December 17, 2024

Sonnet BioTherapeutics Reports Fiscal Year 2024 Financial Results and Provides Corporate Update

Continued progress with both clinical trials of lead program, SON-1010, for solid tumors and Platinum-Resistant Ovarian Cancer (PROC)

Executed licensing agreement to support initiation of a Phase 2 clinical trial of SON-080 in Diabetic Peripheral Neuropathy (DPN)

Multiple value-driving milestones expected throughout calendar year 2025 as well as pipeline expansion opportunities across the solid tumor market

Total annual operating expenses reduced by an approximate 37% as compared to fiscal year 2023

Approximately 43% of total annual operating expenses during fiscal year 2024 were covered by non-dilutive funding received during fiscal year 2024 from the New Jersey Tax Certificate Transfer and Australia R&D Tax Incentive Programs

PRINCETON, NJ, Dec. 17, 2024 (GLOBE NEWSWIRE) -- Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, reported today financial results for the fiscal year ended September 30, 2024 and provided a corporate update.

"We are very pleased with the progress we have made across all facets of the company's operations. On the financial front, we have delivered on our stated objective of cutting costs through an approximate 37% reduction in total operating expenses versus last year, which will help to extend our cash runway, combined with being able to leverage non-dilutive funding and capital markets financings. Additionally, we have executed on our partnership plans to advance both our SON-080 program and SON-1210 program to their respective next stages of development and continue to believe in their potential to address indications of significant unmet need," commented Pankaj Mohan, Ph.D., Founder and Chief Executive Officer of Sonnet. "Looking ahead, our focus is on advancing our lead program, SON-1010, and we are pleased to be on track for key data readouts from our ongoing SB101 trial for solid tumors and our SB221 trial for PROC. We look forward to the upcoming data readouts to help further unlock the intrinsic value of our F_HAB technology platform."

Recent Highlights

- Announced topline safety data following successful completion of SON-1010 monotherapy dose escalation in the Phase 1 SB101 trial;
- Announced the publication of extensive discovery, development, and preclinical data

regarding SON-1010, demonstrating its mechanism of action in a paper entitled, "SON-1010: an albumin-binding IL-12 fusion protein that improves cytokine half-life, targets tumors, and enhances therapeutic efficacy," in *Frontiers in Immunology*;
- Granted U.S. Patent No. 12,134,635 covering two of its novel drug candidates, SON-1411 (IL-18^{BPR}-F_HAB-IL12) and SON-1400 (IL-18^{BPR}-F_HAB), each containing a modified version of recombinant human interleukin-18 (BPR = Binding Protein Resistant);
- Entered into a licensing agreement with Alkem Laboratories Limited for the research, development, manufacturing, marketing, and commercialization of the SON-080 molecule for the treatment of DPN in India;
- Received preliminary approval for the sale of tax credits from the New Jersey Technology Business Tax Certificate Transfer Program administered by the New Jersey Economic Development Authority (NJEDA); and
- Entered into a Master Clinical Collaboration Agreement with the Sarcoma Oncology Center to advance the development of SON-1210 in combination with chemotherapy for the treatment of metastatic pancreatic cancer.

Lead Clinical Programs Update

***SON-1010**: Targeted Immune Activation Cancer Therapy, Turning 'Cold' Tumors 'Hot', Initially Targeting Solid Tumors and Platinum-Resistant Ovarian Cancer (PROC)*

Phase 1 Trial (SB101 Trial): Advanced Solid Tumors (Monotherapy)

This first-in-human study is primarily designed to evaluate the safety, tolerability, PK, and PD of multiple ascending doses of SON-1010 in cancer patients and is being conducted at several sites across the United States. The Company recently completed enrollment and dose escalation in the Phase 1 SB101 clinical trial of SON-1010 (IL12-F_HAB) in adult patients with advanced solid tumors. Additionally, the Company reported that results of SON-1010 at the highest dose have been formally evaluated by the Safety Review Committee. The study has enrolled 24 subjects to date. Primary outcome measures for the study were to evaluate the safety and tolerability of SON-1010 and establish the MTD.

For more information about the SB101 clinical trial, visit clinicaltrials.gov and reference identifier NCT05352750.

Phase 1b/2a Trial (SB221 Trial): Advanced Solid Tumors and PROC (Combo with Atezolizumab)

The second trial 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) in combination with atezolizumab given intravenously (IV) (in collaboration with Genentech, a member of the Roche Group). This study was recently expanded to include the MTD of SON-1010 from SB101. Enrollment remains ongoing and an update on safety at the MTD in that trial is expected in Q1 2025.

For more information about the SB221 clinical trial, visit clinicaltrials.gov and reference identifier NCT05756907.

