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): **November 2, 2022**

SONNET BIOTHERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its 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)

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 7.01. Regulation FD.

On November 2, 2022, Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") issued a press release announcing that the safety of SON-1010 dosing in several cohorts has been formally reviewed in both Phase 1 clinical trials and that dose escalation is continuing as early data becomes available, among other clinical updates. A copy of the press release is attached hereto as Exhibit 99.1. In addition, the Company used the slides attached hereto as Exhibit 99.2.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, 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 November 2, 2022, Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") announced that the safety of SON-1010 dosing in several cohorts has been formally reviewed in both Phase 1 clinical trials and that dose escalation is continuing as early data becomes available. SON-1010 is a proprietary version of human interleukin-12 (IL-12), configured using Sonnet's Fully Human Albumin Binding ($F_{H}AB^{®}$) platform. SB101 is a multiple-dose trial for adult patients with advanced solid tumors (NCT05352750) that commenced in April and has now started treating the fourth dose cohort. SB102 is a single-ascending dose trial in healthy volunteers (NCT05408572) that started in July and is dosing the third cohort. Safety Review Committees found no safety concerns and approved advancing to the next higher dose levels for both studies.

The clinical dose-escalation strategy was developed based on the ability to use this non-cytotoxic drug in a single-ascending dose (SAD) study in healthy volunteers to rapidly provide clean PK/PD data without interpretation challenges from prior cancer treatment effects. The initial safety and PD data are being used to evaluate the immune response

to SON-1010 and predict the effect of further dose escalation. IL-12 has been shown to stimulate the production of interferon-gamma (IFNγ), which is necessary for its antitumor effects. Sonnet is using the known protective effects of IL-12 dose timing to minimize toxicity and extend the maximum tolerated dose (MTD).

The adverse events have generally been mild/moderate, transient in nature, and have all been tolerable. In addition, they have been less numerous and less intense with subsequent doses. Acute inflammation in both studies was assessed with a Luminex bead assay for multiple cytokine analytes. IL-12p70 (used to measure SON-1010 concentration) was readily quantified and demonstrated extended pharmacokinetics. The resulting increase in IFNγ (showing an IL-12 effect and potential for tumor control) was dose-related, controlled, and prolonged. There was minimal/no signal for IL-1β, IL-6, IL-8, or TNFα and no indication of cytokine release syndrome (CRS). IL-10 was also induced at a low level, as expected. Even though these patients with advanced solid tumors have been heavily pretreated and many had actively progressive disease at study entry, all but one patient remain on study.

Of the 6 patients from the first two cohorts evaluable for follow-up at this latest cutoff, 5 of the 6 had stable disease at the first follow-up scan, with one patient progressing who is now off study. As of the most recent scan, 2 of the 5 stable disease patients remain stable, while the others had tumor growth that may simply represent tumor inflammation or unconfirmed progression. One patient with endometrial stromal sarcoma who was progressing at study entry now has evidence of improvement after 6 months on SON-1010 with smaller tumors and complete resolution of her ascites.

About SON-1010

SON-1010 is a candidate immunotherapeutic recombinant drug that links unmodified single-chain human IL-12 with the albumin-binding domain of the single-chain antibody fragment A10m3. This was selected to bind both at normal pH, as well as at an acidic pH typically found in the TME. The F_HAB technology targets tumor and lymphatic tissue, providing a mechanism for dose sparing and an opportunity to improve the safety and efficacy profile of not only IL-12, but a variety of potent immunomodulators using the platform. Interleukin-12 can orchestrate a robust immune response to many cancers and pathogens. Given the types of proteins induced in the TME, such as the Secreted Protein and Rich in Cysteine (SPARC) and glycoprotein 60 (GP60), 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-1010 is designed to deliver IL-12 to local tumor tissue, turning 'cold' tumors 'hot' by stimulating IFNγ, which activates innate and adaptive immune cells and increases the production of Programed Death Ligand 1 (PD-L1) on tumor cells.

About the SB101 Phase 1 Trial

This first-in-human study is primarily designed to evaluate the safety of multiple ascending doses of SON-1010 in cancer patients and will be conducted at several sites across the United States. While the optimal dose is unknown at this stage, the potential to target tumors, the extended PK mechanism and our preclinical data suggest the therapeutic dose may be lower compared to native human IL-12. The study, utilizing a standard 3+3 oncology design in at least five cohorts, should establish the MTD and the recommended Phase 2 dose (RP2D) using monthly subcutaneous injections of SON-1010. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, and anti-tumor activity. This study will form the basis for potential combinations with other types of immunotherapies and the future development of bispecific candidates using the FHAB platform.

