SAB Biotherapeutics Provides Company Update for Q2 2023 Financial Results

August 21, 2023 12:30 PM EDT

SIOUX FALLS, S.D., Aug. 21, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SABS), (SAB), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, fully-human immunoglobulins (hIgG), also known as fully-human polyclonal antibodies, without the need for human donors, today reported financial results for the second quarter ended June 30, 2023, and provided a company update.

"We are pleased to share the significant progress achieved during the second quarter of 2023. Our commitment to advancing transformative immunotherapies remains unwavering, with a renewed strategic focus on Type 1 Diabetes through our SAB-142 program, a first-in-class fully human immunotherapeutic being developed for delaying onset and progression of Type 1 Diabetes. SAB-142 is a purified, fully human polyclonal anti-thymocyte globulin (hATG), which we believe is a promising solution for the limitations and side effects often associated with existing rabbit-derived ATG treatments. The promising safety and pharmacologic data from the GLP toxicology study for SAB-142, presented at the Federation of Clinical Immunology Societies conference, underscored its potential to reshape diabetes treatment," said Eddie J. Sullivan, Ph.D., Co-Founder, President, and Chief Executive Officer of SAB Biotherapeutics. “Our recent R&D Day, featuring SAB-142 as a centerpiece, further solidified our dedication to addressing autoimmune disorders with significant unmet needs. Furthermore, our influenza therapy, SAB-176, was highlighted at prominent industry events like the BIO 2023 International Convention and the International Society for Influenza and Other Respiratory Virus Diseases conference. Additionally, we achieved a regulatory milestone with FDA approval for five sections of our New Animal Drug Application (NADA), a pivotal step for our DiversitAb™ production system and hIgG antibody investigational drugs. As we continue to navigate dynamic medical landscapes, we remain steadfast in our mission to deliver impactful immunotherapies for the betterment of patients worldwide.”

Pipeline Updates and Anticipated Milestones

SAB continues to execute on its strategy for the development of proprietary immunotherapeutic fully-human antibodies, or fully-human immunoglobulins (hIgGs), to treat and prevent immune and autoimmune disorders with a strategic focus on Type-1 Diabetes disease modification.

SAB-142: Type 1 Diabetes

- Presented positive safety and pharmacologic data from a GLP toxicology study for SAB-142, a first in class fully human immunotherapeutic being developed for delaying onset and progression of Type 1 Diabetes (T1D), at the Federation of Clinical Immunology Societies (FOCIS) in Boston. Results from the IND-enabling GLP tox study confirmed that SAB-142 affects the same subsets of immune cells associated with T1D as commercially available rabbit-derived anti-thymocyte globulin (rATG) *in vivo*.
- Hosted 2023 R&D Day virtual and in-person events, affirming SAB’s strategic focus in the autoimmunity space with SAB-142, a disease-modifying fully human hIgG aimed at preventing onset or disease progression of Type 1 Diabetes, and subsequently can be expanded into other immunology indications. SAB-142 therapeutic highlights from the R&D Day event included:
  - SAB-142, a purified, fully human polyclonal anti-thymocyte globulin (hATG), is a validated therapeutic approach with support from clinicians, key opinion leaders, and the Juvenile Diabetes Research Foundation (JDRF).
  - Safety and immunogenicity databases of more than 700 human subjects treated with the SAB antibodies supports an anticipated 0% serum sickness rate and zero neutralizing anti-drug antibodies with SAB-142 in upcoming trials.
  - Special guest KOL speaker Dr. Michael Haller, Professor and Chief of Pediatric Endocrinology at the University of Florida, Gainesville and SAB Scientific Advisory Board member, presented his important research on low-dose ATG and Type 1 diabetes and SAB-142's potential in the T1D space.
  - Clinical development plan designed in partnership with JDRF.
  - IND approval and First-in-man Phase 1 clinical trials expected in Q4 2023 with interim data expected Q2 2024
  - Topline data expected in Q4 2024.

- Established regulatory path for T1D indication and the SAB-142 modality.

SAB-176: **Influenza**

- Presented "*Therapeutic Immunoglobulin (hIgG) for Pre- and Post-Exposure Prophylaxis and Treatment of Influenza"* at the **BIO 2023 International Convention** in Boston, with a primary focus on SAB-176 as an effective treatment option for influenza, along with insights into the recent Breakthrough Therapy and Fast Track Designations granted by the U.S. Food and Drug Administration (FDA).
- Presented favorable safety and efficacy data from Phase 1 and 2a clinical trials of its influenza immunotherapy, SAB-176, at the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV-AVG) conference.
- Received Breakthrough Therapy Designation (BTD) and Fast Track designation from the US Food and Drug Administration (FDA) for post-exposure prophylaxis for Type A and Type B influenza illnesses in high-risk patients for SAB-176.
- Received FDA guidance and regulatory alignment on advancing SAB-176 into the next phase of development, including a Phase 2b trial study design to evaluate the safety and efficacy of SAB-176 in high-risk patients with Type A or Type B influenza illness, including those who have anti-viral treatment resistant strains.
- FDA guidance for SAB-176 alignment with SAB's manufacturing approach to address multiple strains of influenza through hyperimmunization of seasonal strains on an annual basis.

