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Sonnet BioTherapeutics Provides Fiscal Year 2021 Business and Financial Update

PRINCETON, NJ / ACCESSWIRE / December 17, 2021 /Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) ("Sonnet" or the "Company"), a biopharmaceutical company developing innovative targeted biologic drugs, announced today its financial results for the fiscal year ended September 30th, 2021 and provided a business update.

Pankaj Mohan, Ph.D., Founder and CEO commented, "This year has been incredibly exciting for Sonnet. We identified a new bispecific candidate, SON-1410, and were granted patent-protection for our F_HAB technology. Additionally, we generated compelling new data to progress our therapeutic pipeline, including successful preclinical studies for SON-1010 and SON-080, which set the stage for future clinical studies. We believe this positions us well for continued growth and advancement of our pipeline in 2022."

Fiscal Year 2021 and Recent Corporate Updates

Financings Completed: On August 24th, Sonnet successfully completed its follow-on offering of 35,294,117 shares of common stock and investor warrants for total net proceeds of approximately \$27.6 million.

In June 2021, Sonnet completed the final issuance of shares of its common stock under the At-the-Market Sales Agreement, pursuant to which the Company executed issuances of an aggregate of 7,454,238 shares for total net proceeds of \$15.2 million.

Issuance of U.S. Patent for Platform Technology: On June 8th, Sonnet announced the USTPO issued U.S. Patent No. 11,028,166 entitled, "Albumin Domain Fusion Proteins". The patent 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 patent carries a term effective until March 2039.

Completed Licensing Agreement with New Life Therapeutics: On May 3rd, Sonnet announced a definitive agreement with New Life Therapeutics of Singapore for the license of low-dose Interleukin 6, or IL-6, for the treatment of Diabetic Peripheral Neuropathy (DPN). The licensed territory includes the ASEAN countries of Singapore, Malaysia, Indonesia, Thailand, The Philippines, Cambodia, Brunei, Vietnam, Myanmar and Lao PDR.

Appointment of Richard Kenney and Manuel DaFonseca: On March 22nd, Sonnet announced the appointment of Richard Kenney, M.D. as Chief Medical Officer and Manuel DaFonseca, as Head of Clinical Operations.

Sonnet is pleased to provide the following updates on its pipeline assets:

SON-1010 (IL12-F_HAB): On February 1st, Sonnet announced that it had successfully completed a non-human primate (NHP), non-GLP repeat-dose toxicology study of SON-1010. The drug candidate was well tolerated at doses far exceeding levels expected in future human clinical trials, without producing detectable cytokine imbalances. SON-1010 demonstrated an enhanced pharmacokinetic (PK) profile as compared to recombinant IL-12. Analysis of interferon-γ levels, a key biomarker of antitumor activity, continued to suggest potent pharmacodynamic (PD) effects in the monkeys studied.

On May 10th, Sonnet announced the completion of a successful GLP repeat dose toxicology study of SON-1010 in NHPs. The No Observed Adverse Event Level (NOAEL) following repeated administration was more than 50 times the anticipated equivalent human clinical dose in NHPs with no evidence of cytokine release syndrome. PK analysis of serum samples confirmed an enhanced profile of IL12-F_HAB over recombinant human IL-12, with a half-life around 40 hours in NHPs. A significant increase in interferon-γ, a key pleiotropic cytokine associated with anti-tumor mechanisms, was observed following dosing with IL12-F_HAB.

An IND for SON-1010 has been submitted to the FDA and additional product stability data will be submitted in the first quarter of 2022. Subject to FDA approval, we expect to initiate a US clinical trial in oncology patients with solid tumors during the first half of 2022. We are also preparing to initiate an Australian clinical trial in healthy volunteers during the first half of 2022 to study the compound's PK and PD, in preparation for potential combination studies.

SON-080 (low-dose IL-6): On January 25th, Sonnet announced that Sonnet CH, a wholly owned subsidiary of Sonnet headquartered in Switzerland, had successfully completed a multiple dose NHP study of SON-080. The toxicology study demonstrated a wide safety margin with no adverse effects observed in male or female cynomolgus monkeys at the doses tested. Sonnet intends to file for an ex-US Phase 1b/2a pilot-scale efficacy study with SON-080 in CIPN during the first half of 2022. Pursuant to the license agreement the Company entered with New Life Therapeutics Pte., Ltd of Singapore in May 2021, Sonnet and New Life will be jointly responsible for developing SON-080 in DPN with the objective of initiating an ex-US pilot efficacy study in the second half of 2022.

SON-1210 (IL12-F_HAB-IL15): SON-1210, Sonnet's first bispecific candidate, is undergoing cell line and process development activities. Early development materials were used in a mouse tumor model study, and additional biodistribution studies are planned. This work will inform the Company's decision about dosing in a forthcoming NHP study, expected to be initiated in the first half of 2022. Scale up and cGMP manufacturing is scheduled to be completed in the first half of 2022, which will support the GLP NHP study, as well as First-In-Human (FIH) studies. Sonnet expects to initiate the regulatory authorization process for solid tumor indications in the second half of 2022.