About the SB102 Phase 1 Trial

The SB102 study is designed to robustly evaluate the safety, PK and PD of single ascending doses of SON-1010, using larger groups of healthy volunteers, and is being conducted at a single site in Australia. The study is done in a blinded fashion, comparing a single dose of SON-1010 to placebo utilizing five cohorts. Both PK and PD will be closely followed during dose escalation in this double-blind, placebo-controlled study, along with an assessment of the cellular immune responses at each dose using sophisticated fluorescence activated cell sorting (FACS) analysis. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure PK, PD, and immunogenicity.

Safe Harbor for Forward-Looking Statements

Certain statements contained in this communication may constitute 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. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements containing the words "predicts," "plans," "expects," "anticipates," "believes," "goal," "target," "estimate," "potential," "may," "might," "could," "see," "seek," "forecast," and similar words. Forward-looking statements are based on the Company's current plans and expectations and involve risks and uncertainties which are, in many instances, beyond the Company's control, and which could cause actual results to differ materially from those included in or contemplated or implied by the forward-looking statements. Such risks and uncertainties include, among others, the success of the Company's clinical and preclinical activities and uncertainties and factors detailed in the Company's filings with the SEC, including in the Company's Annual Report for the year ended September 30, 2021 on Form 10-K, which was filed with the SEC. As a result of such risks, uncertainties and factors, the Company's actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. The Company is providing the information in this communication as of this date and assumes no obligations to update the information included in this communication or revise any forward-looking statements, 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 November 2, 2022
99.2	Presentation, dated November 2, 2022
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.
a Delaware corporation
(Registrant)

Date: November 2, 2022

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

Name: Pankaj Mohan, Ph.D.

Title: Chief Executive Officer

Exhibit 99.1

Sonnet BioTherapeutics Announces Interim Data in Two Phase 1 Dose-Escalation Trials of SON-1010

- **The SB101 and SB102 studies have together dosed 36 subjects to date as dose escalation continues**
- **Cytokine data show extended pharmacokinetics of SON-1010 with controlled induction of IFNγ and no signs of cytokine release syndrome**
- **All but one patient remain on study, with evidence of tumor improvement at 6 months in one patient**

PRINCETON, NJ / ACCESSWIRE / November 2, 2022 / Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) (the "Company" or "Sonnet"), a clinical-stage company developing targeted immunotherapeutic drugs, announced today that the safety of SON-1010 dosing in several cohorts has been formally reviewed in both Phase 1 clinical trials and that dose escalation is continuing as early data becomes available. SON-1010 is a proprietary version of human interleukin-12 (IL-12), configured using Sonnet's Fully Human Albumin Binding ($F_HAB^®$) platform. SB101 is a multiple-dose trial for adult patients with advanced solid tumors NCT05352750) that commenced in April and has now started treating the fourth dose cohort. SB102 is a single-ascending dose trial in healthy volunteers (NCT05408572) that started in July and is dosing the third cohort. Safety Review Committees found no safety concerns and approved advancing to the next higher dose levels for both studies. The data will be presented at a webinar at 8:30 am ET today. The data will also be presented at an upcoming medical conference.

"We have now dosed 12 cancer patients at increasing drug levels in the SB101 study and 24 healthy volunteers in SB102," said Richard Kenney, M.D., Sonnet's Chief Medical Officer. "No dose-limiting toxicities have occurred to date using this novel approach to enhance the safety of cytokine-based immunotherapy and we are starting to get encouraging data back on the pharmacokinetic (PK) and pharmacodynamic (PD) responses. By linking the IL-12 cytokine to an albumin-binding domain that can target tumor tissue and extend the cytokine half-life in the body, we believe our proprietary F_HAB technology will allow us to use higher doses of cytokines without triggering unacceptable toxicity. This could be the key to inducing a successful local immune response to Il-12 in the tumor microenvironment (TME)."

