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): January 9, 2023

SONNET BIOTHERAPEUTICS HOLDINGS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35570**	**20-2932652**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Overlook Center, Suite 102 Princeton, New Jersey	**08540**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(609) 375-2227**

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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 per share	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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

On January 9, 2023, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing a clinical collaboration agreement with Roche for the clinical evaluation of the Company's SON-1010 with Roche's atezolizumab in patients with platinum-resistant ovarian cancer ("PROC"). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the 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 January 9, 2023, the Company announced a clinical collaboration agreement with Roche for the clinical evaluation of the Company's SON-1010 with Roche's atezolizumab in patients with PROC. The Company intends to raise additional capital to help fund the clinical trial ("SB221"), which will commence during the second calendar quarter of 2023.

SB221 will be conducted to assess the safety and preliminary efficacy of SON-1010 in combination with Roche's atezolizumab in patients with PROC. The companies would provide SON-1010 and atezolizumab, respectively, for use in the study. SB221 is a global Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of SON-1010 administered subcutaneously, either alone or in combination with atezolizumab

given intravenously. The study is designed in Part 1 to rapidly establish the maximum tolerated dose of the combination in patients with advanced solid tumors in small dose-escalation groups and to expand the dataset at the recommended Phase 2 dose. This would be followed in Part 2 by an assessment in patients with PROC of the potential for improved efficacy of the combination over SON-1010 alone or the standard of care.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

Exhibit No.	Description
99.1	Press Release issued by Sonnet BioTherapeutics Holdings, Inc., dated January 9, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: January 9, 2023

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

Exhibit 99.1

Sonnet BioTherapeutics Announces a Collaboration with Roche for the Clinical Evaluation of SON-1010 with atezolizumab in Ovarian Cancer

- **Sonnet's lead product, SON-1010, to be evaluated in combination with Roche's atezolizumab (Tecentriq®)**
- **Sonnet will sponsor the clinical study in patients with platinum-resistant ovarian cancer, scheduled to commence during the second calendar quarter of 2023, and Roche will supply atezolizumab**

PRINCETON, NJ / ACCESSWIRE / January 09, 2023/ Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN), a clinical-stage company developing targeted immunotherapeutic drugs, announced today a clinical collaboration agreement with Roche. A clinical trial (SB221) will be conducted to assess the safety and preliminary efficacy of SON-1010 (IL12-F_HAB) in combination with Roche's atezolizumab in patients with platinum-resistant ovarian cancer (PROC). Interleukin-12 (IL-12) is a cytokine, or an immune cell-signaling protein, that enhances the activity of natural killer (NK) cells and T cells. SON-1010 is a proprietary version of native human IL-12, configured using Sonnet's fully human albumin binding (F_HAB®) platform, which targets the tumor microenvironment (TME) and extends the pharmacokinetics (PK) and subsequent pharmacodynamics (PD) of the molecule. Atezolizumab is an immune checkpoint inhibitor approved for the treatment of some of the most aggressive and difficult-to-treat forms of cancer. The characteristics of ovarian cancer present a unique opportunity to assess the combination of these two agents in an indication that persists as a large unmet medical need.

"As this is Sonnet's first combination clinical study and an opportunity to use our lead F_HAB-derived candidate, SON-1010, with atezolizumab, it is a very important milestone for the company. We believe that the combination of our best-in-class IL12-F_HAB immune-enhancer candidate with atezolizumab could enable the next generation of cancer treatment." said Pankaj Mohan, Ph.D., Sonnet's Founder and Chief Executive Officer. "We anticipate initiating the clinical study during the second calendar quarter of 2023 and will look to a successful safety evaluation for the opportunity to expand the collaboration".

Sonnet and Roche have entered into a Master Clinical Trial and Supply Agreement (MCSA), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer (PROC) patient setting. Further, the companies would provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a safety and efficacy study.

"The extended PK of SON-1010, along with its ability to target and be retained within the TME, makes it a potentially best-in-class version of IL-12", said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "Ovarian cancer has a high expression of proteins that bind albumin, which will concentrate SON-1010 in the TME. The induced immune responses can make this relatively 'cold' tumor immunologically 'hot'. Ovarian cancer patients who are resistant to platinum compounds have very few options for successful treatment. This combination provides a novel alternative that may improve their rate of response."

SB221 is a global Phase 1b/2a multicenter, dose-escalation and randomized proof-of-concept study to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered subcutaneously (SC), either alone or in combination with atezolizumab given intravenously (IV). The study is designed in Part 1 to rapidly establish the maximum tolerated dose (MTD) of the combination in patients with advanced solid tumors in small dose-escalation groups and to expand the dataset at the recommended Phase 2 dose (RP2D). This would be followed in Part 2 by an assessment in patients with PROC of the potential for improved efficacy of the combination over SON-1010 alone or the standard of care. Both companies look forward to this collaboration as an opportunity to improve outcomes for patients with ovarian cancer.

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, bifunctional 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. Sonnet's F_HAB was designed to specifically target tumor and lymphatic tissue, with an improved therapeutic window for optimizing the safety and efficacy of immune modulating biologic drugs. 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.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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

Michael V. Morabito, Ph.D.
Solebury Strategic Communications
917-936-8430
mmorabito@soleburystrat.com
