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): September 9, 2024

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 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 (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 Disclosure.

Sonnet BioTherapeutics Holdings, Inc. (the "Company") has prepared presentation materials (the "Corporate Presentation") that management intends to use as part of the Company's participation in the Virtual Investor Closing Bell Series to be held on Monday, September 9, 2024, at 4:00 PM ET. A copy of the Corporate Presentation has been posted to the Company's website and is attached as Exhibit 99.1 hereto and incorporated by reference into this Item 7.01.

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 9.01. Financial Statements and Exhibits.

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

Exhibit No.	**Description**
99.1	Corporate Presentation by Sonnet BioTherapeutics Holdings, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

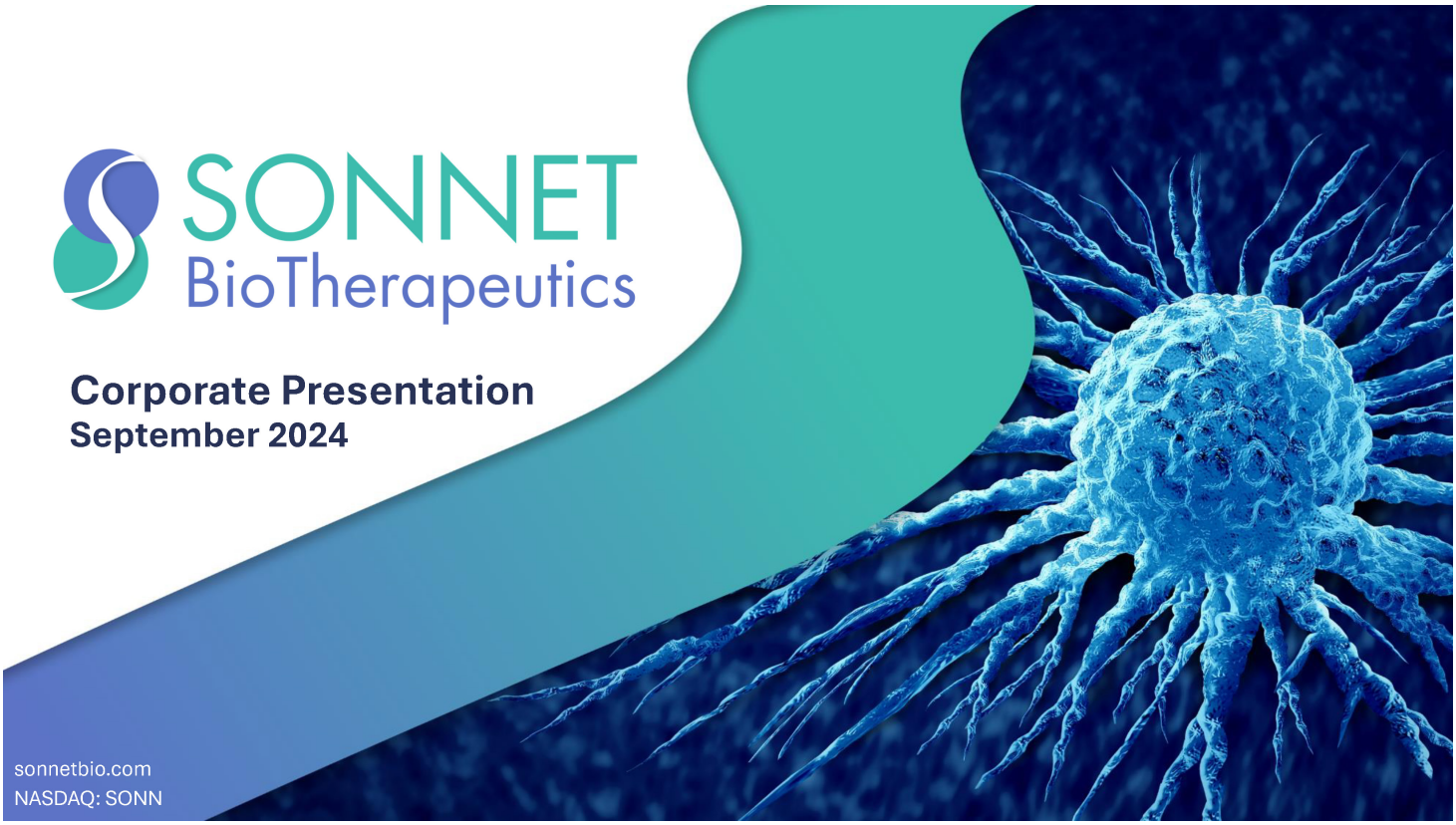
SIGNATURES

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: September 9, 2024

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



Forward-Looking Statements

This presentation contains certain forward-looking statements about Sonnet BioTherapeutics 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 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. Unless the context requires otherwise, references to "Sonnet," "Company," "we," "us" and "our" refer to Sonnet BioTherapeutics Holdings, Inc.

Investment Highlights

Developing targeted immuno-oncology drugs that turn 'cold' tumors 'hot'

Fully modular technology enables the design of single or bifunctional biologic compounds that target albumin, which binds to FcRn, GP60 and SPARC. Albumin is elevated in the TME.

Validated albumin-binding approach affords targeted delivery with enhanced tumor penetration, retention, and local activation of an immune effect

Lead programs designed to address high-value solid tumor markets

Demonstrated encouraging results in immune activation and tumor reduction

Existing material supply agreement with Roche and pipeline evaluation agreement with JNJ

Multiple important milestones expected in near-term

Development Pipeline

	PROGRAM	INDICATIONS	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	PARTNER
F_HAB Technology	SON-1010 (IL12-F_HAB)	Solid Tumors						
	SON-1010 (IL12-F_HAB) Combination with atezolizumab (Tecentriq®)	Platinum-Resistant Ovarian Cancer (PROC)						Roche
	SON-1210 (IL12-F_HAB-IL15)	Solid Tumors						
	SON-1210 (IL12-F_HAB-IL15)	Pancreatic Cancer						SARCOMA ONCOLOGY CENTER
	SON-1411 (IL18-F_HAB-IL12)	Solid Tumors						
	SON-1400 (IL18-F_HAB)	Solid Tumors						
	SON-080 (Low-dose IL-6)	Chemotherapy Induced Peripheral Neuropathy (CIPN)						
		Diabetic Peripheral Neuropathy (DPN)						New Life Therapeutics

