SAB BIO Reports Q3 2026 Financial Results and Provides Business Highlights

November 5, 2026

Adult and adolescent cohorts fully enrolled in registrational SAFEGUARD study of SAB-142; Pediatric cohort (ages 5–11) actively enrolling with overall enrollment on track for completion in Q4 2026

Received FDA Fast Track designation for SAB-142 in new-onset Stage 3 T1D

Operational runway through 2028 to support registrational clinical development and pre-commercial activities of SAB-142 for Stage 3 T1D

Conference call today at 8:30 AM ET

MIAMI, Nov. 05, 2026 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), a clinical-stage biopharmaceutical company developing a fully human anti-thymocyte immunoglobulin (hATG) for type 1 diabetes (T1D) and other autoimmune diseases, today announced financial results for the third quarter ended September 30, 2026, and provided business highlights.

“We made solid progress advancing SAB-142 during the third quarter, driven by continued enthusiasm for the SAFEGUARD study. With the pediatric stepdown approved in September and our adult and adolescent cohorts fully enrolled and closed for screening, we remain on track to complete enrollment in the fourth quarter,” said **Samuel J. Reich, Chief Executive Officer of SAB BIO**. “The FDA's recent Fast Track designation is another important milestone, recognizing the significant unmet need in newly diagnosed Stage 3 type 1 diabetes and providing an opportunity for closer collaboration with the agency as we advance SAB-142 through clinical development. Our priorities are clear: complete SAFEGUARD enrollment, execute our clinical and regulatory strategy, and advance toward topline data in the second half of 2027. We believe SAB-142 has the potential to meaningfully change the treatment of type 1 diabetes, and we are focused on delivering on that promise.”

Recent Pipeline Achievements and Anticipated Milestones for SAB-142

Registrational Phase 2b SAFEGUARD study (NCT07187531)

- Adult and adolescent cohorts in SAFEGUARD are fully enrolled and closed for screening, with pediatric patients ages 5–11 actively enrolling.
    - In September 2026, the SAFEGUARD Study Data Monitoring Committee (DMC) approved the final stepdown, expanding enrollment to pediatric patients.
    - Enrollment continued to accelerate in Q3, and the pediatric stepdown is expected to further support enrollment.
- Over 60 clinical sites are actively enrolling across U.S., Australia, New Zealand, U.K. and European Union.
- The SAFEGUARD study will enroll approximately 159 Stage 3 T1D patients (ages 5-40) within 100 days of diagnosis.
    - Part A, a dose-ranging study in 12 adult T1D patients, completed enrollment in Q1 2026.
    - Part B is a randomized, double-blind, placebo-controlled, dose-ranging study enrolling approximately 147 pediatric, adolescent and adult T1D patients.
- SAFEGUARD is on track for full enrollment in Q4 2026 with topline data expected in 2H 2027.

Phase 3 PRISE-hATG study (NCT07670650)

- The PRISE-hATG study expects to dose the first patient in Q4 this year.
    - Seven clinical sites are planned across the United States, Europe and UK.

- This investigator-led study is funded through a grant from Breakthrough T1D and co-funded by SAB BIO.
    - The principal investigator of the study is Dr. Michael J. Haller, Professor and Chief of Pediatric Endocrinology at the University of Florida.
    - European co-principal investigators on the study are Prof. Dr. Chantal Mathieu at Katholieke Universiteit Leuven and UZ Leuven in Leuven, Belgium; Professor Tim Tree in the Department of Immunobiology at King’s College London, UK; and Dr. Loredana Marcovecchio at the University of Cambridge in Cambridge, UK.
- The PRISE-hATG study is a registrational clinical trial that could expand the potential future label of SAB-142 to patients with Stage 3 T1D with onset up to 2 years from diagnosis.

Business Highlights

- **FDA Fast Track designation for SAB-142**: In October 2026, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to SAB-142 for treatment of new-onset Stage 3 T1D. Fast Track designation is intended to facilitate the development and expedite the review of therapies for serious conditions where there is an unmet medical need and to help bring important new treatments to patients earlier.

