SAB Biotherapeutics Provides Company Update for Q3 2022 Financial Results

November 15, 2022

SIOUX FALLS, S.D., Nov. 15, 2022 (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 polyclonal antibodies without the need for human donors, today reported financial results for the third quarter ended September 30, 2022, and provided a company update.

"We continue to utilize our capabilities and infrastructure to advance our development pipeline in immunotherapeutics directed at unmet medical needs in respiratory diseases and in gastrointestinal disease with our Clostridioides difficile (C. diff) program and have discovery programs in autoimmune disease and oncology. During the quarter we were able to show data that further validates our platform at targeted medical conferences. Additionally, we signed a contract manufacturing agreement with Emergent BioSolutions, one of the few companies experienced in both human and animal plasma fractionation and purification uniquely qualified to manufacture SAB's novel fully-human polyclonal antibody products," said Eddie J. Sullivan, Ph.D., Co-Founder, President, and Chief Executive Officer of SAB Biotherapeutics.

Pipeline Updates and Anticipated Milestones

SAB continues to execute on its strategy to build a proprietary immunology pipeline addressing respiratory and gastrointestinal diseases that disproportionately affect patients who are immunocompromised or have autoimmune disorders. Below are some key highlights and milestones from the quarter:

- During the quarter, the company presented an overview of its DiversitAb™ polyclonal platform and data on SAB-176 and SAB-185 at the 2022 Plasma Product Biotechnology Conference in Limassol, Cyprus. The data presented showed the benefits of fully-human polyclonal antibodies derived from SAB's Transchromosomic (Tc) Bovine™ over plasma derived antibodies from humans. The SAB fully-human polyclonal antibody platform maintains its efficacy against multiple variants of several highly mutating viruses.
- The company also presented at a conference hosted by the International Society for Influenza and other Respiratory Virus Diseases (ISIRV) in Belfast, Northern Ireland. The data presented showed its fully-human polyclonal antibody platform maintains its efficacy against multiple variants of several highly mutating viruses. The Phase 2a challenge trial showed that SAB-176 reduced the viral load in subjects exposed to pandemic H1N1 influenza virus, improved symptoms by day four, and shortened the timeframe for viral shedding. The data also showed that SAB-185 COVID-19 polyclonal antibody therapeutic candidate was effective in animal models against all tested SARS-CoV2 variants, including some of the recently evolving Omicron variants. "Both of these programs show the power of polyclonal antibodies to broadly neutralize highly mutating viruses and the differentiation of SAB's novel therapeutic products vs monoclonal biologic therapies," Dr. Sullivan said. "These data highlight that our technology produces neutralizing antibodies that create an envisioned evergreen therapeutic aimed to maintain efficacy against rapidly mutating pathogens."
- SAB-176, the Company's anti-influenza human polyclonal therapeutic, will move into advanced Phase 2b development, and SAB-195, the Company's anti-C. diff. human polyclonal antibody therapeutic, will move to IND-enabling activities and IND filing.
- In October, the company announced it has entered into an exclusive manufacturing services agreement with Emergent BioSolutions Inc. Emergent will provide contract development and manufacturing (CDMO) services to produce SAB's fully-human polyclonal antibody products. Under the terms of the agreement, Emergent will provide end-to-end Good Manufacturing Practice (cGMP) manufacturing services to SAB, including process development and manufacturing clinical investigational drug product to support SAB's clinical programs, and commercial manufacturing services upon regulatory approval of SAB's therapeutics. The agreement also provides the opportunity for Emergent to utilize SAB's novel DiversitAb™ platform, the only one in the world that produces fully-human polyclonal antibodies without the need for human donors.

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- **Financial Guidance:** SAB received $8.6 million from the DoD contract on November 10, 2022, for work performed. Additionally, SAB and the DoD continue to engage in a comprehensive negotiation over several million dollars claimed by SAB as contract closeout costs. 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 July 2023.

- **Cash Position:** Cash and cash equivalents were $8.3 million as of September 30, 2022, compared to $16.6 million on June 30, 2022, which was driven primarily by SAB's third quarter cash operating loss of $7.1 million.

- **Research and Development (R&D) Expenses:** R&D expenses were $7.4 million for three months ended September 30, 2022, compared to $15.1 million for the three months ended September 30, 2021. The decrease was primarily due to decreases in laboratory supplies, contract manufacturing costs, clinical trial expense, and outside lab services due to a decrease in work performed.

- **General and Administrative (G&A) Expenses:** G&A expenses were $4.0 million for the three months ended September 30, 2022, compared to $3.6 million for the three months ended September 30, 2021. The increase was primarily due to increased compensation costs and increased insurance and compliance costs associated with being a public company.

- **Net Income:** Net loss was $7.1 million for the three months ended September 30, 2022, for an earnings per basic and diluted share of $(0.16), as compared to a net loss of $4.1 million for the three months ended September 30, 2021, for an earnings per basic and diluted share of $(0.16).

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics, Inc. (SAB) We are 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, including the development and efficacy of our influenza program, C. diff. program, Type 1 Diabetes program, and other discovery programs, the likelihood that a patent will issue from any patent application, the results, including timing, of the development of SAB-176, SAB-185 and SAB-195 (including any IND filing or proposed clinical trials), financial projections and future financial and operating results (including estimated cost savings and cash runway), the outcome of and potential future government and other third-party collaborations or funded programs (including negotiations with the DoD).

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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