SONNET BioTherapeutics

F_HAB Platform Technology Mechanism of Action

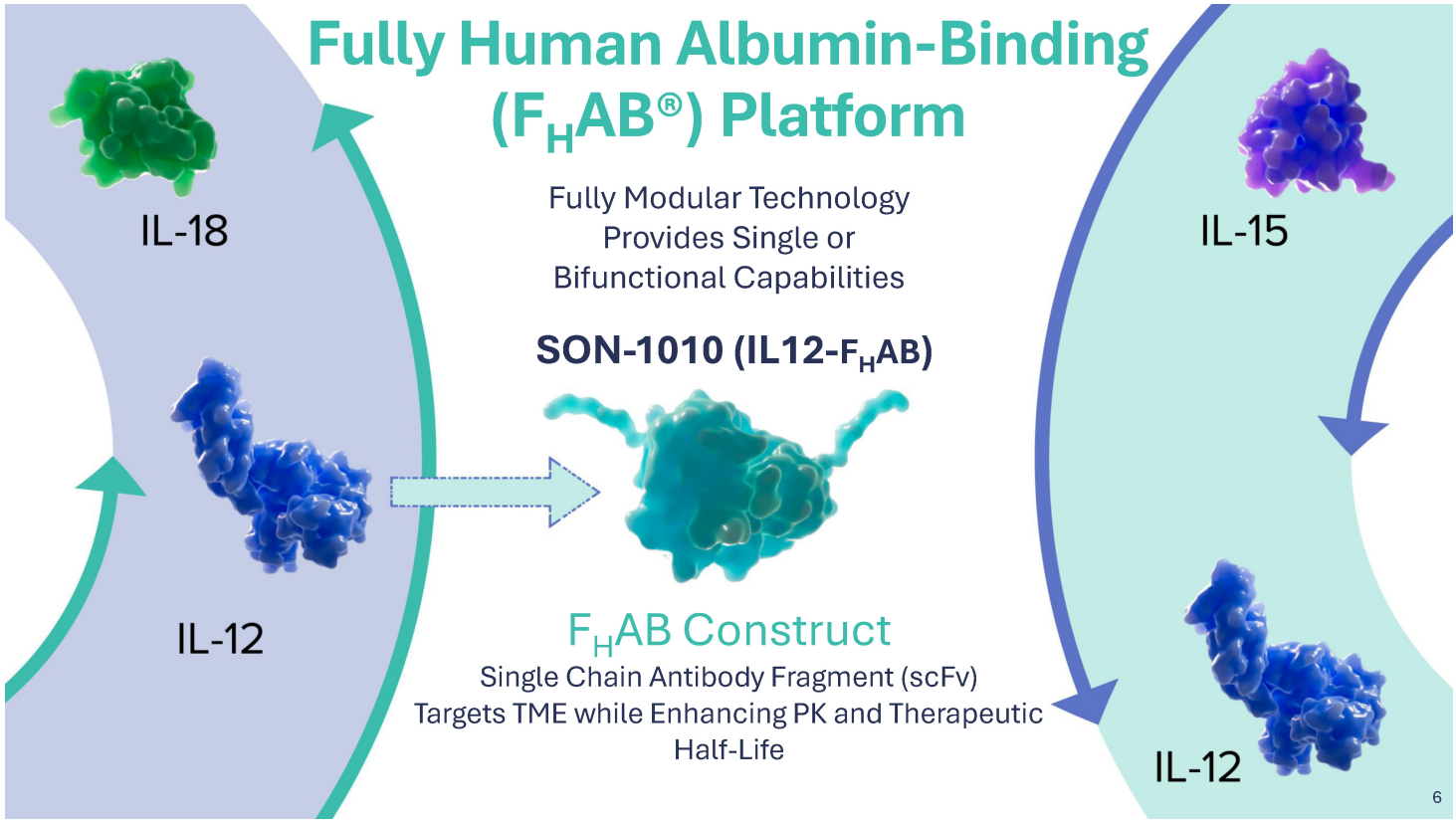
View Video

5

Fully Human Albumin-Binding (F_HAB®) Platform

Fully Modular Technology
Provides Single or
Bifunctional Capabilities

SON-1010 (IL12-F_HAB)

