

**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 19, 2024

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</u> <u>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 August 19, 2024, Sonnet BioTherapeutics Holdings, Inc. (the "Company") issued a press release announcing it has entered into a Master Clinical Collaboration Agreement (the "Agreement") with the Sarcoma Oncology Center, to advance the development of SON-1210, the Company's proprietary, bifunctional version of human Interleukins 12 (IL-12) and 15 (IL-15), configured using the Company's Fully Human Albumin Binding (FHAB®) platform, in combination with chemotherapy for the treatment of metastatic pancreatic cancer.

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 August 19, 2024, the Company announced it has entered into the Agreement with the Sarcoma Oncology Center to advance the development of SON-1210. Preclinical data has demonstrated the potential of SON-1210, the first albumin-binding bifunctional IL-12/IL-15 fusion protein, for solid tumor immunotherapy. An Innovative Immuno Oncology Consortium ("IIOC") led by Oncology experts funded by the Sarcoma Oncology Center will conduct an investigator-initiated Phase 1/2a study of SON-1210 in pancreatic cancer, an indication with significant unmet medical need. Under the terms of the Agreement, the IIOC, led by Dr. Sant Chawla, Director of the Sarcoma Oncology Center, in collaboration with the Company, will prepare a protocol and conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin ("NALIRIFOX") for the specific treatment of metastatic pancreatic cancer. NALIRIFOX is U.S. FDA approved for the treatment of metastatic pancreatic cancer in the front-line and refractory setting. The Company will provide the study drug, SON-1210, and support services for the planned Phase 1/2a study.

As previously announced, the Company successfully completed two IND-enabling toxicology studies of SON-1210 in non-human primates (NHPs), which demonstrated no overt toxicity in the GLP study apart from the expected, and mild, on-target changes in hematology and clinical chemistry parameters that resolved completely within 14 to 21 days post-dosing. A significant increase in interferon gamma (IFN γ), which was transient in nature, was noted as early as one day following administration, with no apparent increase in other proinflammatory cytokines. IFN γ is a well-known pharmacodynamic biomarker that is required for anti-tumor efficacy in preclinical models. Other signs of cytokine imbalance, or uncontrolled increase of pro-inflammatory cytokines (including TNF- α , IL-1 β , and IL-6) were notably absent from all dose levels tested in the study.

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 Company's Master Clinical Collaboration Agreement with the Sarcoma Oncology Center 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 August 19, 2024.
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: August 19, 2024

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



Sonnet BioTherapeutics Enters into Clinical Collaboration Agreement to Commence Investigator-Initiated and Funded Phase 1/2a Study of SON-1210 in Combination with Chemotherapy for the Treatment of Pancreatic Cancer

Preclinical data has demonstrated the potential of SON-1210, the first albumin-binding bifunctional IL-12/IL-15 fusion protein, for solid tumor immunotherapy

An Innovative Immuno Oncology Consortium (“IIOC”) led by Oncology experts funded by the Sarcoma Oncology Center will conduct an investigator-initiated Phase 1/2a study of SON-1210 in pancreatic cancer, an indication with significant unmet medical need

Company management recently participated in a Virtual Investor KOL Connect segment with world-renowned leaders in pancreatic cancer development - Sant Chawla, MD and Andrew Hendifar, MD; [Access the segments here](#)

PRINCETON, NJ / ACCESSWIRE / August 19, 2024 / Sonnet BioTherapeutics Holdings, Inc. (the “Company” or “Sonnet”) (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today announced it has entered into a Master Clinical Collaboration Agreement (the “Agreement”) with the Sarcoma Oncology Center, to advance the development of SON-1210, the Company’s proprietary, bifunctional version of human Interleukins 12 (IL-12) and 15 (IL-15), configured using Sonnet’s Fully Human Albumin Binding (F_HAB[®]) platform, in combination with chemotherapy for the treatment of metastatic pancreatic cancer.

“We are very pleased to enter into this strategic development collaboration to advance SON-1210 with this prestigious organization and in a program that we believe has the potential to address a significant area of unmet need. We expect that this development approach will provide us with valuable information in a high-value cancer indication that will add to our growing body of data, which we believe will potentially drive value in our platform and enable us to preserve cash resources,” commented Pankaj Mohan, Ph.D., Founder and CEO of Sonnet.

Dr. Hendifar, a renowned physician developing new therapies for pancreatic cancer and neuroendocrine tumors and Associate Professor of Medicine, Medical Director – Pancreatic Cancer, Co-Director – Hematology-Oncology Fellowship Program and Medical Director - Gastrointestinal Oncology Disease Research Group at Cedars-Sinai, added, “Pancreatic cancer incidence is growing worldwide and the advancements in the standards of care beyond chemotherapies has been limited. We believe a novel immunotherapy such as SON-1210 offers an exciting opportunity to improve outcomes for patients.”

