

**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 28, 2025

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35570</u> (Commission File Number)	<u>20-2932652</u> (IRS Employer Identification No.)
<u>100 Overlook Center, Suite 102 Princeton, New Jersey</u> (Address of principal executive office)		<u>08540</u> (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:

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value per share	SONN	The Nasdaq Capital 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.

On January 28, 2025, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing that the European Patent Office (the "EPO") has granted EU Patent No. EP3583125 B1, entitled "*Albumin Binding Domain Fusion Proteins*," which covers the Company's Fully Human Albumin Binding ("F_HAB[®]") technology, and includes therapeutic fusion proteins that utilize F_HAB for tumor targeting and retention and provide extended pharmacokinetics (PK).

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 (the "SEC"), 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 28, 2025 the Company announced that the EPO has granted Patent No. EP3583125 B1, entitled "*Albumin Binding Domain Fusion Proteins*," which covers the Company's F_HAB technology and includes therapeutic fusion proteins that utilize F_HAB for tumor targeting and retention, and provide extended pharmacokinetics (PK). The EU patent carries a term effective until February 20, 2038. In addition to the U.S. and EU, the Company's global intellectual property coverage now extends to China, Japan, Russia and New Zealand.

The Company's F_HAB platform consists of a single, fully human construct of a F_HAB antibody fragment that has high affinity to bind to human albumin. The platform provides an off-the-shelf lock and load opportunity to rapidly develop numerous therapeutic biologics.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act and Private Securities Litigation Reform Act, as amended, including those relating to the outcome of the Company's clinical trials, the Company's cash runway, 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 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 SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this Current Report. 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.	Description
99.1	Press Release dated January 28, 2025.
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.

Date: January 28, 2025

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



Sonnet BioTherapeutics Further Expands Global Intellectual Property Portfolio with Issuance of EU Patent for F_HAB[®] Platform Technology

European Patent Office (EPO) grants EU Patent No. EP3583125 B1 covering the Company's Fully Human Albumin Binding (F_HAB[®]) domain fusion proteins

In addition to the U.S. and EU, Sonnet's global IP coverage now extends to China, Japan, Russia and New Zealand

Management releases "What This Means" segment discussing the newly granted EU patent; Access here

PRINCETON, NJ / Globe Newswire / January 28, 2025 / Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today announced that the European Patent Office (EPO) has granted Patent No. EP3583125 B1, entitled "Albumin Binding Domain Fusion Proteins," which covers Sonnet's Fully Human Albumin Binding (F_HAB[®]) technology and includes therapeutic fusion proteins that utilize F_HAB for tumor targeting and retention and provide extended pharmacokinetics (PK). The EU patent carries a term effective until February 20, 2038. Additionally, the Company announced the release of a "What This Means" segment to discuss the EU patent and its global IP estate, which is now available here.

"The granting of this EU patent represents another milestone that provides expanded global protection along with building our intellectual capital and differentiation from any existing or emerging competitive technologies that may leverage the beneficial characteristics of binding to human serum albumin," commented Pankaj Mohan, Ph.D., Founder and CEO of Sonnet. "Further, this European patent issuance expands the global IP protection for our product pipeline beyond previous patents issued in China, Japan, Russia and New Zealand, which we believe provides further validation for our F_HAB platform."

Sonnet's F_HAB platform consists of a single, fully human construct of a F_HAB antibody fragment that has high affinity to bind to human albumin. The platform provides an off-the-shelf lock and load opportunity to rapidly develop numerous therapeutic biologics.

John Cini, Ph.D., Co-Founder and CSO of Sonnet commented, "The F_HAB platform technology provides each of Sonnet's pipeline drug candidates with either a mono- or bi-functional mechanism of action, thus allowing for the potential of biological synergy between cytokines. Preclinical comparative *in vivo* studies with wild type cytokines have shown that F_HAB-derived drug candidates have reproducibly extended pharmacokinetics, enhanced payload delivery to the tumor and improved efficacy."

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet is an oncology-focused biotechnology company with a proprietary platform for developing targeted biologic drugs with single or 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 platform 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.

Sonnet's lead program, SON-1010, or IL-12-F_HAB, is in development for the treatment of solid tumors and ovarian cancer. SON-1010 is being evaluated in an ongoing Phase 1/2a study through a Master Clinical Trial and Supply Agreement, along with ancillary Quality and Safety Agreements, with Roche in combination with atezolizumab (Tecentriq[®]) for the treatment of platinum-resistant ovarian cancer (PROC). The Company is also evaluating its second program, SON-1210, an IL12-F_HAB-IL15 for solid tumors, in collaboration with the Sarcoma Oncology Center to commence an investigator-initiated and funded Phase 1/2a study for the treatment of pancreatic cancer.

The Company's SON-080 program is a low dose of rhIL-6 in development for Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN). SON-080 demonstrated encouraging results in a Phase 1b/2a clinical trial, being well tolerated with no evidence of a pro-inflammatory cytokine response. In October 2024, Sonnet announced an India license agreement with Alkem Laboratories, Inc. who will assume responsibility for advancing development of the SON-080 program into a Phase 2 study in DPN.

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 cash runway, 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.

Investor Relations Contact:

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