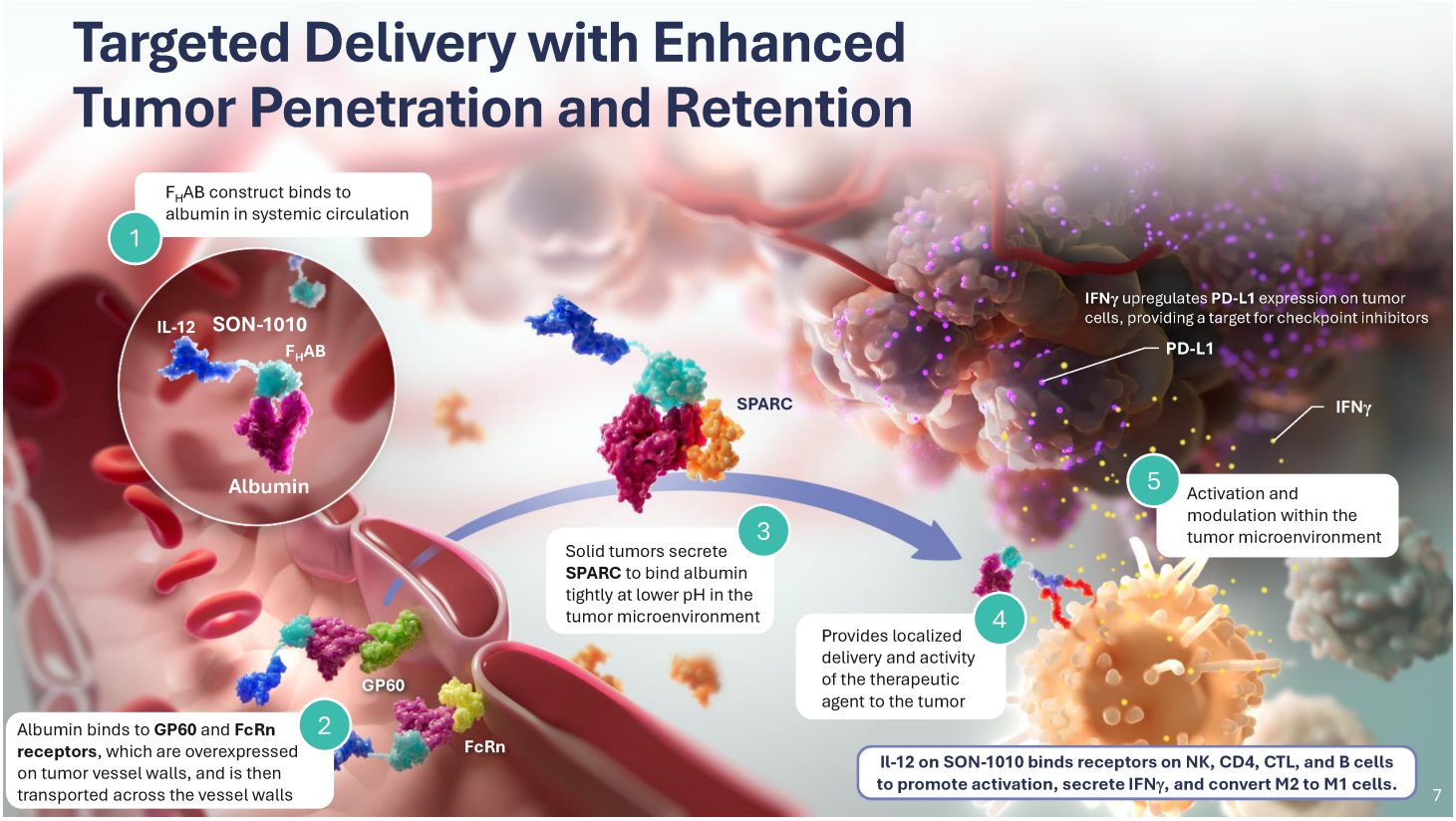


F_HAB Construct

Single Chain Antibody Fragment (scFv)
Targets TME while Enhancing PK and Therapeutic Half-Life

6

Targeted Delivery with Enhanced Tumor Penetration and Retention



Cytokine Payloads with Demonstrated Anti-Tumor Potential

Customizable Platform to Drive Desired Immune Responses

IL-12 (Interleukin-12)

- Activates T cells and NK cells
- Reducing immunosuppression by conversion of M2→M1
- Enhancing anti-tumor effects by promoting Th1 differentiation and IFN-γ production, crucial for anti-tumor immunity

IL-18 (Interleukin-18)

- Activates T cells and NK cells
- Boosting local IFN-γ production and NK cell activity
- Works synergistically with IL-12 to enhance Th1 responses and overall anti-tumor immunity
- Increases chemokines CXCL9 & 10 expression which increases TH1, NK & CD8+ T cells infiltrate into tumors

IL-15 (Interleukin-15)

- Activates T cells and NK cells
- Enhances local T cell and NK cell activation without promoting Tregs
- Sustained and effective anti-tumor immunity by decreasing CD8 memory loss by apoptosis allowing long term immunosurveillance of the cancer

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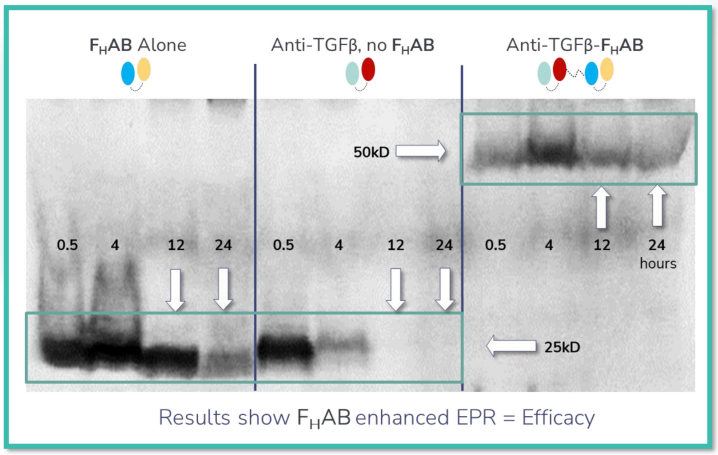
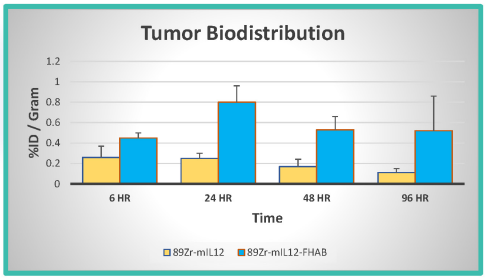
Demonstrated Tumor Uptake and Retention

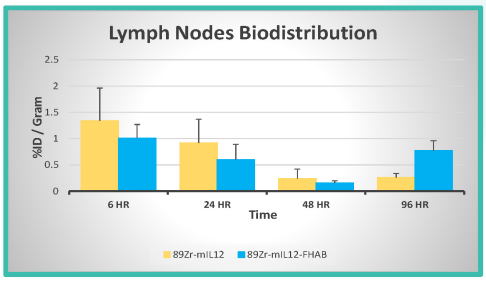
SPARC-Mediated Binding with Optimized Tumor Retention Using Albumin, Most Abundant Protein in the Blood and Elevated in the TME



Results show F_HAB enhanced EPR = Efficacy



Comparative accumulation in B16F10 melanoma tumors of ^{89}Zr-mIL12 versus ^{89}Zr-mIL12-F_HAB



Comparative accumulation in lymph nodes of ^{89}Zr-mIL12 versus ^{89}Zr-mIL12-F_HAB

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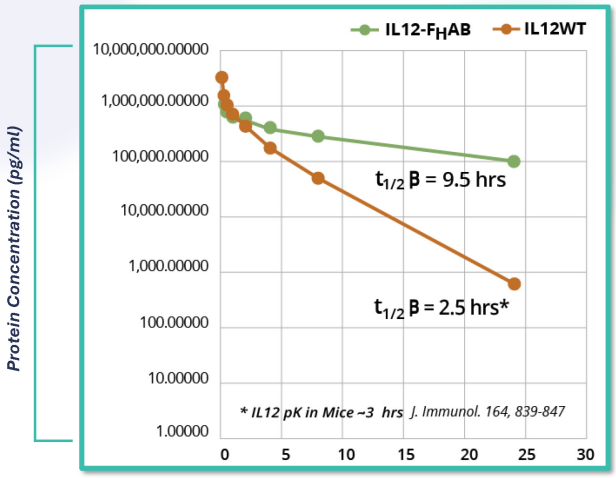
Enhanced Pharmacokinetic Characteristics

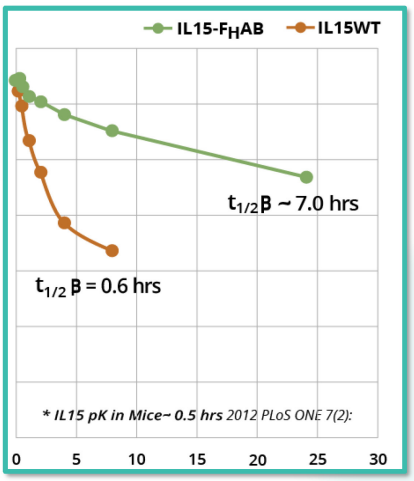
F_HAB Has Shown to Extend Plasma Half-Life of Cytokine Payloads