Under the terms of the Agreement, the IIOC, led by Dr. Sant Chawla, Director of the Sarcoma Oncology Center, in collaboration with Sonnet, will prepare a protocol and conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin (“NALIRIFOX”) for the specific treatment of metastatic pancreatic cancer. NALIRIFOX is U.S. FDA-approved for the treatment of metastatic pancreatic cancer in the front-line and refractory settings. Sonnet will provide the study drug, SON-1210, and support services for the planned Phase 1/2a study.

“We are very excited to enter this collaboration with Sonnet. Cancers are hungry for albumin and albumin-bound drugs are taken up preferentially by cancer cells,” added Dr. Chawla, a leading authority in medical treatment and clinical research for bone and soft-tissue sarcomas and sarcoma therapy. “We know this is a validated mechanism for enhancing efficacy and reducing toxicity and there are no immunotherapies approved for pancreatic cancer. SON-1210’s dual IL-12, IL-15 approach builds upon the success of SON-1010 in extending the cytokine half-life and turning cold tumors hot, which is being studied at our center as well.

John Cini, Ph.D., Chief Scientific Officer and a Co-Founder of Sonnet concluded, “Clinical trials using cytokines have had limited success to date due to their short half-lives, the inability to directly target cancer cells, and high rates of adverse events. Sonnet’s fully human albumin-binding platform has been specifically designed to address these issues. Based on our F_HAB construct, we have shown that we can increase tumor-targeting and retention by 4-5 fold over unmodified cytokines. We are targeting pancreatic cancer, an area with tremendous unmet need, which has increased expression of the FcRn and GP60 receptors, as well as the SPARC complex. SON-1210, our bifunctional IL-12/IL-15 candidate, has been shown to increase immune activity and persistence in preclinical cancer models, and we are excited to initiate human studies with this unique candidate. SON-1210 may act synergistically with NALIRIFOX, the first new chemotherapy approved for front-line pancreatic cancer in over a decade.”

Additionally, the Company recently participated in a Virtual Investor KOL Connect segment with Dr. Chawla and Dr. Hendifar. The KOL Connect segments are now available [here](#).

As previously announced, the Company successfully completed two IND-enabling toxicology studies of SON-1210 in non-human primates (NHPs), which demonstrated no overt toxicity in the GLP study apart from the expected, and mild, on-target changes in hematology and clinical chemistry parameters that resolved completely within 14 to 21 days post-dosing. A significant increase in interferon gamma (IFN γ), which was transient in nature, was noted as early as one day following administration, with no apparent increase in other proinflammatory cytokines. IFN γ is a well-known pharmacodynamic biomarker that is required for anti-tumor efficacy in preclinical models. Other signs of cytokine imbalance, or uncontrolled increase of pro-inflammatory cytokines (including TNF- α , IL-1 β , and IL-6) were notably absent from all dose levels tested in the study.

About SON-1210

SON-1210 is an immunotherapeutic bifunctional drug candidate that links unmodified single-chain human IL-12 and human IL-15 with the albumin-binding domain of the single-chain antibody fragment F_HAB separating the two cytokines with linkers to avoid steric hindrance. The F_HAB single chain was selected to bind well at normal pH, as well as at an acidic pH that is typically found in the tumor microenvironment (TME). The F_HAB technology targets tumor and lymphatic tissue, providing a mechanism for dose-sparing, enhanced PK, and an opportunity to improve the safety and efficacy profile of not only IL-12 and IL-15, but a variety of other potent immunomodulators using the platform. We believe these dual-targeting cytokines can orchestrate a robust immune response to many cancers and pathogens, particularly when presented together on the same molecule. Given the types of proteins induced in the TME, such as Secreted Protein Acidic and Rich in Cysteine (SPARC), several types of cancer such as non-small cell lung cancer, melanoma, head and neck cancer, sarcoma, and some gynecological cancers are particularly relevant for this approach. SON-1210 is designed to deliver IL-12 and IL-15 to local tumor tissue, with the intention of turning ‘cold’ tumors ‘hot’ by stimulating IFN γ , which activates both innate and adaptive immune cells in the TME, as well as increasing the production of Programmed Death Ligand 1 (PD-L1) on tumor cells.

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of 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 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 Master Clinical Collaboration Agreement with the Sarcoma Oncology Center, 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 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.

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