SAB BIO Reports Third Quarter Financial Results and Recent Business Highlights

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- *Initiated registrational Phase 2b SAFEGUARD trial of SAB-142 in new-onset, Stage 3 autoimmune T1D patients*
- *Multiple SAFEGUARD trial sites activated; on-track to dose first patient by year-end*
- *Recent data presented at EASD and IPSAD provide further validation for SAB-142 as a novel, potentially best-in-class, disease-modifying, immunotherapeutic approach to redefine treatment of Stage 3 T1D*
- *Strong cash position with operational runway through 2028, enabling completion of registrational Phase 2b SAFEGUARD study*

MIAMI, Nov. 13, 2025 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), a clinical-stage biopharmaceutical company developing human anti-thymocyte immunoglobulin (hATG) for type 1 diabetes (T1D) and other autoimmune diseases, today announced financial results for the third quarter ending September 30, 2025, and provided business highlights.

“We made significant progress this quarter, specifically executing on our clinical plans, and I am pleased that we initiated the registrational Phase 2b SAFEGUARD study of our lead candidate SAB-142. We have activated multiple sites around the world, and we are on-track to dose the first patient by year-end,” said Samuel J. Reich, Chairman and CEO, SAB BIO. “This quarter, we also showcased the results of our Phase 1 study in multiple presentations at EASD and ISPAD. These data, including a favorable safety profile and a competitive dosing regimen, continue to support the development of SAB-142 as a novel, potentially best-in-class, disease-modifying, immunotherapeutic approach for the treatment of Stage 3 T1D. We look forward to sharing additional Phase 1 data, including redosing data, later this year.”

Recent Highlights and Achievements

SAFEGUARD

- Initiated the SAFEGUARD (**SAF**ety and **E**fficacy of human anti-thymocyte immuno**G**lob**U**lin SAB-142 **AR**resting progression of type 1 **D**iabetes) clinical trial of SAB-142 as a novel, potentially best-in-class, disease-modifying immunotherapeutic approach in development to treat T1D by delaying the onset or progression of disease.
- Activated multiple clinical trial sites in the US, Australia, and New Zealand.
- Enrollment is ongoing, and the Company is on-track to dose the first patient by year-end.
- The Company previously aligned with the U.S. Food and Drug Administration (FDA) on the design and advancement of the SAFEGUARD Phase 2b trial as a registrational trial following a constructive Type B regulatory meeting in May.

Clinical Data

- Presented four oral and two poster presentations at the 51st Annual Conference of the International Society for Pediatric and Adolescent Diabetes (ISPAD) November 5-8, 2025, showcasing progress in the development of SAB-142.

    - Key data presented included data from the Phase 1 study showcasing the clinically validated, multi-specific mechanism of action with sustained immunomodulation of SAB-142.
- Presented four oral presentations at the 61st Annual Meeting of the European Association for the Study of Diabetes (EASD).
    - Key data presented included safety data from the Phase 1 trial of SAB-142 demonstrating a favorable safety profile, characterized as not causing serum sickness or anti-drug antibodies at the target dose.
- INNODIA presented the MELD-ATG study data at EASD demonstrating rabbit ATG's benefit to preserve C-peptide in Stage 3 autoimmune T1D patients, providing further validation of a de-risked mechanism of action for SAB-142.
    - Data demonstrated statistically significant preservation of C-peptide and statistically significant improvement in glycemic control.

Upcoming Anticipated Milestones

- On-track to dose the first patient in SAFEGUARD by the end of the year.
- On-track to share data from SAFEGUARD in 2H 2027.
- The Company plans to present final data from the Phase 1 study of SAB-142, including data from a cohort of T1D participants and data from redosed participants, by the end of the year.
    - Previously, the Company presented data from a Phase 1 trial of SAB-142 in healthy volunteers demonstrating a competitive and favorable safety profile at EASD, ISPAD, and in a Company sponsored R&D presentation.

Q3 2025 Financial Results

- SAB BIO held cash, cash equivalents, and available for sale securities of $161.5 million as of September 30, 2025, compared to $20.8 million as of December 31, 2024.

- R&D expenses were $9.0 million and $7.8 million for the three months ended September 30, 2025 and 2024, respectively. R&D expenses were $23.6 million and $22.6 million for the nine months ended September 30, 2025 and 2024, respectively. The increase is driven by the ongoing investments made to advance the SAB-142 program into Phase 2 clinical trials.

- General and administrative expenses were $3.7 million and $3.5 million for the three months ended September 30, 2025 and 2024, respectively. General and administrative expenses were $9.6 million and $11.5 million for the nine months ended September 30, 2025 and 2024, respectively. This decrease was driven by reduced payroll related costs and professional fees to prioritize the Company's continued research activities and development of its product candidates.

- Other income was $58.1 million and $1.0 million for the three months ended September 30, 2025 and 2024, respectively. Other income was $63.3 million and $10.2 million for the nine months ended September 30, 2025 and 2024, respectively. This increase was driven by the change in fair value of warrant liabilities.

- SAB BIO reported net income of $45.4 million and a net loss of $10.3 million for the three months ended September 30, 2025 and 2024, respectively, and net income of $30.1 million and a net loss of $22.7 million for the nine months ended September 30, 2025 and 2024, respectively.

About SAB-142
SAB-142 is a potentially disease-modifying, redosable immunotherapy in clinical development for the treatment of autoimmune type 1 diabetes (T1D). SAB-142 is a multi-specific, fully human anti-thymocyte globulin (hATG) with a mechanism of action analogous to that of rabbit ATG (rATG). rATG has demonstrated in multiple clinical trials the ability to slow disease progression in patients with new or recent onset of Stage 3 T1D. SAB-142, like rATG, directly targets multiple immune cells involved in destroying pancreatic beta cells, including modulation of “bad acting” T-lymphocytes like Cytotoxic T-cells. By stopping immune cells from attacking beta cells, this treatment has the potential to preserve insulin-producing beta cells.

About SAB BIO
SAB BIO is a clinical-stage biopharmaceutical company focused on developing multi-specific, high-potency, human immunoglobulin G (hIgG) to treat and prevent immune and autoimmune disorders. The Company’s lead candidate, SAB-142, targets autoimmune T1D with a disease-modifying therapeutic approach that aims to change the T1D treatment paradigm by delaying onset and potentially preventing disease progression of Stage 3 T1D patients. Using advanced genetic engineering and antibody science, SAB BIO developed a proprietary platform which holds the potential to generate additional novel therapeutic candidates utilizing the human immune response, without the need for human donors or convalescent plasma. SAB BIO has optimized genetic engineering in the development of transchromosomic cattle, or Tc Bovine, to produce hIgG. SAB BIO’s drug development production system is able to generate a diverse repertoire of specifically targeted, high-potency, hIgGs that can address a wide range of serious unmet needs in human diseases. For more information, visit www.sab.bio.

Forward-Looking Statements
Certain statements made in this current report 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,” “to be,” “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 statements about the Company’s expected cash runway, the development and clinical trial results of the Company’s T1D program and other discovery programs, and the timing of dosing, enrollment, and other milestones related to the Company’s programs. These statements are based on the current expectations of SAB BIO 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, each as may be amended or supplemented from time to time, 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 BIO 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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