**SONNET BIOTHERAPEUTICS HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation)	<b>001-35570</b> (Commission File Number)	<b>20-2932652</b> (IRS Employer Identification No.)
<b>100 Overlook Center, Suite 102 Princeton, New Jersey</b> (Address of principal executive offices)		<b>08540</b> (Zip Code)
Registrant's telephone number, including area code: <b>(609) 375-2227</b>		
<b>N/A</b> (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 22, 2023, Sonnet BioTherapeutics Holdings, Inc. (the "Registrant") disseminated a letter from Pankaj Mohan, Ph.D., the Registrant's Founder and Chief Executive Officer, to its stockholders. A copy of the letter 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, 2022. 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**

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99.1      [Stockholder Letter, dated August 22, 2023](#)  
104      Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

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 22, 2023

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

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Dear Sonnet Shareholders,

August 22, 2023

I wanted to connect with our shareholders to provide a business update and discuss future opportunities for our assets. Since our last shareholder meeting in September 2022, Sonnet has focused on business development, which we believe sets the stage for two potential partnership opportunities that have been previously disclosed with Roche and Janssen, on immune checkpoint inhibitors and cell-based therapies, respectively.

1) The immune checkpoint inhibitors (ICIs) represent an extremely successful class of cancer therapies with close to \$40 billion in reported combined 2022 annual revenue for certain large pharmaceutical players, such as Merck, Bristol-Myers, Roche, Astra Zeneca, Pfizer, and others. There is a significant industry initiative to enhance these ICIs with immune-activators/stimulators. However, the toxicity associated with several immune activators in combination with that of the ICIs creates a potential impediment to commercial approval. We believe Sonnet's platform, which offers a longer half-life and solid tumor targeting/retention, could enable commercialization of an ICI combination, especially in cancer indications where the ICIs have not been very effective, such as with platinum-resistant ovarian cancer (PROC). We are collaborating with Roche to evaluate this combination in the clinic for PROC. As you are aware, the trial was accepted by the Australian regulatory agency earlier this year and more recently, the FDA accepted the IND to begin clinical study in the US. We expect to see the first safety data within the next few quarters.

2) Cell-based therapy is another important advancement in medical oncology, where the patient's isolated T-cells are genetically engineered to fight cancer. Based on a number of publications, immune-activators have a significant role to play, especially for solid tumors. Sonnet is collaborating with Janssen to evaluate SON-1010, SON-1210, and SON-1410 with Janssen's CAR-T cell-based therapy. We expect data to be available in the next few quarters.

Sonnet's proprietary technology, the "Fully Human Albumin Binding" (FHAB) domain, was designed to target solid tumors, to be retained in the tumor microenvironment (TME) and to extend drug half-life. SON-1010, our lead drug candidate that presents IL-12 on our FHAB platform, is a powerful immune-enhancer that we believe offers a differentiated approach for the therapeutic application of this cytokine. Sonnet carefully evaluated responses to SON-1010 dosing in both normal healthy volunteers and cancer patients. The preliminary data that we previously shared with you demonstrates potential targeting of tumor tissue in cancer patients, along with a long half-life and early clinical benefit. SON-1210 is our first bifunctional candidate that integrates IL-12 and an additional immunomodulatory cytokine, IL-15. Together, these two cytokines exhibited synergies in preclinical cancer models and we have shown its safety in GLP toxicology studies. Furthermore, we have successfully manufactured SON-1210 and we believe we are ready to begin the regulatory preparations to enter the clinic. The molecule is currently under evaluation by Janssen as part of its engineered cell-based programs. This asset is followed by SON 1410, another bifunctional FHAB candidate comprising IL-18 and IL-12, which is also under evaluation by Janssen. Finally, SON-080, which is a low-dose version of fully human IL-6 that we in-licensed, is currently undergoing clinical testing in chemotherapy-induced peripheral neuropathy (CIPN). This candidate has been progressing in the clinic, though somewhat slowly due to patient recruitment challenges. There remains persistent unmet medical need in both CIPN and the potentially much larger indication of diabetic peripheral neuropathy (DPN), which are important drivers of our decision to continue to pursue development in these indications.

We are excited about advancing our collaborations and the potential partnerships that could generate important data sets within the next fiscal year and which, if successful, we believe represent an opportunity to bring non-dilutive capital into the company. Further, we have significantly reduced the operating expenses to focus on assets with near-term partnering interest as we navigate through a tough financial market while maintaining our Nasdaq listing. We understand your concerns about dilutive financings, and we are working diligently to capitalize the company as efficiently as possible. Together, let us advance our initiative of innovating groundbreaking new cancer therapies and I look forward to interacting with you in our 2023 Annual Shareholder meeting on August 31.

Sincerely,

Pankaj Mohan, Ph.D., MBA  
Founder & CEO  
Sonnet BioTherapeutics

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