IL-12: 4x Improvement



IL-12: MW = 70 Kd *Time (Hours)*

IL-15: 10x Improvement



IL-15: MW = 13 Kd *Time (Hours)*

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Validated Approach

Albumin and GP60/SPARC Pathway Validated by Multiple Anti-Cancer Therapies

Abraxane®
nanoparticle albumin bound paclitaxel

Abraxis Bio Science → Celgene

Acquisition in 2010

NANOBODY

Bivalent anti-RANKL construct
Nanobody that binds to Albumin

Ablynx → sanofi

January 2018 Acquisition

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SON-1010 (IL12-F_HAB)

Targeted Immune Activation Cancer Therapy, Turning 'Cold' Tumors 'Hot'

Initially Targeting Solid Tumors and
Platinum-Resistant Ovarian Cancer (PROC)

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Significant Unmet Need

Platinum-Resistant Ovarian Cancer (PROC)

58% of Patients **Diagnosed at Late Stage** of Disease with Only a **31% 5-year Survival**[2,3]

Current Therapies are Lacking

No durable responses

Recently approved Elahere® only benefits 42% of patients[4]

Market Opportunity[1]

19,710	Estimated new cases annually in the US
13,270	Approximate deaths annually in the US
$5.2B	Total market opportunity
$8.9B	Expected to grow at a 14.8% CAGR by 2028

1. Research & Markets Ovarian Cancer drugs global Market Report 2023
2. Ovarian cancer population screening and mortality after long-term follow-up in the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS): a randomised controlled trial. National Library of Health.(2021). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8192829/
3. *Ovarian cancer survival rates: Ovarian cancer prognosis*. Ovarian Cancer Survival Rates | Ovarian Cancer Prognosis | American Cancer Society. (n.d.). https://www.cancer.org/cancer/types/ovarian-cancer/detection-diagnosis-staging/survival-rates.html
4. https://www.elahere.com/pdf/prescribing-information.pdf

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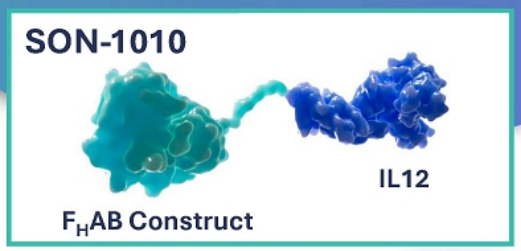
SON-1010 (IL12-F_HAB)

Ongoing Studies for Solid Tumors and Platinum-Resistant Ovarian Cancer (PROC)

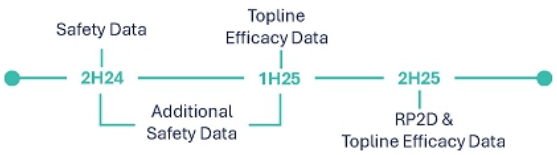
Targeted systemic delivery and activation of local immune responses within the tumor microenvironment

Material Supply Agreement with Roche for the study of PROC using SON-1010 in Combination with atezolizumab (Tecentriq®)



Key Milestones:

Phase 1: Solid Tumors (Monotherapy)



Phase 1b/2a: PROC (Combo with Atezolizumab)

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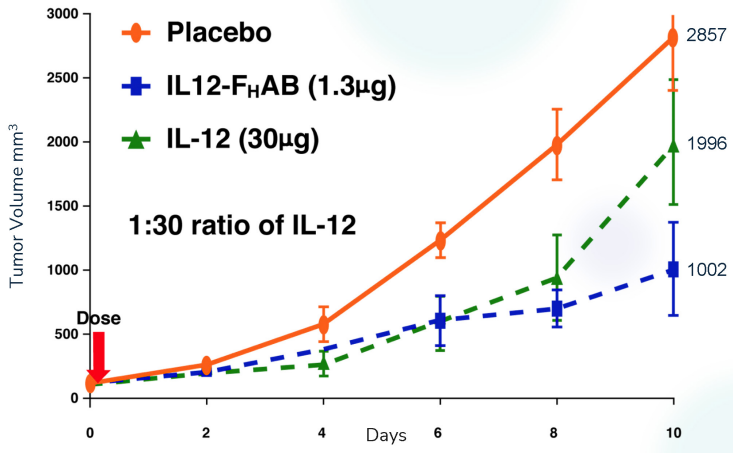
Demonstrated to Reduce Tumor Growth



SON-1010 (IL12-F$_H$AB) vs IL-12 Alone in Mouse B16F10 Melanoma Model

SON-1010 is ~35-Fold More Potent Than IL-12 Alone at Day 10

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Development Plan Towards Potential Approval

SB102 Completed / SB101 Late-Stage
Phase 1 Ongoing
SON-1010 Monotherapy
Solid Tumors

SB221
Phase 1b/2a Ongoing
SON-1010 Combo with atezolizumab
PROC

Potential Future
Phase 2b Dose Finding Study

Potential Future
Phase 3 Study
(pop PK)

BLA
Submission

Potential for Breakthrough Therapy

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SB101/SB102

Ongoing Phase 1 Study

Program Highlights:

- 7 of the first 16 patients (44%) have evidence of clinical benefit (SD at 4 months)
- Dose-related IFNγ response
- No dose limiting toxicities to-date
- Favorable safety profile

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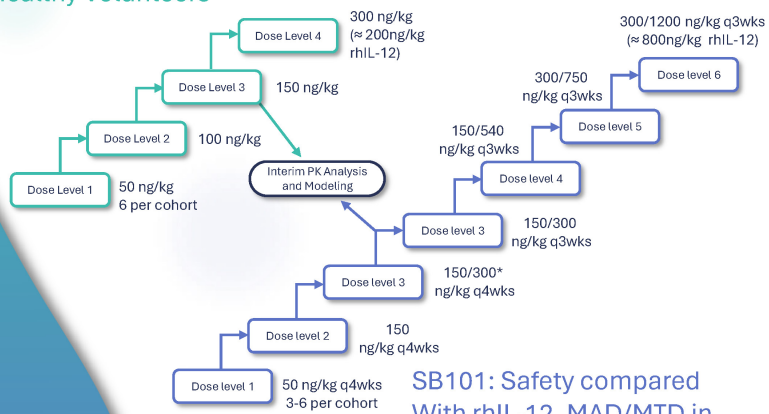
SB102: SAD for PK/PD/FACS in Healthy Volunteers



