SAB Biotherapeutics Provides Company Update and Reports Full Year 2021 Financial Results

March 29, 2022

SAB executing on its strategy to build a proprietary immune and autoimmune disorders pipeline, including respiratory diseases that affect immunocompromised patients

Plans to announce full data from Phase 2a trial that evaluated SAB-176 for the treatment of seasonal influenza mid-2022 – first full clinical data set from DiversitAb platform

SAB continues to advance on Rapid Response Antibody Program collaboration with US Department of Defense

Generated robust data set, demonstrated proof-of-concept and validated platform through accelerated clinical development of SAB-185, a high-potency fully-human polyclonal therapeutic, to address pandemic need for novel treatments against emerging biothreats, respiratory viruses and viral mutations

Sufficient cash and government funding anticipated to operate through third quarter 2023

SIOUX FALLS, S.D., March 29, 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 provided a business update and reported financial results for the full year ended December 31, 2021.

“2021 was a pivotal year for SAB Biotherapeutics, as we successfully closed our business combination and debuted on the NASDAQ exchange, while advancing SAB-185 and SAB-176, our novel polyclonal antibodies for COVID-19 and influenza. Our work on SAB-185 propelled our science forward with a real-world proof-of-concept. It contributed greatly to our scientific knowledge and gave us tremendous confidence in what SAB can achieve with our innovative technology to address a variety of acute and chronic unmet medical needs. It also demonstrated the potential of our rapid response platform to address future global public health threats. The historic impact of influenza and the evolving COVID-19 pandemic continues to impact at-risk patients, such as those with underlying conditions or those who are immunocompromised. The need for potent therapeutics remains clear,” said Eddie J. Sullivan, Ph.D., co-founder, President and Chief Executive Officer of SAB Biotherapeutics. “We are extremely proud of our team and SAB’s role in responding to the COVID-19 health crisis. SAB remains dedicated to rapidly developing therapies that can play a role in both this pandemic and in future threats to public health.”

Dr. Sullivan continued, “Moving forward into 2022, we remain focused on leveraging the breadth of the platform to monetize both our pipeline programs and those outside our core therapeutic focus, including respiratory disease, oncology and monoclonal discovery. We continue to execute on the Rapid Response Antibody Program through our contract with the US Department of Defense, initiated in 2019, which has expanded and advanced significantly due to the accelerated progress made during the COVID-19 pandemic response. We also remain on track to release initial proof-of-principle data in demonstrating the potential of multi-targeted human polyclonals in oncology. With multiple milestones rapidly approaching, including the first clinical data from our platform, and the anticipated readout of the full dataset from our Phase 2a study of SAB-176 in seasonal influenza, we believe we are well positioned to deliver on the promise of our strategy to continue building a robust pipeline spanning immune and autoimmune disorders, and bringing much needed therapeutics to patients.”

2021 and Pipeline Updates and 2022 Anticipated Milestones

- **Phase 2 Full Data Readout for SAB-185 Expected to be Available Mid-2022.** SAB-185 is a polyclonal antibody therapeutic candidate for the treatment of COVID-19. SAB-185 could be a valuable clinical tool for immunocompromised patients, and potentially as a therapeutic against future SARS-CoV-2 variants. SAB intends to continue to study SAB-185 in COVID-19 and is evaluating clinical plans for further development in targeted patient groups, including the potential for prophylactic or therapeutic use in targeted high-risk populations, along with the potential development of an injectable formulation, in addition to other indications.
    - SAB-185 was being assessed as part of the Phase 3 NIH ACTIV-2 master protocol evaluating treatments for COVID-19 in patients with mild-moderate infections at higher risk for progression to hospitalization.
    - As announced on February 25, 2022, due to low Omicron-related COVID-19 hospitalization and death rates that

made the study design statistically unworkable, it was discontinued, as were trials from other companies participating in ACTIV-2, sponsored and funded directly by NIH.

