August 14, 2023

Sonnet BioTherapeutics Provides Fiscal Year 2023 Third Quarter Business and Earnings Update

- ***Combination study of SON-1010 with Roche's atezolizumab (Tecentriq®) has been initiated in Australia***
- ***First SON-1010 Phase 1 study has been completed and comparison of the human pharmacokinetic data supports targeting of tumor tissue***
- ***Early safety data from the SON-080 trial in CIPN is expected after the study's Data Safety Monitoring Board (DSMB) convenes, prior to calendar year end***
- ***Collaboration with Janssen,where in vitro and in vivo efficacy of SON-1010, SON-1210, and SON-1410 are being evaluated in combination with certain Janssen cell therapy assets, remains ongoing***

PRINCETON, NJ / ACCESSWIRE / August 14, 2023 /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 three months ended June 30, 2023 and provided a business update.

"Sonnet continues to successfully forge ahead with our pipeline development," said Pankaj Mohan, Ph.D., Founder and CEO. "The initiation of the clinical trial with SON-1010 and Roche's atezolizumab is an important event for the company and for our mission to innovate potentially life-saving treatments for cancer patients. Further, our collaboration with Janssen is ongoing and we hope to have information to share with investors in the coming quarters. During the quarter, we were able to present important data from our SON-1010 clinical trials at the American Association for Cancer Research (AACR), as well as deliver two F_HAB technology presentations at the Cytokine-Based Drug Development Summit. As part of our financing initiative, we completed a $2.25 million registered direct offering and concurrent private placement in June, which was strategically executed to result in the Company remaining in compliance with the Nasdaq continued listing requirement in shareholder equity. Our plan to extend our cash runway into the 2024 calendar year remains in place and involves receiving R&D tax credits from New Jersey and Australia."

"We are quite pleased with the progress of our clinical programs," said Dr. Richard Kenney, CMO. "Both of the SON-1010 Phase 1 first-in-human studies are wrapping up, with final data analysis in the healthy volunteer study and ongoing enrollment of the highest dose cohort in the cancer study, which will establish the maximum tolerated dose. The latter will be expanded in platinum-resistant ovarian cancer (PROC) to confirm the clinical benefit in that population at the maximum tolerated dose before moving on to the next study. Comparing the pharmacokinetics for the two studies shows a compelling difference in SON-1010 excretion patterns that suggests the F_HAB molecule is being taken up and retained by the tumors, as it was designed to do. We are starting our combination study using SON-

1010 with atezolizumab in Australia and are working to enroll several cohorts by the end of this year. Regarding the SON-080 trial in CIPN, we continue to anticipate a DSMB meeting this calendar year, after which we will be in a position to disclose the early safety findings."

FY 2023 Third Quarter and Recent Corporate Updates

Sonnet provided the following corporate updates:

- On April 18, 2023, we presented additional data from the SB101 study of SON-1010 at the 2023 AACR Annual Meeting. SB101 is a single-ascending dose (SAD) trial in adult patients with advanced solid tumors that commenced in the second quarter of 2022 and is currently enrolling the final dose cohort. Of the 15 patients from the first five cohorts of SB101 evaluable for follow-up at this latest cutoff, 9 had stable disease at the first follow-up scan, 4 of which were already progressing at study entry. At the four-month follow-up, 5 of 14 patients remained stable at the second scan, suggesting clinical benefit of SON-1010 in 36% of patients. As an example, the very first patient dosed, who has an aggressive endometrial sarcoma, had target tumor shrinkage with complete resolution of ascites at one point and has been clinically stable for over a year. SON-1010 has been safe and tolerable at all doses tested to date. Adverse events have generally been mild/moderate and transient in nature, with no study discontinuations for safety reasons. In addition, adverse effects have been less numerous and less intense with subsequent doses. The geomean half-life (t½) of SON-1010 was 113 hours in SB101 and 122 hours in SB102, compared to the published value of 12 hours for recombinant IL-12 observed in prior studies. Comparison of the PK curves between the two studies suggests that SON-1010 may be targeting tumors, as it was designed to do. Cytokine analysis following each dose revealed controlled and prolonged induction of interferon gamma (IFNγ) that peaked at 24 to 48 hours and returned to baseline after 2 to 4 weeks, which may improve tumor control. A small increase in IL-10 was observed with each dose, as might be expected in response to IFNγ. There was either a minimal or no signal for IL-1β, IL-6, IL-8, and TNFα and no indication of any potential for cytokine release syndrome (CRS) at these doses.
- The ex-U.S. Phase 1b/2a study with SON-080 in CIPN remains ongoing. Pursuant to a license agreement the Company entered with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, Sonnet and New Life will be jointly responsible for developing SON-080 in DPN. The DSMB overseeing the study is expected to meet during the third calendar quarter of 2023. Following the completion of the DSMB review, we anticipate announcing initial safety data from the CIPN study and will consider initiating a Phase 2 study in DPN.
- In February 2023, the Company announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. SON-1210 (IL12-F_HAB -IL15), Sonnet's lead bispecific construct, combines the F_HAB with fully human IL-12 and fully human IL-15. Sonnet is prepared to initiate the regulatory authorization process for SON-1210 in 2023, pending the outcome of any partnering activity.
- Preclinical development continues for SON-1410 (IL18-F_HAB-IL12), Sonnet's proprietary bispecific combination of IL-18 and IL-12, where cell line development for GMP application is underway. After some delays in 2023, process development activities will continue into 2024, with the potential to generate a drug suitable for human studies.