SB101: Safety compared With rhIL-12, MAD/MTD in End-stage Solid Tumors

* Desensitizing first dose, followed by maintenance dose

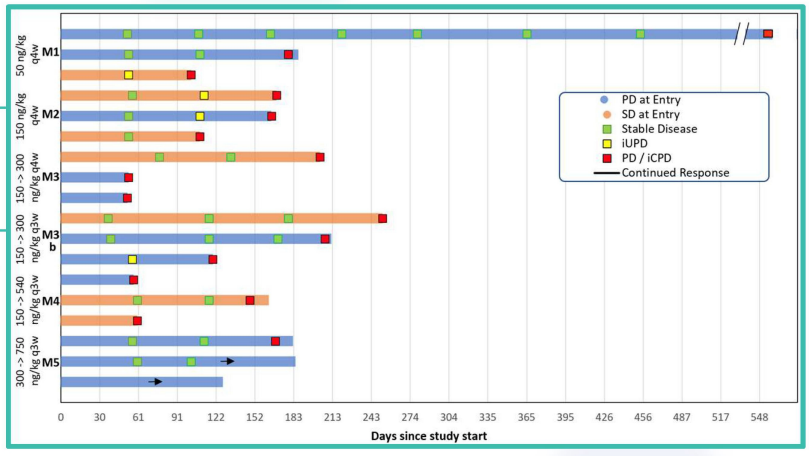
SB101: Phase 1 Study

Clinical Benefit

Mean Progression Free Survival of 166 Days

7 of 16 (44%) Patients remained stable at 4 months, suggesting clinical benefit

The first patient, whose endometrial sarcoma was progressing at study entry, had smaller tumors and complete resolution of her ascites at 11 months. She finally progressed at 23 months and her ascites has partially returned



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AACR Annual Meeting 2017, Poster #588

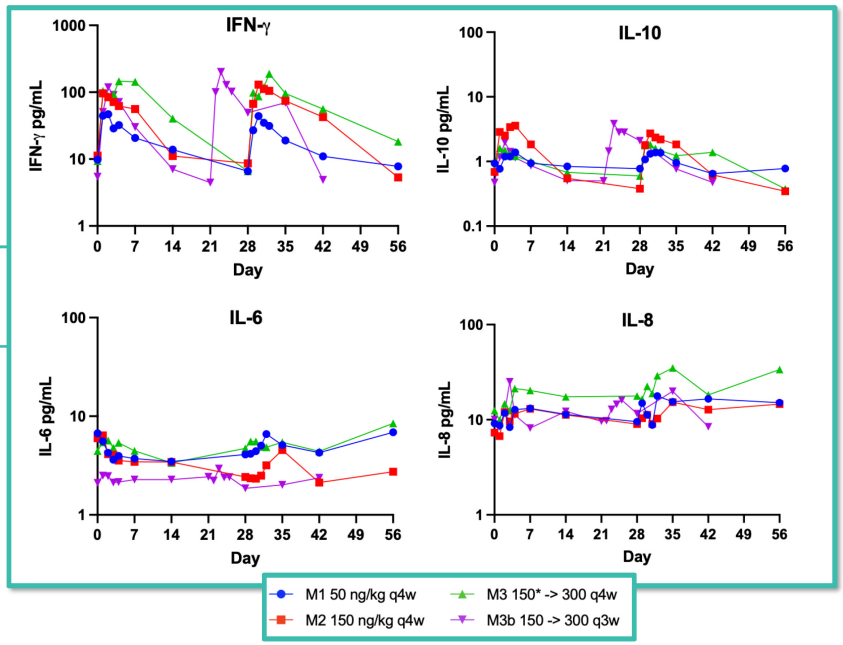
SB101: Phase 1 Study

Immune System Activation

Increase in key Inflamatory Markers: IFNγ, IL-1β, IL-2, IL-4, IL-6, IL-8, IL-10, and TNFα

Dose-Related, Controlled and Prolonged Increase in IFNγ

No Evidence of Cytokine Release Syndrome at Any Dose



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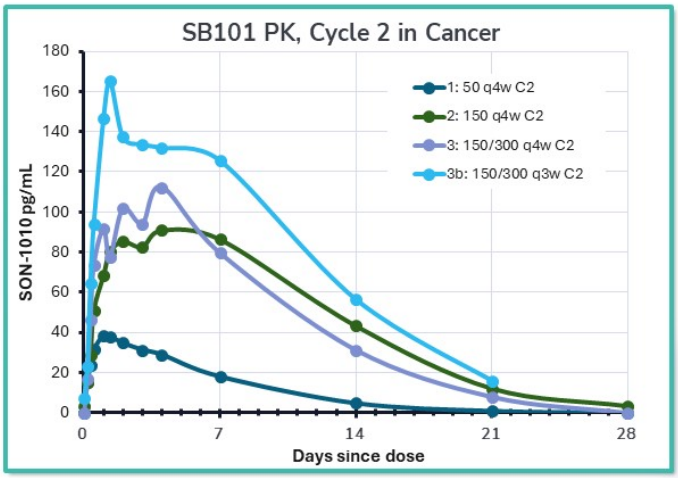
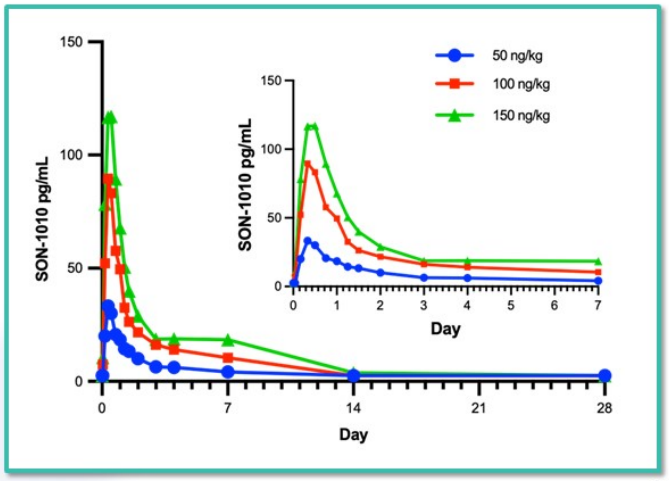
SB101/102: Phase 1 Study

PK Demonstrates Extended Half-Life of IL-12

Mean Half-Life was 113 Hours with SON-1010, Compared to 12 Hours with rhIL-12

Enhanced Dose-Related Single Compartment Kinetics in Cancer Patients Compared to Two Compartments in Healthy Volunteers





SB221: Phase 1b/2 Study

SON-1010 Combination with Atezolizumab in PROC

Material Supply Agreement with Roche for atezolizumab (Tecentriq®)

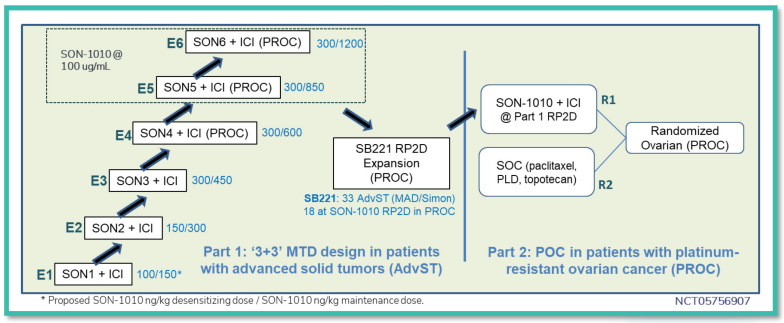
Enrolling Subjects with PROC and Have Recurrence Within 6 Months Following Last Dose of a Platinum-Containing Regimen