SAB-185: COVID-19

- Released top-line Phase 3 clinical data results for our hIgG antibody therapeutic candidate, SAB-185, which demonstrated sustained symptom resolution in patients with COVID-19 caused by the Omicron variant compared to those who received REGEN-COV® in a Phase 3 NIH trial.
  - Specifically, 66% of participants treated with SAB-185 reached full symptom resolution for at least four consecutive days by Day 28 vs. 50% of participants on REGEN-CO.® The median time to symptom resolution for at least four consecutive days was seven days shorter for SAB-185.

Regulatory:

- Provided a regulatory update announcing the approval by the FDA for five of seven sections required for a pending New Animal Drug Application (NADA) for our antibody-generating platform in Transchromosomic (Tc) bovine, which will be used for approval in support of Biologics License Applications (BLAs) with the FDA Center for Biologics Evaluation and Research (CBER) for our hIgG antibody investigational drugs.

Audit/Compliance:

- On August 21, 2023, we announced that EisnerAmper LLP was appointed as our independent registered public accounting firm for the fiscal year ending December 31, 2023, effective August 22, 2023.

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Financial Guidance: Based on its current operating plans, SAB reaffirms that it expects its existing business plan, cash and cash equivalents, and anticipated cash flows will be sufficient to fund its operating expenses and capital expenditure requirements through October 2023.

- **Cash Position:** Cash and cash equivalents were $7.8 million as of June 30, 2023, compared to $15.0 million on December 31, 2022, were driven primarily by continued net operating

losses as we advance our lead therapeutic candidates.

- **Research and Development (R&D) Expenses:** R&D expenses were $3.7 million for three months ended June 30, 2023, compared to $8.6 million for the three months ended June 30, 2022. R&D expenses were $8.2 million for the six months ended June 30, 2023, compared to $21.9 million for the six months ended June 30, 2022. The decrease was primarily due to targeted cost reduction measures pausing certain unfunded research activities for our COVID-19 therapeutic and prioritizing our focus in the autoimmunity space with SAB-142, a disease-modifying fully human hIgG aimed at preventing onset or disease progression of Type 1 Diabetes.

- **General and Administrative (G&A) Expenses:** G&A expenses were $2.9 million for the three months ended June 30, 2023, compared to $4.3 million for the three months ended June 30, 2022. G&A expenses were $6.3 million for the six months ended June 30, 2023, compared to $9.5 million for the six months ended June 30, 2022. The decrease was primarily due to discretionary cost reduction measures and increased efficiencies as we continue to mature as a publicly traded company.

- **Net Loss:** Net loss was $6.9 million for the three months ended June 30, 2023, for an earnings per basic and diluted share of $(0.14), as compared to a net loss of $4.8 million for the three months ended June 30, 2022, for an earnings per basic and diluted share of $(0.11). Net loss was $14.2 million for the six months ended June 30, 2023, for an earnings per basic and diluted share of $(0.28), as compared to a net loss of $3.8 million for an earnings per basic and diluted share of $(0.09).

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics, Inc. (SAB) is a clinical-stage biopharmaceutical company focused on the development of powerful and proprietary immunotherapeutic polyclonal human antibodies to treat and prevent infectious diseases and immune and autoimmune disorders. Our development programs include infectious diseases resulting from outbreaks and pandemics, as well as immunological, gastroenterological, and respiratory diseases that have significant mortality and health impacts on immune compromised patients. SAB has applied advanced genetic engineering and antibody science to develop Transchromosomic (Tc) Bovine™. Our versatile DiversitAb™ platform is applicable to a wide range of serious unme needs in human diseases. It produces natural, specifically targeted, high-potency, fully-human polyclonal immunotherapies without the need for human donors. SAB currently has multiple drug development programs underway and collaborations with the US government and global pharmaceutical companies. For more information on SAB, visit: https://www.SAb.bio/ and follow SAB on Twitter and LinkedIn.

Forward-Looking Statements

Certain statements made herein that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding future events, the development and efficacy of our influenza program, C. diff. program, type 1 diabetes program, and other discovery programs, the results, including timing, of the development of SAB-176, SAB-185, and SAB-142, including SAB-176 Fast Track designation and Breakthrough Therapy designation, and the outcome of potential future government and other third-party collaborations or funded programs.

These statements are based on the current expectations of SAB and are not predictions of actual performance, and are not intended to serve as, and must not be relied on, by any investor as a guarantee, prediction, definitive statement, or an assurance, of fact or probability. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties and other factors which may be beyond our control. Actual events and circumstances are difficult or impossible to predict, and these risks and uncertainties may cause our or our industry’s results, performance, or achievements to be materially different from those anticipated by these forward-looking statements. A further description of risks and uncertainties can be found in the sections captioned “Risk Factors” in our most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q, and other filings with or submissions to, the U.S. Securities and Exchange Commission, which are available at https://www.sec.gov/. Except as otherwise required by law, SAB disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events, or circumstances or otherwise.

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