- SAB's strong clinical data demonstrated in trials to date has given us increased confidence in our progress in developing SAB-185, which has contributed greatly to the collective body of science in virology, infectious disease and polyclonal therapy development. The extensive pre-clinical and clinical programs completed have expanded our knowledge over the past two years of the potential for Tc bovine-derived fully-human polyclonal antibody development. This accelerated development path, driven by the pandemic need for novel therapeutics to address emerging viruses and their mutations, and the work we anticipate completing in the coming months, is expected to significantly benefit scientific discovery and future patients.
- We previously achieved positive review from an independent Data Safety Monitoring Board (DSMB) on the predefined interim Phase 2 safety and efficacy goal for advancement to Phase 3. The positive DSMB review was later confirmed on subsequent review of the full data set.
- In December, we reported data demonstrating that SAB-185 retains in-vitro neutralization against the Omicron SARS-CoV-2 variant. Throughout 2021, we announced data supporting the potent neutralization of the Omicron, Gamma, Delta, Lambda and other circulating variants of concern in nonclinical studies, in addition to preclinical data indications that SAB-185 is believed to be significantly more potent than human-derived convalescent immunoglobulin G (IgG).

- **Continued execution on Rapid Response Antibody Program.** The Rapid Response Antibody Program was initiated in 2019 through a three-stage, multi-year contract with the US Department of Defense (DOD) that was accelerated and expanded significantly due to the COVID-19 pandemic and increased need for therapeutics. SAB continues to build out this program, with multiple targets and other strategic activities to support the warfighter, in addition to facilitating readiness for future emerging threats.
  - Since 2019, progress on the Rapid Response Antibody Program has resulted in strategic company infrastructure, including full platform vertical integration with antigen development and production, plasma production, expanded manufacturing and quality control capacities. It has also resulted in expansion of our capabilities across all areas of late-stage biologics development including regulatory, quality assurance and clinical.
- **Phase 2a challenge study full data readout for SAB-176 expected mid-2022.** SAB-176 is a polyclonal antibody therapeutic candidate recently evaluated in a Phase 2a Challenge study for the treatment of seasonal influenza.
  - In December, we announced Phase 2a topline data achieving statistically significant reductions in viral load and clinical symptoms while also appearing safe and well-tolerated.
- **Planned advanced IND-enabling studies for SAB-142.** SAB-142 is a fully-human antithymocyte globulin therapeutic candidate for Type 1 diabetes and organ transplantation (induction/rejection) currently in preclinical development. The initial pilot study was completed in the first quarter of 2022 with further studies planned pending availability of appropriate study models.
- **Initial Proof-of-Principle Data for Immuno-oncology Expected in the Second Quarter of 2022.**

2021 Highlights and Strategy Update

- **Successfully closed business combination with Big Cypress Acquisition Corp.** SAB transitioned to a public company: The business combination, which closed in October 2021, resulted in cash proceeds, net of transaction costs, to SAB of approximately $34.3 million.
- Added to **NASDAQ Biotechnology Index**.
- **R&D strategy focused on validating DiversitAb Platform and developing novel therapies for autoimmune disease.** SAB plans to continue antigen development capabilities for its "strain add" strategy to further accelerate its capability to rapidly respond to new targets and diseases variants.
- **Business development strategy leverages the full breadth and capabilities of platform.** SAB continues to execute on a multi-pronged business strategy to monetize pipeline programs, as well as those outside our core therapeutic focus, including respiratory disease, oncology and monoclonal discovery with both potential partners and collaborations with the US government.
- **Positive data readouts:**
  - Announced multiple sets of robust in-vitro data supporting potent neutralization of SAB-185 against multiple SARS-CoV-2 variants, including Delta and Omicron.
  - Continuing to evaluate future clinical plans for SAB-185, including potential targeted applications, such as treatment in high-risk patient groups and alternate routes of administration.
- **Management Updates:**
  - **Appointed Russell Beyer as Chief Financial Officer.** Appointed in September 2021, Beyer has more than 25 years of experience overseeing financial functions at pharmaceutical and other Fortune 100 firms including AstraZeneca, Teva Pharmaceuticals and HBO.