Part 1:

- Enrolling: 30-51 Subjects

Part 2:

- Enrolling: 80 Subjects
- Interim Results at 32 Events



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F_HAB Enabling Technology with Pipeline Expansion Capabilities

Demonstrating Promising Data in Solid Tumors

SON-1210
IL12-F_HAB-IL15

SON-1411
IL18-F_HAB-IL12

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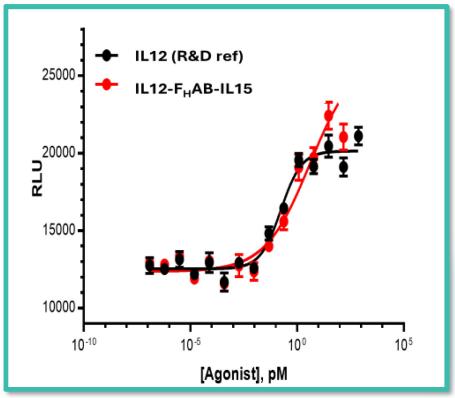
SON-1210: IL12-FHAB-IL15

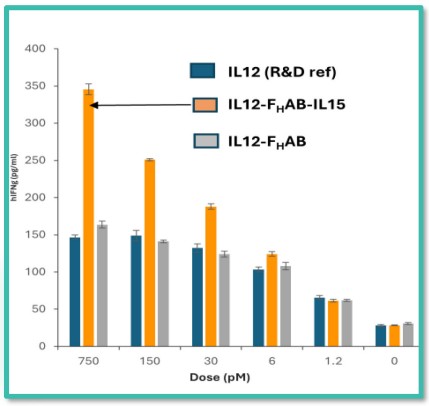
Improved Activity on Key Inflammatory IFNγ

IL12 Combined with IL15 Had Synergistic Effect of IFNγ Production[1]

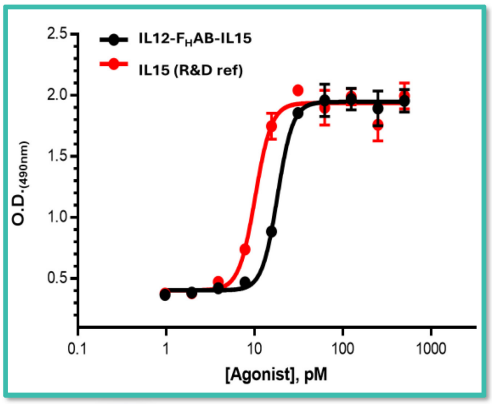
Lymphoblast proliferation assay (IL-12)



IFN-γ release assay (IL-12)



CTLL-2 proliferation assay (IL-15)



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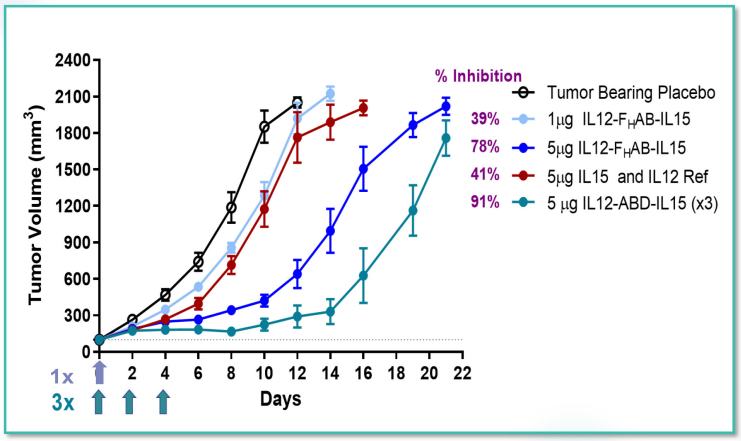
1. No steric hindrance on bioactivity. IL12 used at equimolar concentration.

SON-1210: IL12-FHAB-IL15

Ongoing Study in Solid Tumors



Greater reduction in tumor volume than higher doses of the individual cytokines in the B16F10 mouse model

Controlled induction of IFNγ with no signs of cytokine release syndrome or off-target toxicity

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Cini JK, et al (2023) SON-1210 - a novel bifunctional IL-12 / IL-15 fusion protein that improves cytokine half-life, targets tumors, and enhances therapeutic efficacy. Front. Immunol. 14:1326927. doi: 10.3389/fimmu.2023.1326927

SON-1210: IL12-FHAB-IL15

Advancing as Treatment of Pancreatic Cancer

Highly aggressive and often fatal disease that originates in the pancreas, typically detected late due to vague or absent early symptoms, leading to challenging treatment and a low survival rate.

~66,440 people with pancreatic cancer[1]

12.8% 5-Year Survival for Diagnosis[2]

~85% of cases have no targeted therapy option[3]

$2.51B market in 2023 and expected to grow to $7.91B in 2032[4]

SON-1210:

First albumin-binding bifunctional IL-12/IL-15 fusion protein, for solid tumor immunotherapy

Collaboration with Sarcoma Oncology Center to commence and **fund** Investigator-Initiated Phase 1/2a Study

IND Submission	1st Patient Dose
Expected 2H 2024	Expected 1H 2025

"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."

-Dr. Sant Chawla, Director of the Sarcoma Oncology Center

SARCOMA ONCOLOGY CENTER

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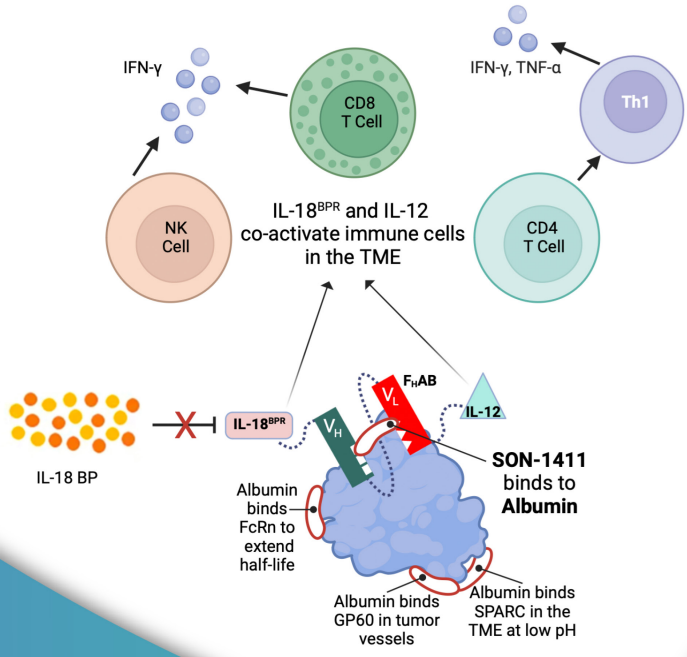
1. Pancreatic cancer: Cancer of the pancreas. Cancer of the Pancreas | American Cancer Society. (n.d.). https://www.cancer.org/cancer/types/pancreatic-cancer.html
2. Cancer Stat Facts: Pancreatic Cancer. National Cancer Institute Surveillance, Epidemiology, and End Results Program. (n.d.). https://seer.cancer.gov/statfacts/html/pancreas.html
3. Liu, L., Mrozek, M., (2023). Genetics, genomics and emerging molecular therapies of pancreatic cancer. Cancers, 15(3), 779. https://doi.org/10.3390/cancers15030779
4. Pancreatic cancer market size, share, and trends 2024 to 2034. Precedence Research. (n.d.). https://www.precedenceresearch.com/pancreatic-cancer-market