The clinical dose-escalation strategy was developed based on the ability to use this non-cytotoxic drug in a single-ascending dose (SAD) study in healthy volunteers to rapidly provide clean PK/PD data without interpretation challenges from prior cancer treatment effects. The initial safety and PD data are being used to evaluate the immune response to SON-1010 and predict the effect of further dose escalation. IL-12 has been shown to stimulate the production of interferon-gamma (IFNγ), which is necessary for its antitumor effects. Sonnet is using the known protective effects of IL-12 dose timing to minimize toxicity and extend the maximum tolerated dose (MTD).

The adverse events have generally been mild/moderate, transient in nature, and have all been tolerable. In addition, they have been less numerous and less intense with subsequent doses. Acute inflammation in both studies was assessed with a Luminex bead assay for multiple cytokine analytes. IL-12p70 (used to measure SON-1010 concentration) was readily quantified and demonstrated extended pharmacokinetics. The resulting increase in IFNγ (showing an IL-12 effect and potential for tumor control) was dose-related, controlled, and prolonged. There was minimal/no signal for IL-1β, IL-6, IL-8, or TNFα and no indication of cytokine release syndrome (CRS). IL-10 was also induced at a low level, as expected. Even though these patients with advanced solid tumors have been heavily pretreated and many had actively progressive disease at study entry, all but one patient remain on study.

Of the 6 patients from the first two cohorts evaluable for follow-up at this latest cutoff, 5 of the 6 had stable disease at the first follow-up scan, with one patient progressing who is now off study. As of the most recent scan, 2 of the 5 stable disease patients remain stable, while the others had tumor growth that may simply represent tumor inflammation or unconfirmed progression. One patient with endometrial stromal sarcoma who was progressing at study entry now has evidence of improvement after 6 months on SON-1010 with smaller tumors and complete resolution of her ascites.

"We are highly encouraged by these data, some of which shows early signs of SON-1010 activity in the tumors at these initial dose levels that are accompanied by a tolerable safety profile," said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer. "As the first F_HAB technology-derived candidate dosed in patients, we believe the demonstration of extended PK with SON-1010 represents a significant step forward in Sonnet's approach to immunotherapy with the F_HAB platform. These studies are expected to form the basis for combinations with other immunotherapies that could have synergistic effects on cancer and that we expect will support potential licensing activities."

About SON-1010

SON-1010 is a candidate immunotherapeutic recombinant drug that links unmodified single-chain human IL-12 with the albumin-binding domain of the single-chain antibody fragment A10m3. This was selected to bind both at normal pH, as well as at an acidic pH typically found in the TME. The F_HAB technology targets tumor and lymphatic tissue, providing a mechanism for dose sparing and an opportunity to improve the safety and efficacy profile of not only IL-12, but a variety of potent immunomodulators using the platform. Interleukin-12 can orchestrate a robust immune response to many cancers and pathogens. Given the types of proteins induced in the TME, such as the Secreted Protein and Rich in Cysteine (SPARC) and glycoprotein 60 (GP60), 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-1010 is designed to deliver IL-12 to local tumor tissue, turning 'cold' tumors 'hot' by stimulating IFNγ, which activates innate and adaptive immune cells and increases the production of Programed Death Ligand 1 (PD-L1) on tumor cells.

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About the SB102 Phase 1 Trial

The SB102 study is designed to robustly evaluate the safety, PK and PD of single ascending doses of SON-1010, using larger groups of healthy volunteers, and is being conducted at a single site in Australia. The study is done in a blinded fashion, comparing a single dose of SON-1010 to placebo utilizing five cohorts. Both PK and PD will be closely followed during dose escalation in this double-blind, placebo-controlled study, along with an assessment of the cellular immune responses at each dose using sophisticated fluorescence activated cell sorting (FACS) analysis. The primary endpoint explores the safety and tolerability of SON-1010, with key secondary endpoints intended to measure PK, PD, and immunogenicity.

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 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 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.