"Our mission to advance the company's pipeline while containing our costs remains in place, and we continue to be confident in the potential of our F_HAB technology. We are looking forward to our future data releases," commented Jay Cross, CFO.

FY 2023 Third Quarter Ended June 30, 2023 Financial Results

- As of June 30, 2023, Sonnet had $7.0 million cash on hand.
- Research and development expenses were $2.4 million for the three months ended June 30, 2023, compared to $5.6 million for the three months ended June 30, 2022. The decrease of $3.2 million was primarily due to the establishment of cost savings by transitioning product development activities to cost advantaged locations such as India and Australia and by reducing expenditures on tertiary programs such as SON-3015, which has been placed on a development hold, as well as a decrease in share-based compensation expense.
- General and administrative expenses were $1.5 million and $2.3 million for the three months ended June 30, 2023, and 2022, respectively. The decrease in general and administrative expenses is a result of cost-saving initiatives.

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 Section21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the offering, the closing of the offering, the amount and anticipated use of proceeds from the offering, the timing of an IND submission, 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
(unaudited)

	June 30, 2023	September 30, 2022
Assets		
Current assets:		
Cash	$ 7,021,071	$ 3,052,879
Incentive tax receivable	749,169	717,305
Prepaid expenses and other current assets	1,862,683	1,643,743
Total current assets	9,632,923	5,413,927
Property and equipment, net	36,577	46,211
Operating lease right-of-use asset	209,944	256,594
Deferred offering costs	-	113,280
Other assets	155,366	-
Total assets	$ 10,034,810	$ 5,830,012
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Related-party notes payable	$ -	$ 748
Accounts payable	3,024,441	4,752,340
Accrued expenses and other current liabilities	3,315,404	3,193,972
Operating lease liability	70,446	51,328
Deferred income	55,882	166,431
Total current liabilities	6,466,173	8,164,819
Operating lease liability	150,185	203,912
Total liabilities	6,616,358	8,368,731
Commitments and contingencies		

Stockholders' equity (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; 38,389,648 and 5,544,528 issued and outstanding at June 30, 2023 and September 30, 2022	3,839	554
Additional paid-in capital	109,981,627	88,871,786
Accumulated deficit	(106,567,014)	(91,411,059)
Total stockholders' equity (deficit)	3,418,452	(2,538,719)
Total liabilities and stockholders' equity (deficit)	$ 10,034,810	$ 5,830,012

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

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 36,850	$ 62,071	$ 110,550	$ 287,190
Operating expenses:				
Research and development	2,409,471	5,648,952	9,972,055	16,320,090
General and administrative	1,542,689	2,280,345	5,330,967	6,259,494
Total operating expenses	3,952,160	7,929,297	15,303,022	22,579,584
Loss from operations	(3,915,310)	(7,867,226)	(15,192,472)	(22,292,394)
Foreign exchange (loss) gain	(31,432)	(9,794)	36,517	5,894
Net loss	$ (3,946,742)	$ (7,877,020)	$ (15,155,955)	$ (22,286,500)
Per share information:				
Net loss per share, basic and diluted	$ (0.13)	$ (1.82)	$ (0.86)	$ (5.17)
Weighted average shares outstanding, basic and diluted	29,376,018	4,330,489	17,568,549	4,314,635

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

SOURCE: Sonnet BioTherapeutics, Inc.

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https://www.accesswire.com/773690/Sonnet-BioTherapeutics-Provides-Fiscal-Year-2023-Third-Quarter-Business-and-Earnings-Update