Upcoming Events
SAB BIO plans to participate in the following investor events:

- **UBS Global Biopharma Conference**
  - Date: November 16-17, 2026
  - Location: London, United Kingdom
- **Jefferies Global Healthcare Conference**
  - Date: November 16-19, 2026
  - Location: London, United Kingdom
- **9th Annual Evercore Healthcare Conference**
  - Date: November 30-December 2, 2026
  - Location: Coral Gables, FL
- **Citi Global Healthcare Conference**
  - Date: December 1-3, 2026
  - Location: Miami, FL

Q3 2026 Financial Highlights

- **Cash Position**: Cash, cash equivalents, and investment securities of $205.3 million at September 30, 2026, providing operational runway through 2028. This total includes $13.4 million in gross proceeds received in the third quarter from exercises of previously issued Enrollment Date and Data Release Date warrants from the July 2025 private placement financing.
- **R&D Expenses**: Research and development (R&D) expenses of $18.1 million and $9.0 million for the three months ended September 30, 2026, and September 30, 2025, respectively. The increase is primarily driven by ongoing clinical trial costs and related headcount to support the advancement of SAB-142 through the registrational SAFEGUARD study. R&D expenses include non-cash stock-based compensation expense of $3.9 million and $0.5 million for the three months ended September 30, 2026 and 2025, respectively.
- **G&A Expenses**: General and administrative (G&A) expenses of $7.8 million and $3.7 million for the three months ended September 30, 2026, and September 30, 2025, respectively. The increase is primarily driven by personnel related costs, including non-cash stock-based compensation. G&A expenses include non-cash stock-based compensation expense of $3.6 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively.
- **Other income (expense)**: Other income of $3.6 million and $58.1 million for the three months ended September 30, 2026, and September 30, 2025, respectively. The decrease primarily reflects the change in fair value of warrant liabilities recognized in 2025.
- **Net income (loss)**: Net loss of $22.3 million and net income of $45.4 million for the three months ended September 30, 2026, and September 30, 2025, respectively.

Webcast and Conference Call Information
SAB BIO will host a conference call to discuss its third quarter financial results and provide business updates on Thursday, November 5, 2026 at 8:30 AM ET. A live webcast of the conference call can be accessed in the “Events” section of the Company’s website at ir.sab.bio. A replay will be available after the event.

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. By stopping immune cells from attacking beta cells, this treatment has the potential to preserve insulin-producing beta cells.

About the SAFEGUARD Trial
SAFety and **E**fficacy of human anti-thymocyte immuno**G**lob**U**lin SAB-142 **AR**resting progression of type 1 **D**iabetes (SAFEGUARD) trial is a randomized, double-blind, placebo-controlled multi-center Phase 2b study designed to assess the safety, efficacy, and tolerability of SAB-142 in patients with new onset Stage 3 T1D. The SAFEGUARD trial is actively enrolling and dosing participants at multiple sites around the world. SAB-142 is in development as a novel, potentially best-in-class, disease-modifying immunotherapeutic approach to treat T1D by delaying the progression of disease. SAFEGUARD Part A is a dose-ranging study in adult patients. SAFEGUARD Part B is a randomized double-blind, placebo-controlled, dose-ranging study.

Enrolled patients will receive two SAB-142 or placebo infusions six months apart. All patients, including the placebo-control group, with residual beta cells at 12 months are eligible for the 12-month long-term efficacy and safety extension study (Part C) upon Part A and B study completion. Additional details are available on www.clinicaltrials.gov (NCT07187531) and at https://safeguardstudy.com/.

About PRISE-hATG

Personalized **R**esponse and **I**mmunologic **S**urveillance of **E**ndogenous C-Peptide Preservation in New, Recent, and Extended New Onset T1D Treated with **h**uman **A**nti-**T**hymocyte **G**lobulin is a randomized, double-blind, placebo-controlled investigator-led study. This study is designed to assess the safety, efficacy, and tolerability of SAB-142 in individuals in an extended time period (up to 2 years) after diagnosis. Sampling procedures and analytical methods are harmonized with the Phase 2b SAFEGUARD trial, enabling cross-cohort comparisons. Additional details are available on www.clinicaltrials.gov (NCT07670650).

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. Using advanced genetic engineering and antibody science, SAB BIO developed a proprietary technology 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. 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. SAB-142 is being evaluated in two clinical trials: the registrational Phase 2b SAFEGUARD study for those newly diagnosed with Stage 3 T1D and the investigator-led Phase 3 PRISE-hATG study for people up to two years following a Stage 3 T1D diagnosis. For more information, visit www.sab.bio.

Forward-Looking Statements

Certain statements made in this press release 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 development and clinical trial results of the Company's T1D program and other discovery programs, the expected timing of completion of enrollment and topline data for the SAFEGUARD study, the expected timing of first patient dosing in the PRISE-hATG study, the potential benefits of Fast Track designation for SAB-142, and the Company's expected cash runway.

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. For example, Fast Track designation may not result in a faster development process, review or approval and does not increase the likelihood that SAB-142 will receive marketing approval. 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, 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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