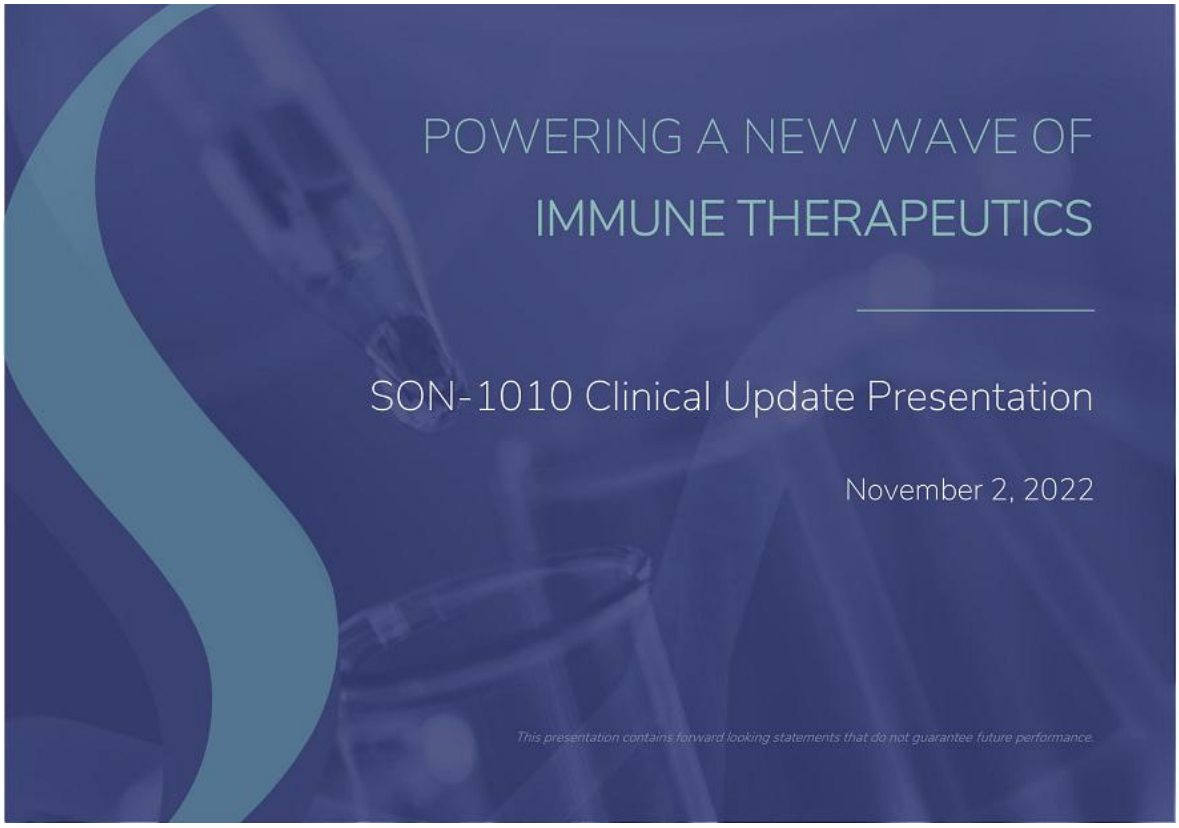
These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential, "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements 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

SOURCE: Sonnet BioTherapeutics, Inc.

