December 15, 2022

Sonnet BioTherapeutics Provides Fiscal Year 2022 Business and Financial Update

PRINCETON, NJ / ACCESSWIRE / December 15, 2022 /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, 2022 and provided a business update.

Pankaj Mohan, Ph.D., Founder and CEO commented, "This was a defining year for Sonnet, as we initiated two Phase 1 clinical trials with SON-1010 that yielded encouraging initial safety data and a Phase 1b/2a trial with SON-080 that is expected to yield data in the first half of 2023. Work is progressing as scheduled on our pipeline, and we are particularly pleased with the Janssen collaboration, which marked an important milestone for our business development activities. Partnering continues to be a focal point of our business strategy, with our R&D pipeline being prioritized based on external interest. Beginning in our second fiscal quarter of 2023, we are committing to generating significant operating expense reductions of approximately 30% in accordance with our prioritization goals. Further, we fully integrated Sonnet's low-cost R&D engine with product development activities in cost advantaged locations, including India and Australia. On behalf of our team, we are looking forward to a very productive 2023."

Fiscal Year 2022 and Recent Corporate Updates

Sonnet's Execution Platform: Sonnet has built a unique, highly capable low-cost execution platform for the development of our pipeline. The highly experienced small team of executives and senior managers has assembled a best-in-class global network of outsourced vendors for rapid execution. Most of the vendors are strategic collaborators, providing a preferential status with negotiated cost. Sonnet has chosen a strategic CMC collaborator in India and has negotiated the cost to be significantly less than the expense incurred from a similar US- or Europe-based vendor. Sonnet is conducting two of the company's three ongoing clinical trials in Australia, which carries a substantial cost reduction relative to US trials via the Australian government's R&D credit program. The major advantages of this approach include optimized direct investment into projects with expenses that can be rapidly scaled up or down depending on the number of projects.

Financings Completed: On August 15, Sonnet closed a private placement of preferred stock and warrants for net proceeds of $2.1 million. The preferred stock sold in the private placement converted into an aggregate of 552,283 shares of common stock on September 30, 2022, at a conversion price of $4.074 per share, and as of the date of this press release all of the warrants sold in the private placement are outstanding, entitling the holders thereof to purchase an aggregate of 276,140 shares of common stock at an exercise price of $4.074 per share between February 15, 2023 and the expiration date of August 15, 2027.

In addition, as of the market close on December 14, 2022, Sonnet has sold an aggregate of

3,056,526 shares of its common stock under the At-the-Market Sales Agreement with BTIG, LLC dated August 15, 2022, for total net proceeds of $6.5 million, including 2,391,989 shares sold for net proceeds of $4.6 million subsequent to September 30, 2022.

Announced Collaboration Agreement with Janssen Biotech: On October 31st, Sonnet announced a collaboration agreement with Janssen Biotech, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, where *in vitro* and *in vivo* efficacy of SON-1010 (IL12-F_HAB), SON-1210 (IL12- F_HAB-IL15) and SON-1410 (IL18-F_HAB-IL12) will be evaluated in combination with certain Janssen proprietary cell therapy assets. The agreement was facilitated by Johnson & Johnson Innovation. Under the terms of the agreement, Sonnet shall supply the three referenced compounds for use in head-to-head in vitro and in vivo efficacy studies. If successful and subject to the provisions of the agreement, Janssen could exercise its option and Sonnet could then seek an expanded collaboration.

Intellectual Property in Process: Beyond various provisional patents that have been applied for globally, on November 24th, Sonnet received a Decision to Grant Patent No. 2019-566563 from the Japan patent office. Entitled, "Albumin Domain Fusion Proteins", the intellectual property covers Sonnet's Fully Human Albumin Binding (F_HAB) technology and includes therapeutic fusion proteins that utilize F_HAB for tumor targeting and retention that also provide extended pharmacokinetics (PK). Pending formal issuance upon receipt of a small registration payment, the patent would carry an estimated term effective until February 20, 2038.

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

SON-1010 (IL12-F_HAB): On November 2nd, Sonnet announced interim data from the SB101 and SB102 dose-escalation studies of SON-1010. 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. The Safety Review Committees found no safety concerns and approved advancing to the next higher dose levels for both studies. Data from the primary analyses of both trials are expected during the second calendar quarter of 2023.

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 observed to date have been generally 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 represent either 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.

SON-080 (low-dose IL-6): On June 22nd, Sonnet announced that a Phase 1b/2a clinical trial of SON-080 had been authorized to commence. This study (SB211) is being conducted at multiple sites in Australia in patients with persistent chemotherapy-induced peripheral neuropathy (CIPN) and is expected to yield initial top line clinical safety data during the first half of 2023. Pursuant to a 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 2023.

