December 14, 2023

# Sonnet BioTherapeutics Provides Fiscal Year 2023 Business and Financial Update

**PRINCETON, NJ / ACCESSWIRE / December 14, 2023 /**Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) ("Sonnet" or the "Company"), a biopharmaceutical company developing innovative targeted biologic drugs focused on oncology, announced today its financial results for the fiscal year ended September 30th, 2023 and provided a business update.

"Sonnet has had a very productive year, exemplified by important achievements across our pipeline. The successful completion of the Phase 1 SB102 study with SON-1010 in healthy volunteers, combined with the initial data reported from the Phase 1 SB101 study in cancer patients propelled us forward into receiving FDA Investigational New Drug (IND) acceptance for the Phase 1b/2a SB221 combination study of SON-1010 with Roche's atezolizumab, in platinum-resistant ovarian cancer (PROC)," commented Pankaj Mohan, Ph.D., Founder and CEO. "Our efforts to advance our pipeline continue and are accompanied by Janssen's ongoing evaluation of SON-1010, SON-1210 and SON-1410 in combination with certain proprietary cell therapy assets. We are also working diligently to complete enrollment of the first portion of the Phase 1b SB211 study of SON-080 in chemotherapy-induced peripheral neuropathy (CIPN), with the hope of having early safety data available during the first quarter of 2024. We also expect to be able to share safety data from the SB102 and SB221 studies of SON-1010 during the first half of the year. In all, 2024 should be another exciting year for the company."

**Fiscal Year 2023 and Recent Corporate Updates**

**Announced Collaboration Agreement with Roche:** On January 9, 2023, Sonnet announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab. The companies have entered into a Master Clinical Trial and Supply Agreement (MCSA), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer (PROC) patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). On August 16, Sonnet announced that the FDA accepted the Investigational New Drug application (IND) for the use of SON-1010 in ovarian cancer, authorizing the companies to move forward with the SB221 trial.

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

SON-1010 (IL12-$F_H$AB): In January 2023, Sonnet announced data from SB102, a single-ascending dose (SAD) Phase 1 clinical trial designed to carefully study the pharmacokinetics (PK) and pharmacodynamics (PD) of SON-1010 in preparation for combination studies. Typical dose-related increases were seen with SON-1010 in the serum after subcutaneous (SC) administration. Drug levels peaked at about 11 hours and the mean elimination half-life

(t½) after the 150 ng/kg dose of SON-1010 was 112 hours, compared to 12 hours for rhIL-12 given SC, as reported in the literature.

In April, Sonnet presented additional data from the SB101 study of SON-1010 at the 2023 AACR Annual Meeting. SB101 is a 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 SB101 who were 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 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. 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. Safety data from final dose escalation in the SB101 study are expected during the first half of 2024.

Following FDA acceptance of the IND in August, Sonnet launched the SB221 study with several patients currently being dosed. This trial consists of a modified 3+3 dose-escalation design in Part 1 to establish the maximum tolerated dose (MTD) of SON-1010 with a fixed dose of atezolizumab. Clinical benefit in PROC will be confirmed in an expansion group to establish the recommended Phase 2 dose. Part 2 of the study will then investigate SON-1010 monotherapy, its use in combination with atezolizumab, or the standard of care (SOC) for PROC in a randomized comparison to show proof-of-concept (POC). Initial safety data from Part 1 of the SB221 study are expected during the first half of 2024.

In September 2023, Sonnet announced the completion of two independent *in vivo* proof-of-concept (POC) studies to show the biodistribution of interleukin-$F_H$AB molecules to the tumor microenvironment (TME), using labs with expertise in radiolabeling biologics and *in vivo* biodistribution analysis. The labs employed different radiolabeling methodologies ($^{99}$mTc or $^{89}$Zr) for mIL-12 and mIL12-$F_H$AB. The two studies were completed using the B16F10 mouse melanoma model to measure the accumulation of radiolabeled product and tumor volume inhibition over various time points. Both studies indicated that mIL12-$F_H$AB had significantly higher tumor accumulation, 2.5-4.7 times higher on average at the longer time points, and increased retention when compared to mIL-12. Accumulation was demonstrated in tumors compared to normal mice, and was transient in liver, kidney, and other organs, as expected. Importantly, radiolabeled mIL12- $F_H$AB also demonstrated measurable accumulation in the draining lymph nodes. Overall, these findings have important implications for therapeutic applications of any mono-(ILx-$F_H$AB) or bi-functional (ILx-$F_H$AB -ILy) molecules demonstrating enhanced tumor targeting and accumulation, as well as the potential for improved efficacy that could lead to a variety of drug candidates.