Exhibit 99.2



SONNET BioTherapeutics

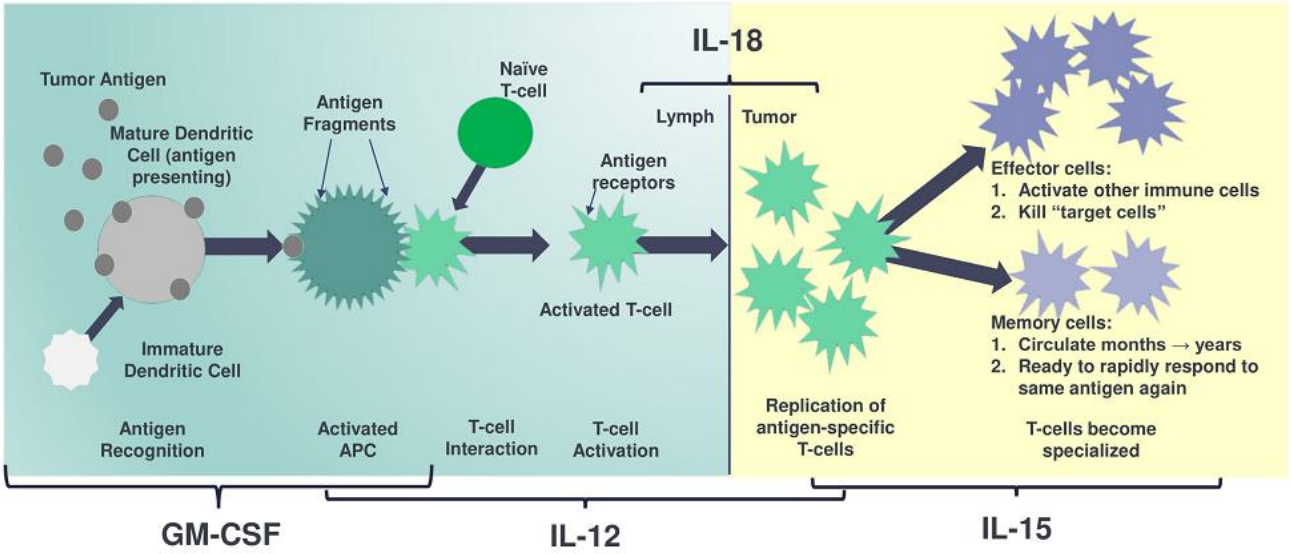
FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements about **Sonnet BioTherapeutics** based on management's current expectations which are subject to known and unknown uncertainties and risks. Words such as "anticipated," "initiate," "expect," "intend," "plan," "believe," "seek," "estimate," "may," and variations of these words or similar expressions are intended to identify forward-looking statements. Our actual results could differ materially from those discussed due to a number of factors, including, but not limited to, our ability to raise additional equity and debt financing on favorable terms, the success of our R&D programs, our ability to obtain regulatory approval of our clinical assets and other risk factors.

We are providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise. Unless the context requires otherwise, references to "Sonnet," "Company," "we," "us" and "our" refer to **Sonnet BioTherapeutics**.

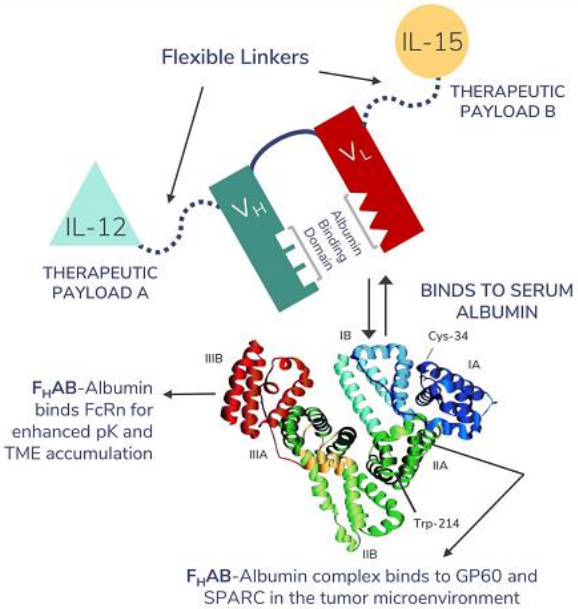
Sonnet Pipeline Targets

Multiple Points of Intervention



Cytokines have shown great promise as cancer therapeutics but suffer from dose-related toxicity and short half-life

Sonnet's Technology Advantage



For a video displaying the F_HAB mechanism, please click here

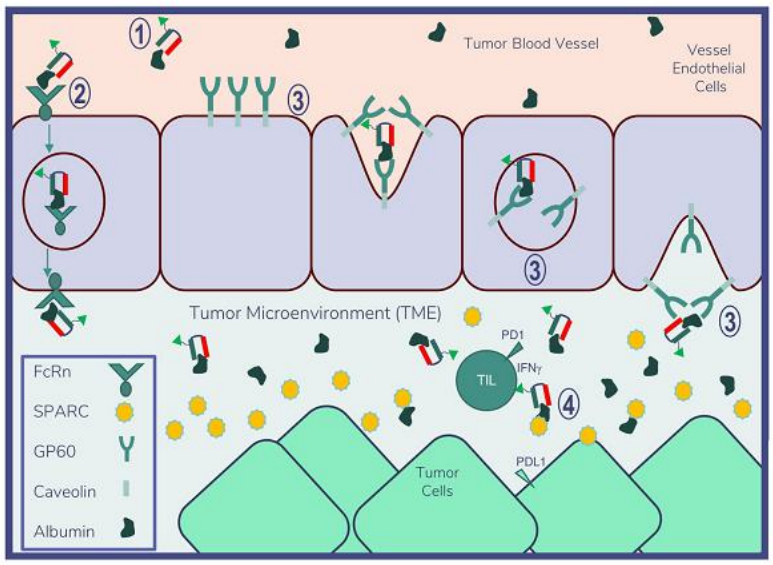
Asset Profile: SON-1010 (IL12-F_HAB)
Stage: Phase 1 study initiated
Indications: Solid Tumors