- **Samuel J. Reich joined as Executive Chairman** following the closing of the merger in October 2021, having served as Chief Executive Officer, Chief Financial Officer and Director of Big Cypress Acquisition Corp. Reich is a bioentrepreneur and inventor holding more than 60 patents world-wide, including contribution to the debut of RNA therapeutics. A molecular biologist by training, he has co-founded and built multiple successful biotech companies with next-generation technology including Acuity Pharmaceuticals, OPKO Health and Biscayne Neurotherapeutics.
- **Jerry Pommer, Chief Compliance Officer**, **and head of regulatory** will be retiring from the Company, effective April 1, 2022, after 22 years of dedication to the DiversitAb platform. **Carlos Carrillo, Senior Vice President of Regulatory Affairs** will serve as the interim acting head of regulatory. Pommer will be retained as a consultant for the Center for Veterinary Medicine–NADA regulatory approval.
- **Charles H. Randall Jr., former Chief Strategy Officer**, departed the Company effective December 31, 2021.

Full Year 2021 Financial Results

- **Cash Position.** Cash and cash equivalents were $33.2 million as of December 31, 2021, as compared to $12.6 million as of December 31, 2020. SAB's government contract work is expected to provide up to an additional $91.7 million in funding. Due to the structure of the contracts, these funds are not reflected on the balance sheet.
- **Research and Development (R&D) Expenses.** R&D expenses were $57.2 million for the year ended December 31, 2021, compared to $27.9 million for the year ended December 31, 2020. The increase was primarily due to increased headcount in the research and development function, contract manufacturing, increased clinical work, and increases in our production capacity and the associated expenses for materials and supplies supporting research and development activities.
- **General and Administrative (G&A) Expenses.** G&A expenses were $17.1 million for the year ended December 31, 2021, compared to $6.8 million for the year ended December 31, 2020. The increase was primarily due to increased headcount in the general and administrative function, and increases in business and regulatory consulting, insurance costs and recruiting expenses. Further, we recognized considerable increased expenses as a result of becoming a public company in quarter four.
- **Net Loss.** Net loss was $17.1 million for the year ended December 31, 2021, for a net loss per basic and diluted share of $0.63, as compared to a net income of $20.1 million for the year ended December 31, 2020, or a net income per basic and diluted share of $0.79 and $0.74, respectively.

Financial Guidance: Based on its current operating plans, SAB expects that its existing cash, cash equivalents and its U.S. Government funding as of December 31, 2021, will be sufficient to fund its operating expenses and capital expenditure requirements into the third quarter of 2023.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics, Inc. (SAB) is a clinical-stage, biopharmaceutical company advancing a new class of immunotherapies leveraging fully human polyclonal antibodies with a focus on building a leading immune and autoimmune disorders pipeline. SAB has applied advanced genetic engineering and antibody science to develop transchromosomic (Tc) Bovine™ that produce fully human antibodies targeted at specific diseases, including infectious diseases such as COVID-19 and influenza, immune and autoimmune disorders including type 1 diabetes and organ transplantation, and cancer. SAB's versatile DiversitAb™ platform is applicable to a wide range of serious unmet needs in human diseases. It produces natural, specifically targeted, high-potency, human polyclonal immunotherapies. 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.sabbiotherapeutics.com/ and follow @SABBantibody on Twitter.

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 SAB-185, our influenza program and other discovery programs, our cash runaway into 2023 and potential future government and third-party collaborations or funded programs.

These statements are based on the current expectations of SAB and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on, by any investor as a guarantee, an assurance, a prediction or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict, will differ from assumption and are beyond the control of SAB. A further description of risks and uncertainties can be found in the prospectus filed by SAB Biotherapeutics, Inc. on December 29, 2021, including in the sections thereof captioned "Risk Factors" as well as in its subsequent reports on Form 10-K, 10-Q and Form 8-K, all of which will be filed with the U.S. Securities and Exchange Commission and available at https://www.sec.gov/

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