SON-1210 (IL12-$F_H$AB-IL15): In February 2023, Sonnet announced data from two successfully completed IND-enabling toxicology studies with SON-1210 in non-human primates. The compound elicited no serious adverse events in repeat, subcutaneous dosing and was well-tolerated using dosing levels at least 50x higher than the highest anticipated human clinical dose level. Sonnet is prepared to initiate the regulatory authorization process for SON-1210, pending the outcome of any partnering activity.

SON-1410 (IL18-$F_H$AB-IL12): Cell line development and process development are ongoing, with early experimental drug supply suitable for formulation and analytical method development activities. After some delays in 2023, activities will continue into 2024 with the potential to generate a drug suitable for preclinical studies and subsequent human studies.

SON-080 (low-dose IL-6): Enrollment of the first portion of the SB211 study in CIPN is nearing completion, which should position the DSMB to complete its review of the preliminary safety data during the first calendar quarter of 2024.

John Cini, Ph.D., Sonnet's CSO and Co-founder commented on the fiscal year's R&D accomplishments, saying, "The biodistribution data we announced in September further confirmed the ability of the $F_H$AB technology to extend therapeutic half-life and potentiate tumor targeting, which, combined with the clinical data we presented at AACR in April, position the platform as a differentiated approach for developing next-generation, cytokine-based oncologic drugs. We are excited about the opportunity to continue to highlight our pipeline assets at upcoming medical conferences and through the publication of peer-reviewed articles that elucidate our findings."

**Financings Completed**: On February 10, 2023, we closed a public offering of common stock and certain warrants for net proceeds of $13.6 million through the issuance and sale of 530,222 shares of our common stock and, to certain investors, pre-funded warrants to purchase 101,090 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 1,262,618 shares of our common stock. The public offering price of each share of common stock (or pre-funded warrant in lieu thereof) and accompanying common warrant was $23.76.

On June 30, 2023, we closed a registered direct offering of common stock (and common stock equivalents in lieu thereof) and a concurrent private placement of certain common stock warrants for net proceeds of $1.9 million through the issuance and sale of 166,363 shares of our common stock and, to certain investors, pre-funded warrants to purchase 60,909 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 227,272 shares of our common stock. The offering price of each share of common stock (or pre-funded warrant in lieu thereof) and accompanying common warrant was $9.90.

On October 26, 2023, we closed a public offering of common stock and certain warrants for net proceeds of $4.1 million through the issuance and sale of 1,306,250 shares of our common stock and, to certain investors, pre-funded warrants to purchase 1,537,500 shares of common stock and accompanying common warrants to purchase up to an aggregate of 5,687,500 shares of our common stock. The public offering price of each share of common stock (or pre-funded warrant in lieu thereof) and accompanying common warrant was $1.60.

**Fiscal Year Ended September 30, 2023 Financial Results**

Jay Cross, CFO, elaborated on Sonnet's performance, saying, "We are very pleased with the progress we made this year in an otherwise challenging environment for small biotechnology companies. We will continue to closely monitor our operating expenses, and we are happy to share the preliminary approval we recently received to sell up to $4.8 million of our New Jersey state net operating losses."

As of September 30, 2023, Sonnet had no debt and $2.27 million cash on hand, which excludes net proceeds of $4.1 million from the October financing. Sonnet believes its cash at September 30, 2023, together with the $4.1 million net proceeds from the October financing, will fund its projected operations into March 2024. In addition, Sonnet expects to receive a $0.8 million net cash refund from the research and development tax incentive program in Australia and recently received preliminary approval of its application to sell up to $4.8 million of its New Jersey state net operating losses through the Technology Business Tax Certificate Transfer Program, subject to execution of such sale, which together Sonnet believes will extend the funding of its projected operations into the third calendar quarter of 2024.