Product Description: Asset delivery and targeting by albumin binding mechanism via the F_HAB domain, which results in accumulation of SON-1010 in the microenvironment of solid tumors (TME) through binding to FcRn, GP60, and SPARC, thereby enhancing penetration and retention with increased efficacy. SON-1010 has demonstrated improved pK via binding to FcRn, similar to full MAbs, and improved tumor delivery, all available in a single patented construct.

Platform Attributes:

- Fully human construct – Low/No Immunogenicity
- Mammalian cell production (CHO) – Glycosylated
- Small size with linear flexibility – Optimized tumor penetration
- Enhanced PK – FcRN binding
- Targeted – GP60 and SPARC
- Asset Optionality: Single or Bispecific payload capacity
- Modular – Rapid asset development

F_HAB: Accumulation in the Tumor Microenvironment



- **Albumin** is elevated in solid tumors
- **FcRn** over expressed in tumors
- **GP60** is over-expressed on tumor vessel endothelial lining
- Over-expression of **SPARC** has been shown in many solid tumors

Tumor architectural changes cause **EPR** that helps maintain the TME

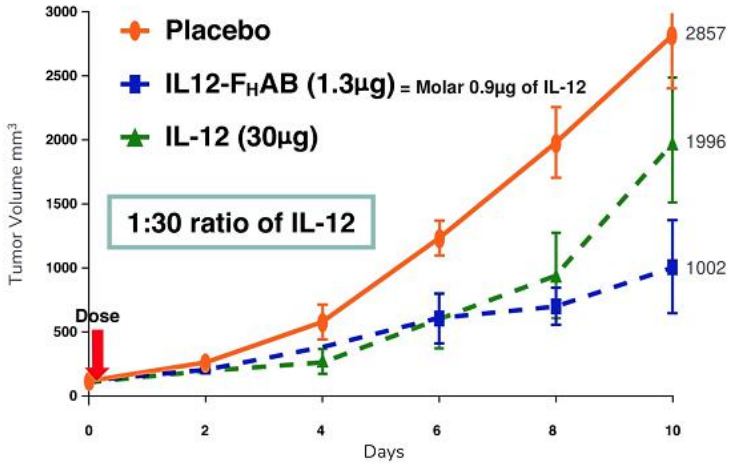
1. IL-F_HAB binds Albumin in the blood
2. IL-F_HAB – Albumin binds to FcRn resulting in transport from blood to TME
3. IL-F_HAB – Albumin binds to GP60, resulting in transport from blood to TME
4. IL-F_HAB – Albumin binds to SPARC

This mechanism of action results in SPARC retaining IL-F_HAB in TME

Hoogenboezem, Adv Drug Deliv Rev. 2018 May; 130: 73-89
Merlot, Front Physiol (2014) 5: 299

SON-1010: Reduces Tumor Volume

IL12-F_HAB (1.3µg) vs IL-12 (30µg) in B16F10 Melanoma



Single dose when tumor was 100 mm³ ; 8 mice/group

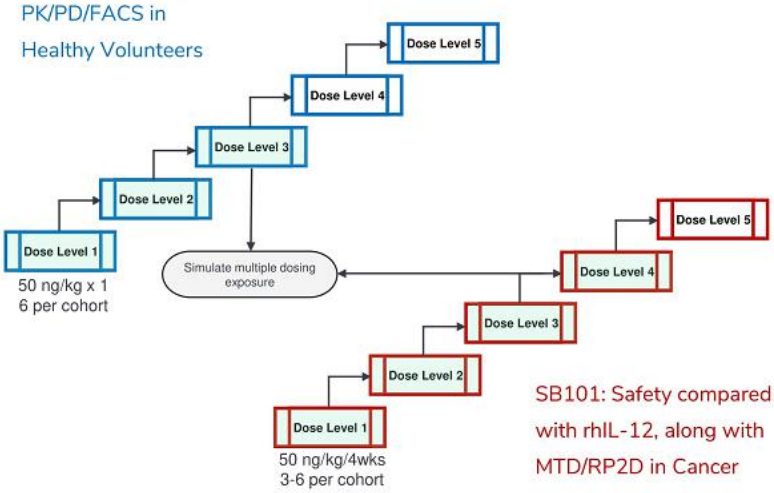
IL-12 (1µg) and IL12-**F_HAB** (1.3µg) are molar equivalent and have similar bioactivity, *in vitro*; however, *in vivo*, **F_HAB** is approximately 30-fold more potent than IL-12 (at day 10, 1.3µg IL12- **F_HAB** > IL-12 30µg)