SON-1411: IL18-F_HAB-IL12

Reduction in Tumor Volume

IL-18 in combination with IL-12 synergistically induces IFNγ by activating NK, CD8, and CD4 T cells, which upregulates PD-L1 on tumor cells



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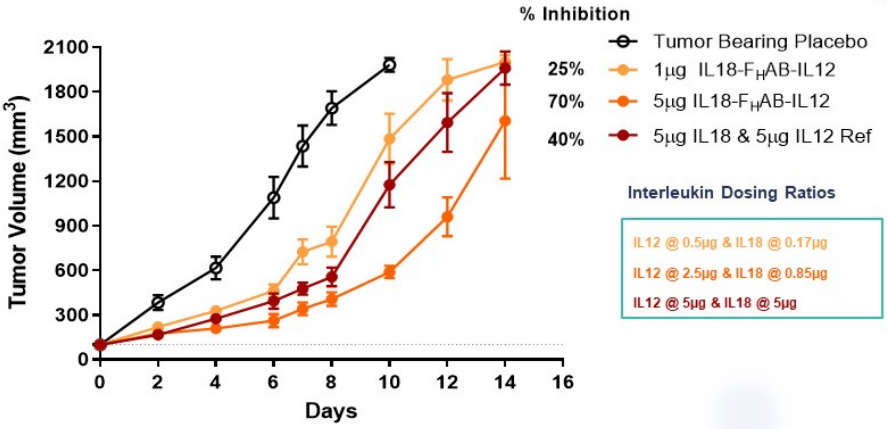
SON-1410

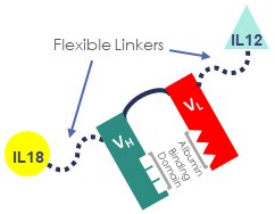
IL18-F_HAB-IL12 Bifunctional Interleukins

A single dose of IL18-F_HAB-IL12 produced a greater reduction in tumor volume than higher doses of the individual cytokines in the B16F10 model.



IL-18 ^{BPR} variant in combination with IL-12 synergistically induces IFNγ by activating NK, CD8, and CD4 T cells, which upregulates PD-L1 on tumor cells

IL18 ^{BPR} variant binds the IL18 Rc like wildtype but does not bind the IL18 Binding Protein, thus having potential for improved synergistic immune activation



Sonnet's Bispecific Construct – SON-1410 Synergistic Biologic Activity:

IL-18: ↑ IL-12 receptor, ↑ IFNγ, ↑ TH1, NK & CD8 cells *infiltrating into tumors – FACS data*

IL-12: ↑ IL-18 receptor, ↑ IFNγ,

IL-12 with IL-18 ↑ CXCL9 & CXCL10 by 50-fold

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1. Cini, et al, AACR Poster #4229, New Orleans, 2022

SON-080 (Low-Dose IL-6)

Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN)

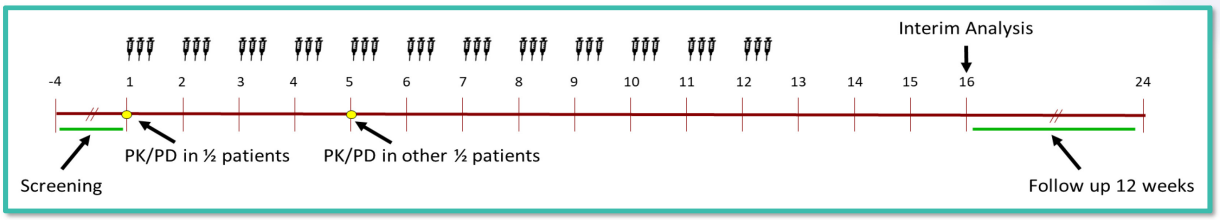
Seeking Partnership to Support Phase 2 Trial

SONNET BioTherapeutics

SON-080

Encouraging Results from Phase 1b/2a Study in CIPN

Randomized, Double-blind, Placebo-controlled Study



Study Design

N=60

Blinded comparison of 20 µg vs 60 µg/dose vs placebo given SC

Duration: 12-week treatment with 12-week follow up

Initial Results (n=9)

SON-080 demonstrated to be well-tolerated at both 20 µg and 60 µg/dose

No evidence of a pro-inflammatory cytokine response, although SAA was elevated during treatment which returned to baseline after the treatment

Pain survey results suggest potential for rapid improvement of symptoms and post-dose durability

Historic over 200 patient safety data – well tolerated

SONNET BioTherapeutics

IP Portfolio

F_HAB Platform

Twenty (20) total patents – 6 issued and 14 pending

Composition of matter, formulations, methods of use and proprietary manufacturing processes

Major markets protected, including U.S., EU, China, Japan, New Zealand, Canada and Russia

Several Scientific presentations at ASCO and publications including Frontiers in Immunology and Protein Expression and Purification, two major Oncology Journals

SONNET BioTherapeutics

SON-080 (Low-dose IL-6)

Two patents issued and unexpired – U.S.