Research and development expenses were $11.8 million for the year ended September 30, 2023, compared to $21.4 million for the year ended September 30, 2022. The decrease of $9.6 million was primarily due to the establishment of cost savings by transitioning product development activities to cost advantaged locations such as India and Australia, by reducing expenditures on tertiary programs such as SON-3015, which has been placed on a development hold, and suspending antiviral development related to SON-1010, as well as a decrease in share-based compensation expense.

General and administrative expenses were $7.1 million for the year ended September 30, 2023, compared to $8.6 million for the year ended September 30, 2022. The decrease of $1.5 million relates primarily to a decrease in share-based compensation, legal and business development expenses, as we are managing expenses for liquidity purposes and are tightening our focus on the research and development projects we have assessed to have the greatest near-term potential.

**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 $F_H$AB (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 $F_H$AB 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. $F_H$AB 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.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

**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 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.

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**Sonnet BioTherapeutics Holdings, Inc.**
**Consolidated Balance Sheets**

| | September 30, | |
|---|---|---|
| | **2023** | **2022** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,274,259 | $ 3,052,879 |
| Prepaid expenses and other current assets | 1,677,396 | 1,643,743 |
| Income tax receivable | 786,574 | 717,305 |
| Total current assets | 4,738,229 | 5,413,927 |
| Property and equipment, net | 33,366 | 46,211 |
| Operating lease right-of-use asset | 193,689 | 256,594 |
| Deferred offering costs | 49,988 | 113,280 |
| Other assets | 414,206 | - |

| | | |
|---|---|---|
| Total assets | $ 5,429,478 | $ 5,830,012 |
| **Liabilities and stockholders' deficit** | | |
| Current liabilities: | | |
| Related party notes | $ - | $ 748 |
| Accounts payable | 2,201,999 | 4,752,340 |
| Accrued expenses and other current liabilities | 3,230,922 | 3,193,972 |
| Current portion of operating lease liability | 73,048 | 51,328 |
| Deferred income | 18,626 | 166,431 |
| Total current liabilities | 5,524,595 | 8,164,819 |
| Operating lease liability, net of current portion | 130,863 | 203,912 |
| Total liabilities | 5,655,458 | 8,368,731 |
| Commitments and contingencies | | |
| Stockholders' deficit: | | |
| Common stock, $0.0001 par value: 125,000,000 shares authorized; 1,750,426 and 251,955 issued and outstanding at September 30, 2023 and 2022, respectively | 175 | 25 |
| Additional paid-in capital | 110,017,598 | 88,872,315 |
| Accumulated deficit | (110,243,753) | (91,411,059) |
| Total stockholders' deficit | (225,980) | (2,538,719) |
| Total liabilities and stockholders' deficit | $ 5,429,478 | $ 5,830,012 |

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

**Sonnet BioTherapeutics Holdings, Inc.**
**Consolidated Statements of Operations**

| | Years ended September 30, | |
|---|---|---|
| | **2023** | **2022** |
| Collaboration revenue | $ 147,805 | $ 349,943 |
| Operating expenses: | | |
| Research and development | 11,814,690 | 21,444,019 |
| General and administrative | 7,125,732 | 8,575,283 |
| Total operating expense | 18,940,422 | 30,019,302 |
| Loss from operations | (18,792,617) | (29,669,359) |
| Foreign exchange loss | (40,077) | (52,482) |
| Net loss | $ (18,832,694) | $ (29,721,841) |
| Per share information: | | |
| Net loss per share, basic and diluted | $ (18.14) | $ (150.52) |

| | | |
|---|---|---|
| Weighted average shares outstanding, basic and diluted | $ 1,038,188 | $ 197,462 |

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

**SOURCE:** Sonnet BioTherapeutics Holdings, Inc.

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