PROOF-OF-CONCEPT

AACR Annual Meeting 2017, Poster #588

Clinical Program: SB101/SB102 Study Designs

SB102: SAD for PK/PD/FACS in Healthy Volunteers



SB101: Safety compared with rhIL-12, along with MTD/RP2D in Cancer

- Rapid enrollment of healthy volunteers in the SAD provides clean PK data without interpretation challenges from prior cancer treatment effects
- Simulation using continual reassessment model allows prediction of safe doses in the MAD that have more potential for effect on the tumor micro-environment, encouraging enrollment
- Clinical pharmacology support and HV SAD allows for much lower cost and faster completion
- MTD/RP2D in solid tumor patients provides path to combination studies

Shen, Clin Transl Sci (2019) 12:6
Karakunnel, J Transl Med (2018) 16:336
Gokhale, Exp Hematol Oncol (2014) 3:11

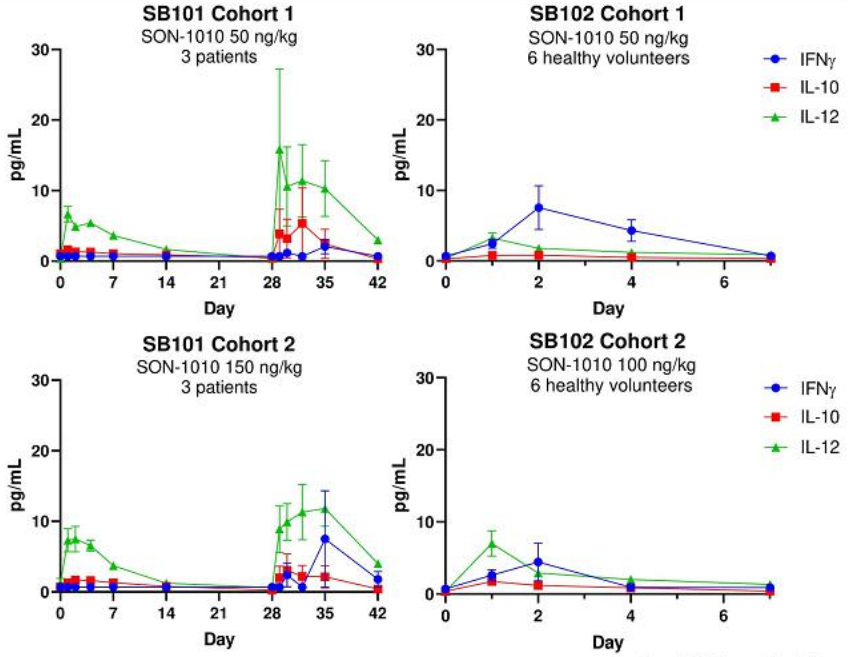
SB101: Safety Data (unaudited, as of 10/31/22)

Related TEAEs by Grade	0.05 ug/kg (N=3), n (%)	0.15 ug/kg (N=3), n (%)	0.15 → 0.3 ug/kg (N=3), n (%)
Tachycardia (Grade 1)		1 (33.3)	
Nausea (Grade 1)	1 (33.3)		
Chills (Grade 1)		1 (33.3)	
Fatigue (Grade 1)		1 (33.3)	
Injection site pain (Grade 1)	1 (33.3)	3 (100.0)	
Pain (Grade 1)	1 (33.3)		
Pyrexia (Grade 1)		1 (33.3)	1 (33.3)
Decreased appetite (Grade 1)	1 (33.3)		
Oedema peripheral (Grade 1)	1 (33.3)	1 (33.3)	
Arthralgia (Grade 1)	1 (33.3)		
Limb discomfort (Grade 1)	1 (33.3)		
Muscular weakness			1 (33.3)
Myalgia (Grade 1)	2 (66.7)		
Pain in extremity (Grade 1)	1 (33.3)	1 (33.3)	
Headache (Grade 1)		1 (33.3)	
Night sweats (Grade 1)		1 (33.3)	
Rash pruritic (Grade 1)	1 (33.3)		
Hot flush (Grade 1)	1 (33.3)		
Fatigue (Grade 2)	3 (100.0)		1 (33.3)
Alanine aminotransferase (ALT) increased (Grade 2)		1 (33.3)	
Aspartate aminotransferase (AST) increased (Grade 2)		1 (33.3)	
Lipase Increased (Grade 3)			1 (33.3)