SON-1010 Upcoming Milestones

- Phase 1: Solid Tumors (Monotherapy)
  - H1 calendar year 2025: Topline Efficacy Data

- Phase 1b/2a: PROC (Combo with Atezolizumab)
  - Q1 calendar year 2025: Additional Safety Data
  - H2 calendar year 2025: RP2D & Topline Efficacy Data

SON-1210: *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 Advanced Solid Tumors and Metastatic Pancreatic Cancer*

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 (IFNγ), which was controlled and prolonged, was noted as early as one day following administration, with no apparent increase in other proinflammatory cytokines. IFNγ 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-1β, and IL-6) were notably absent from all dose levels tested in the study.

In August 2024, the Company entered into a Master Clinical Collaboration Agreement with the Sarcoma Oncology Center, to conduct an investigator-initiated Phase 1/2a clinical study to evaluate SON-1210 in combination with several chemotherapeutic agents including but not limited to NALIRIFOX (the combination of liposomal irinotecan, 5-fluorouracil/leucovorin, and oxaliplatin) for the specific treatment of metastatic pancreatic cancer. The NALIRIFOX regimen is U.S. FDA-approved for the treatment of metastatic pancreatic cancer in the front-line and refractory settings.

SON-1210 Upcoming Milestones

- Q1 calendar year 2025: IND Submission
- H1 calendar year 2025: 1st Patient Dosed in Investigator-Initiated Phase 1/2a Study

SON-080: *Low dose of rhIL-6 for Chemotherapy-Induced Peripheral Neuropathy (CIPN) and Diabetic Peripheral Neuropathy (DPN)*

In October 2024, the Company entered into a licensing agreement (the “Licensing Agreement”) with Alkem Laboratories Limited (“Alkem”) for the research, development, manufacturing, marketing, and commercialization of its SON-080 molecule for the treatment of DPN in India and the manufacturing, marketing, and commercialization of SON-080 for chemotherapy induced neuropathy (CIPN) and autonomic neuropathy in India. Alkem will conduct all clinical trials it believes appropriate to obtain regulatory approval in India of SON-080 for the treatment of DPN.

Summary of Financial Results for the Fiscal Year 2024

As of September 30, 2024, Sonnet had $0.1 million cash on hand. The Company believes

that based on cash on hand at September 30, 2024, together with the approximate $7.7 million recently received through the sale of common stock and warrants in November and December 2024, $0.7 million received from the R&D Tax Incentive Program in Australia in November 2024 to satisfy the Company's incentive tax receivable, and $0.5 million received in October 2024 as an upfront payment related to the License Agreement, which after tax withholdings resulted in a net payment of $0.4 million, it has sufficient funds for projected operations into July 2025.

Research and development expenses were $5.7 million for the year ended September 30, 2024, compared to $11.8 million for the year ended September 30, 2023.

General and administrative expenses were $6.1 million for the year ended September 30, 2024, compared to $7.1 million for the year ended September 30, 2023.

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 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.

Investor Relations Contact:
JTC Team, LLC
Jenene Thomas
908-824-0775
SONN@jtcir.com

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Balance Sheets

	September 30,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 149,456	$ 2,274,259
Prepaid expenses and other current assets	1,206,409	1,677,396
Incentive tax receivable	762,078	786,574
Total current assets	2,117,943	4,738,229
Property and equipment, net	20,523	33,366
Operating lease right-of-use asset	123,417	193,689
Deferred offering costs	15,000	49,988
Other assets	494,147	414,206
Total assets	$ 2,771,030	$ 5,429,478
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,183,416	$ 2,201,999
Accrued expenses and other current liabilities	942,489	3,230,922
Current portion of operating lease liability	84,291	73,048
Deferred income	—	18,626
Total current liabilities	3,210,196	5,524,595
Operating lease liability, net of current portion	46,573	130,863
Total liabilities	3,256,769	5,655,458
Commitments and contingencies (Note 5)		
Stockholders' deficit:		
Preferred stock, $0.0001 par value: 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.0001 par value: 125,000,000 shares authorized; 650,284 and 218,786 issued and outstanding at September 30, 2024 and 2023, respectively	65	22
Additional paid-in capital	117,195,181	110,017,751
Accumulated deficit	(117,680,985)	(110,243,753)

Total stockholders' deficit	(485,739)	(225,980)
Total liabilities and stockholders' deficit	$ 2,771,030	$ 5,429,478

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations

	Years ended September 30,	
	2024	**2023**
Collaboration revenue	$ 18,626	$ 147,805
Operating expenses:		
Research and development	5,737,252	11,814,690
General and administrative	6,130,845	7,125,732
Total operating expense	11,868,097	18,940,422
Loss from operations	(11,849,471)	(18,792,617)
Foreign exchange gain (loss)	84,293	(40,077)
Other income	4,327,946	—
Net loss	$ (7,437,232)	$ (18,832,694)
Per share information:		
Net loss per share, basic and diluted	$ (11.35)	$ (145.13)
Weighted average shares outstanding, basic and diluted	655,240	129,760

Source: Sonnet BioTherapeutics Holdings, Inc.