SAB Biotherapeutics Provides Company Update for Q1 2023 Financial Results

May 16, 2023

SIOUX FALLS, S.D., May 16, 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, yesterday reported financial results for the first quarter ended March 31, 2023, and provided a company update.

"Our first quarter 2023 results demonstrate that we continue to execute on our strategy to develop and deliver powerful immunotherapeutic treatments to patients with significant unmet needs. We recently announced Breakthrough Therapy Designation and Fast Track designation for SAB-176 from the FDA further validating the potential of our immunotherapy platform to treat a wide range of serious infectious diseases specifically impacting high-risk patients most in need of improved treatment options. We remain committed to advancing our programs and delivering much-needed therapies to patients worldwide," said Eddie J. Sullivan, Ph.D., Co-Founder, President, and Chief Executive Officer of SAB Biotherapeutics. "Additionally, we presented favorable safety and efficacy data from Phase 1 and 2a clinical trials of SAB-176, our fully-human, broadly neutralizing immunoglobulin antibody therapeutic, designed to prevent or reduce severe outcomes of Type A and Type B influenza infection in high-risk and immunocompromised patients. Lastly, we are pleased with the results of the Phase 3 NIH trial that showed our antibody therapeutic candidate, SAB-185, demonstrated sustained symptom resolution in patients with COVID-19 caused by the Omicron variant compared to those who received REGEN-COV®," concluded Dr. Sullivan.

Pipeline Updates and Anticipated Milestones

SAB is committed to advancing its strategy of developing a unique immunology platform focused on Type 1 diabetes, and respiratory and gastrointestinal diseases, that particularly impact individuals at high-risk with compromised immune systems or autoimmune disorders. In the following section, we highlight noteworthy accomplishments and milestones achieved during the quarter:

- 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. SAB's influenza therapy is the first fully-human multi-epitope binding broadly neutralizing immunoglobulin antibody therapeutic developed for treating high-risk patients and post-exposure prophylaxis of Type A and Type B influenza. The FDA's Breakthrough Therapy designation process is designed to expedite the development and review of a medicine that is intended to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the drug, SAB-176, may demonstrate substantial improvement over therapies currently available on a clinically significant endpoint.
- 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.
- Received FDA guidance for SAB-176 aligned with SAB's manufacturing approach to address multiple strains of influenza through hyperimmunization of seasonal strains on an annual basis.
- 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. SAB is in the process of completing the remaining two sections of the NADA. Upon formal acceptance of the seven-step safety and effectiveness evaluation, we will use this approval in support of Biologics License Applications (BLAs) with the FDA Center for Biologics Evaluation and Research (CBER) for our hIgG antibody investigational drugs.
- 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. The Phase 2a trial in healthy adults showed that SAB-176 was safe, well-tolerated, and demonstrated a significant reduction in symptoms as well as viral load compared to placebo.
- 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. Only 50% of participants on REGEN-COV® met this endpoint, and the median time to symptom resolution for at least four consecutive days was seven days shorter for SAB-185. The study's primary endpoint was the composite of all-cause hospitalizations and deaths, considered inconclusive for non-inferiority in non-Omicron and Omicron patients.
- Welcomed Erick Lucera to our Board of Directors. Lucera, a 30-year veteran of the biotechnology and medical device industry, has held executive positions at several healthcare companies, most recently as chief financial officer of AVEO

Oncology. We expect Lucera's experience in corporate finance to be valuable as SAB advances its programs through essential milestones.

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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 December 2023.

- **Cash Position:** Cash and cash equivalents were $13.1 million as of March 31, 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 $4.5 million for three months ended March 31, 2023, compared to $13.3 million for the three months ended March 31, 2022. The decrease was primarily due to targeted cost reduction measures pausing certain unfunded research activities for our COVID-19 therapeutic, and prioritizing our earlier stage lead therapeutic candidates in Type 1 diabetes, respiratory and gastrointestinal diseases.

- **General and Administrative (G&A) Expenses:** G&A expenses were $3.4 million for the three months ended March 31, 2023, compared to $5.2 million for the three months ended March 31, 2022. The decrease was primarily due to discretionary cost reduction measures and increased efficiencies as the company continues to mature as a publicly traded company.

- **Net Income:** Net loss was $7.3 million for the three months ended March 31, 2023, for an earnings per basic and diluted share of $(0.15), as compared to a net income of $1.0 million for the three months ended March 31, 2022, for an earnings per basic and diluted share of $0.02.

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 unmet needs in human diseases. I 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, SAB-142 and SAB-195, 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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