- AEs in SB102 were generally mild, transient and tolerable as well after a single dose of SON-1010

SB101: PK and Cytokine Responses

- Acute inflammation was assessed with a Luminex bead assay for multiple analytes in both studies
- IL-12p70 (used to measure SON-1010 concentration) was readily quantitated and shows extended pharmacokinetics
- Increase in IFNγ (showing an IL-12 effect and potential for tumor control) was dose-related, controlled and prolonged
- There was minimal/no signal for IL-1β, IL-6, IL-8, or TNFα and no indication of cytokine release syndrome (CRS)
- IL-10 was induced by IL-12 at a low level

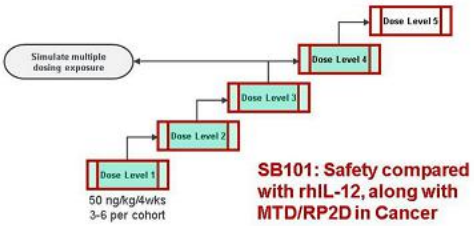


SB101: Influence on Tumor Size

- 5 of the 6 patients had SD at the first follow-up CT at 2 months, with one patient (#3) progressing (who is now off study). As of the 4-month scan, 2 of the 5 SD patients remained stable, while the others had tumor growth that could represent tumor inflammation or may be unconfirmed progressive disease (iUPD by iRECIST).
- One patient (#1) with endometrial sarcoma who was progressing at study entry now has evidence of improvement after 6 months on SON-1010 with smaller tumors and complete resolution of her ascites.
- The plot shows the current time on study for each patient and whether they were stable or progressing at study entry. If patients are clinically stable, they can continue on study until progression is confirmed (iCPD).

SB101 Clinical Program: High Level Summary

- Allometric PK modeling suggests $t_{½}$ in humans is 52 hrs
  - Compares favorably with rhIL-12 $t_{½}$ of 5-12 hrs
  - Early SON-1010 data is consistent with the PK model
- No Dose Limiting Toxicities to date in 12 patients
- Mostly mild with very few Grade 2/3 AEs
  - All have been transient and tolerable
  - AEs are less numerous and less intense after the first dose
  - Labs suggest cell margination and inflammation without clinical toxicity
- Preliminary indication of SON-1010 activity in the tumors
  - All but one patient remain on study, despite PD in many at entry
  - 5 of 6 evaluable patients had SD at 2mo, 2 of 6 had SD at 4mo
  - At 6mo, one patient had evidence of improvement with smaller tumors and complete resolution of ascites
- Cytokine results suggest SON-1010 has extended PK with induction of an IL-12 effect, without Cytokine Release Syndrome



Pipeline Overview

	PROGRAM	INDICATIONS	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III	PARTNER
F_HAB Platform	SON-1010 (IL12-F_HAB)	Solid Tumors						
		Healthy Volunteers						
	SON-1210 (IL12-F_HAB-IL15)	Solid Tumors						
	SON-1410 (IL18-F_HAB-IL12)	Melanoma, Renal Cancers						
	SON-3015 (Anti-IL6-F_HAB-Anti-TGFβ)	Tumor and Bone Metastases						
	SON-080 (Low-dose IL-6)	Chemotherapy Induced Peripheral Neuropathy						
		Diabetic Peripheral Neuropathy						New Life Therapeutics

- SB101 and SB102 will be presented at an upcoming medical conference.
- SON-1010, SON-1210 and SON-1410 will be evaluated preclinically in combination with Janssen's cell therapy assets.
- The next step is to further explore SON-1010 efficacy in the clinic in Phase 2, as well as its potential for use in combination with a checkpoint inhibitor.