SON-1210 (IL12-F_HAB-IL15): SON-1210, Sonnet's first bispecific candidate, is undergoing a non-human primate (NHP) study with the in-life portion on track to be completed in the fourth calendar quarter of 2022. Manufacturing and drug supply are secured with a lyophilized drug product formulation being prepared during the first calendar quarter of 2023, which is expected to be suitable for first-in-human clinical trials. Initiation of the regulatory authorization process is scheduled to commence during the first half of 2023.

SON-1410(IL18-F_HAB-IL12): Regarding SON-1410, Sonnet's second bispecific pipeline candidate, cell line development and process development is ongoing, with early experimental drug supply suitable for formulation and analytical method development activities, in addition to small quantities for use in early development proof-of-concept *in vitro studies*. Process development activities will continue through 2023, with the potential to generate drug suitable for initial *in vivo* mouse studies by the end of the 2023 calendar year.

SON-3015 (anti-IL6-F_HAB-anti-TGFβ): Regarding SON-3015, early-stage bispecific drug has been generated and has been stored for future use in *in vivo* mouse studies. Sonnet has elected to place the SON-3015 development program on hold for expense reduction purposes.

Fiscal Year Ended September 30, 2022 Financial Results

Jay Cross, CFO, elaborated on Sonnet's performance, saying, "2022 was an important year for Sonnet, during which we were able to effectively deploy our capital to make important pipeline progress. As we move into the 2023 calendar year, in addition to our continued

focus on funding the company, we will look to establish cost savings by reducing expenditures on tertiary programs, such as SON-3015, which is being placed on a development hold. In the cases of SON-1210 and SON-1410, work continues and will pivot around potential partnership interest, as the compounds advance towards the clinic. With collaborations in place, we will be in a position to further evaluate our operating expense infrastructure."

- As of September 30, 2022, Sonnet had $3.1 million cash on hand and subsequently raised $4.6 million in net proceeds from the At-the-Market Sales Agreement with BTIG, LLC.
- The Company currently has outstanding 7,934,156 shares of common stock and warrants to purchase an aggregate of 3,972,323 shares of common stock, with a weighted average exercise price per share of $19.21.
- Research and development expenses were $21.4 million for the year ended September 30, 2022, compared to $16.6 million for the year ended September 30, 2021. The increase of $4.8 million was primarily due to increased expenditures for the development of the cell lines for IL12-FHAB, IL12-FHAB-IL15 and SON-080 in connection with the initiation of a Phase 1 clinical trial for SON-1010 and preparation for a Phase 1b/2a pilot-scale efficacy study with SON-080 in CIPN; acquired in-process research and development the milestone payment incurred in connection with various license and research and development agreements, including the XOMA Collaboration Agreement; and an increase in payroll expense as we continue to develop our product candidates.
- General and administrative expenses were $8.6 million for the year ended September 30, 2022, compared to $8.9 million for the year ended September 30, 2021. The decrease of $0.3 million was primarily due to a decrease in payroll and share-based compensation expense.

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, 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 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,	
	2022	**2021**
Assets		
Current assets:		
Cash	$ 3,052,879	$ 27,622,067
Prepaid expenses and other current assets	2,361,048	1,189,474
Total current assets	5,413,927	28,811,541
Property and equipment, net	46,211	59,056
Operating lease right-of-use asset	256,594	123,213
Deferred offering costs	113,280	-
Total assets	$ 5,830,012	$ 28,993,810
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Related-party notes	$ 748	$ 748
Accounts payable	4,752,340	3,781,299
Accrued expenses	3,193,972	2,310,410
Operating lease liability	51,328	94,520
Deferred income	166,431	516,374
Total current liabilities	8,164,819	6,703,351

Operating lease liability	203,912	30,612
Total liabilities	8,368,731	6,733,963
	-	-
Stockholders' (deficit) 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; 5,544,528 and 4,303,617 shares issued and outstanding at September 30, 2022 and 2021, respectively	554	430
Additional paid-in capital	88,871,786	83,948,635
Accumulated deficit	(91,411,059)	(61,689,218)
Total stockholders' (deficit) equity	(2,538,719)	22,259,847
Total liabilities and stockholders' (deficit) equity	$ 5,830,012	$ 28,993,810

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

Sonnet BioTherapeutics Holdings, Inc.
Consolidated Statements of Operations

	Years ended September 30,	
	2022	**2021**
Collaboration revenue	$ 349,943	$ 483,626
Operating expenses:		
Research and development	21,444,019	16,634,553
General and administrative	8,575,283	8,936,509
Total operating expenses	30,019,302	25,571,062
Loss from operations	(29,669,359)	(25,087,436)
Interest income	-	15
Foreign exchange loss	(52,482)	(22,041)
Other income	-	125,501
Net loss	$ (29,721,841)	$ (24,983,961)
Per share information:		
Net loss per share, basic and diluted	$ (6.84)	$ (14.25)
Weighted average shares outstanding, basic and diluted	4,348,166	1,753,378

SOURCE: Sonnet BioTherapeutics Holdings, Inc.

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Business-and-Financial-Update