SON-1410 (IL18-F_HAB-IL12): On August 30th, Sonnet announced that it had selected a novel development candidate after completing comparative studies in a mouse melanoma model. The candidate represents Sonnet's second bispecific compound integrating interleukin 12 (IL-12) with the company's F_HAB platform. The target indications for SON-1410 will be melanoma and renal cancers.

Fiscal Year Ended September 30, 2021 Financial Results

Jay Cross, CFO, elaborated on Sonnet's 2021 fiscal year results, saying, "The Company has made important forward progress with our balance sheet this fiscal year, and we expect to continue to deliver on our stated objectives of advancing our therapeutic pipeline. We believe we are in a good position to maintain our positive momentum through 2022."

- As of September 30, 2021, Sonnet had \$27.6 million cash on hand, an increase from last quarter after a public offering in which the Company sold 33,193,485 shares of its common stock and pre-funded warrants to purchase 2,100,632 shares of common stock.
- The Company currently has outstanding 60,250,637 shares of common stock and warrants to purchase an aggregate of 51,789,522 shares of common stock, with a weighted average exercise price per share of \$1.45. In the event all warrants were exercised for cash, the Company could receive up to \$75.2 million of additional capital.

Research and development expenses were \$16.6 million for the year ended September 30, 2021, compared to \$9.9 million for the year ended September 30, 2020. The increase of \$6.8 million was primarily due to the development of the cell lines for IL12-F_HAB, IL12-F_HAB-IL15 and SON-080, and an increase in payroll and share-based compensation expense, as we continue to expand our operations. General and administrative expenses were \$8.9 million for the year ended September 30, 2021, compared to \$7.5 million for the year ended September 30, 2020. The increase of \$1.4 million was primarily due to an increase in payroll and share-based compensation expense and insurance expenses related to directors and officer's insurance, as we continue to expand our operations to support our research and development efforts, partially offset by a \$1.4 million decrease in professional fees and transaction related fees.

About Sonnet BioTherapeutics Holdings, Inc.

Founded in 2011, 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. 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.

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Sonnet BioTherapeutics Holdings, Inc. Consolidated Balance Sheets

	September 30,	
	2021	2020
Assets		
Current assets:		
Cash	\$ 27,622,067	\$ 7,349,903
Prepaid expenses and other current assets	1,189,474	287,738
Total current assets	28,811,541	7,637,641
Property and equipment, net	59,056	67,889
Operating lease right-of-use asset	123,213	205,919
Other assets	-	82,959
Total assets	<u>\$ 28,993,810</u>	<u>\$ 7,994,408</u>
Liabilities and stockholders' equity		
Current liabilities:		
Related-party notes	\$ 748	\$ 21,184
Accounts payable	3,781,299	2,057,559
Accrued expenses	2,310,410	2,063,678
Operating lease liability	94,520	82,060
Deferred income	516,374	500,000
Total current liabilities	6,703,351	4,724,481
Note payable	-	124,878
Operating lease liability	30,612	125,132
Total liabilities	<u>6,733,963</u>	<u>4,974,491</u>

Commitments and contingencies (note 8)	-	-
Stockholders' equity:		
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; 60,250,637 and 14,724,105 issued and outstanding at September 30, 2021 and 2020, respectively	6,025	1,472
Additional paid-in capital	83,943,040	39,723,702
	(61,689,218)	(36,705,257)
Accumulated deficit		
Total stockholders' equity	<u>22,259,847</u>	<u>3,019,917</u>
Total liabilities and stockholders' equity	<u>\$ 28,993,810</u>	<u>\$ 7,994,408</u>

See 10-K filed today for notes to consolidated financial statements

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations

	Years ended September 30,	
	2021	2020
Collaboration revenue	<u>\$ 483,626</u>	<u>\$ -</u>
Operating expenses:		
Research and development	16,634,553	9,877,555
Acquired in-process research and development	-	6,826,495
General and administrative	<u>8,936,509</u>	<u>7,533,722</u>
Total operating expenses	<u>25,571,062</u>	<u>24,237,772</u>
Loss from operations	(25,087,436)	(24,237,772)
Interest income	15	20,677
Foreign exchange loss	(22,041)	(48,020)
Other income	<u>125,501</u>	<u>-</u>
Net loss	(24,983,961)	(24,265,115)
Deemed dividend arising from warrant amendment	-	(41,338,934)
Net loss attributable to common stockholders	<u>\$ (24,983,961)</u>	<u>\$ (65,604,049)</u>
Per share information:		
Net loss per share, basic and diluted	<u>\$ (1.02)</u>	<u>\$ (6.96)</u>
Weighted average shares outstanding, basic and diluted	<u>24,547,290</u>	<u>9,420,484</u>

See 10-K filed today for notes to consolidated financial statements

SOURCE: Sonnet BioTherapeutics Holdings, Inc.

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