Three patents filed and pending in major markets

- Low-Dose IL-6 Formulations and Methods of Use
- Method of Treating Age-Related
- Frailty with IL-6
- Methods of Treatment of Diabetes-Associated Autonomic Neuropathy

Proven Leadership Team

Pankaj Mohan, Ph.D.
Founder, CEO and Chairman

Jay Cross
Chief Financial Officer

John K. Cini, Ph.D.
Chief Scientific Officer & Co-Founder

Susan Dexter
Chief Technical Officer

Richard Kenney, M.D.
Chief Medical Officer

Multiple Upcoming Milestones Expected to Drive Value

SON-1010

Phase 1: Solid Tumors (Monotherapy)

- Safety Data — 2H24
- Additional Safety Data
- Topline Efficacy Data — 1H25
- RP2D & Topline Efficacy Data — 2H25

Phase 1b/2a: PROC (Combo with Atezolizumab)

SON-1210

Phase 1: Pancreatic Cancer

- IND Submission — 2H24
- 1st Patient Dose — 1H25

SON-080

Phase 1: Peripheral Neuropathies (Monotherapy)

- Reported additional unblinded positive safety and efficacy data — JULY 2024

Ongoing: seeking partnership to support Phase 2 trial

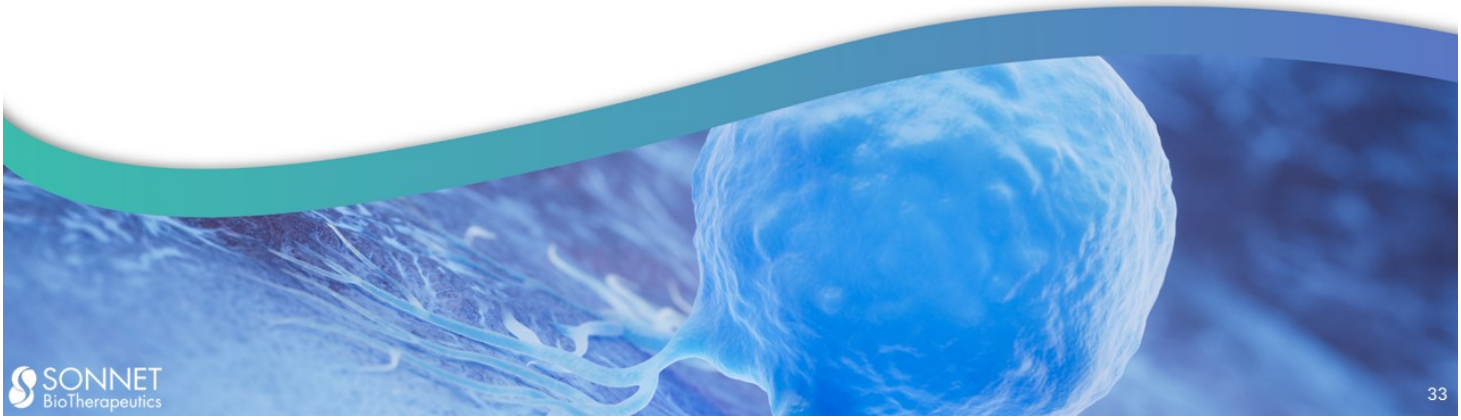
Investment Summary

Advancing Targeted Immune Activation Cancer Therapies to Turn 'Cold' Tumors 'Hot'

Fully Modular Technology Provides Single or Bispecific Payload Applications while Enhancing Payload Characteristics

Lead Programs Demonstrating Encouraging Results in Immune Activation and Tumor Reduction

Multiple Pipeline Expansion Opportunities Throughout High Value Solid Tumor Market



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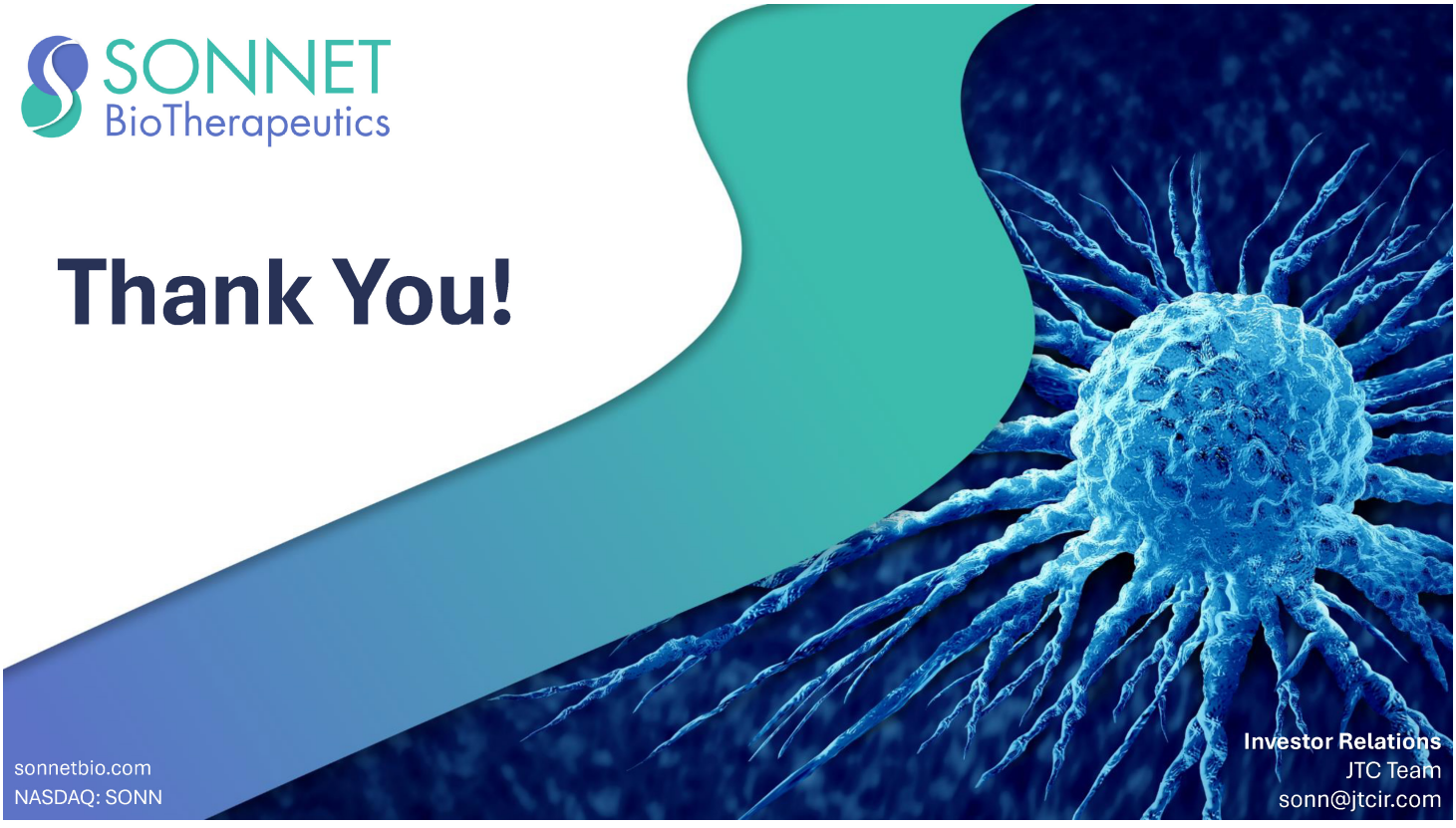
Thank You!



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