

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 29, 2023

SAB BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39871
(Commission File Number)

85-3899721
(IRS Employer
Identification No.)

2100 East 54th Street North
Sioux Falls, South Dakota
(Address of Principal Executive Offices)

57104
(Zip Code)

Registrant's Telephone Number, Including Area Code: 605 679-6980

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.0001 par value per share	SABS	The Nasdaq Stock Market LLC
Warrants, each exercisable for one share of Common Stock at an exercise price of \$11.50 per share	SABSW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On November 29, 2023, SAB Biotherapeutics, Inc., a Delaware corporation (the “Company” or “SAB”) issued a press release (the “Release”) announcing that the first participants of a HUMAN trial (Fully HUman anti-thymocyte biologic in first-in-MAN clinical study) have been dosed in Australia. The Phase 1 randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous SAB-142 in healthy volunteers and participants with Type 1 Diabetes (“T1D”). SAB-142 is a first-in-class fully-human anti-thymocyte immunoglobulin being developed as a disease-modifying treatment to delay the onset and progression of T1D. A copy of the Release is furnished hereto as Exhibit 99.1, and incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements

Certain statements made in this current report and the 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 the development and efficacy of our T1D program, and other discovery programs, the closing of each tranche of the Company’s private placement offering, the timely funding to the Company by each investor in the private placement offering, 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.

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, as amended, 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 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.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated November 29, 2023
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SAB Biotherapeutics, Inc.

Date: November 29, 2023

By: /s/ Eddie J. Sullivan

Eddie J. Sullivan
Chief Executive Officer

SAB Biotherapeutics Announces Commencement of the HUMAN Phase 1 Clinical Trial with SAB-142, a Potential Disease-Modifying Treatment for Type 1 Diabetes

First subject has been dosed in the first-in-man Phase 1 clinical study of SAB-142, the first fully-human anti-thymocyte immunoglobulin (ATG)

SAB-142 directly and specifically targets multiple immune cells involved in the destruction of insulin-producing pancreatic beta cells to potentially preserve beta cell function

SAB Biotherapeutics is pursuing IND and CTA filings with U.S. FDA and EMA in 2024 to clinically advance development of SAB-142 into Phase 2b study

SIOUX FALLS, S.D., November 29, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that is developing fully-human anti-thymocyte immunoglobulin (hIgG) for disease-modification of Type 1 Diabetes (T1D) through delaying the onset and/or progression of the disease, today announced that the first participants of a **HUMAN** trial (Fully **HU**man anti-thymocyte biologic in first-in-**MAN** clinical study) have been dosed in Australia. This Phase 1 randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous SAB-142 in healthy volunteers and participants with T1D. SAB-142 is a first-in-class fully-human anti-thymocyte immunoglobulin being developed as a disease-modifying treatment to delay the onset and progression of T1D.

In October 2023, SAB received approval by the Australian Human Research Ethics Committee (HREC) to commence the Phase 1 clinical trial investigating safety, tolerability, pharmacokinetic, pharmacodynamic, and immunogenicity of SAB-142. The primary objective of the trial is two-fold: 1) to generate data on differentiated safety and immunogenicity of this fully-human immunoglobulin, and 2) to establish a Proof of Biological Activity (POBA) for SAB-142. Establishing POBA will focus on validating the immunological effects associated with an anti-thymoglobulin mechanism of action in modulating autoimmune response associated with progression of T1D. Those immunological effects have been previously elucidated in efficacy trials in T1D patients with rabbit-derived anti-thymocyte globulin (ATG). More information about the Phase 1 clinical trial with SAB-142 (ACTRN:12623001089628) can be found [here](#).

“This marks an important milestone in our development of SAB-142 as our lead asset enters the clinic,” said Alexandra Kropotova, MD, MBA, Executive Vice President and Chief Medical Officer of SAB. “We believe SAB-142 has the potential to be a best-in-class treatment for disease-modification through safe and precise immunomodulation in T1D, based on its validated mechanism of action and safety advantages over rabbit-derived ATG, which has shown significant promise in T1D disease modification. I would also

like to extend gratitude on behalf of the entire SAB team to the trial participants and to our Phase 1 partners Avance and Nucleus Network, without whom this trial wouldn't be possible."

The program is expected to rapidly expand globally, subject to regulatory approvals in the United States, United Kingdom and European Union countries. SAB is on track to file an Investigational New Drug (IND) application for SAB-142 with the U.S. Food and Drug Administration (FDA) in 2024, along with filings in UK and EU countries to enable efficient progress towards the Phase 2b development.

"For people living with T1D, the burden of disease is significant and there's increasing focus – and need – within the research community to focus on disease-modification, a departure from the focus on symptom management that has long been the norm," said Dr. Kristi McLendon, principal investigator at the Nucleus Network, who is leading the Phase 1 trial. "We are grateful to partner with SAB on this Phase 1 investigation that will explore the therapeutic potential of a new, potentially best-in-class immunotherapeutic option for patients."

About SAB-142

SAB-142 is a fully-human alternative to rabbit anti-thymocyte globulin (ATG). SAB-142's mechanism of action is similar to that of rabbit ATG, which has been clinically validated in multiple clinical trials for type 1 diabetes, demonstrating the ability to slow down disease progression in patients with new or recent onset of Stage 3 type 1 diabetes.

Two clinical trials have shown that a single, low dose of rabbit ATG has demonstrated the ability to modulate the body's immune response to help slow beta cell destruction and preserve the ability of these cells to generate insulin, which the body needs to regulate blood sugar and carry out all human activities.

SAB-142, like rabbit ATG, directly targets multiple immune cells involved in destroying pancreatic beta cells. By stopping immune cells from attacking beta cells, this treatment has potential to preserve insulin-producing beta cells. However, most humans treated with rabbit ATG develop serum sickness and anti-drug antibodies from exposure to the rabbit-derived antibody. SAB-142 is a human antibody, intended to allow safe, consistent re-dosing for type 1 diabetes, a lifelong chronic disease, without the potential risk of inducing the major adverse immune reactions that can occur with administration of a fully animal ATG.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics (SAB) is a clinical-stage biopharmaceutical company focused on developing fully human, multi-targeted, high-potency immunoglobulins (IgGs), without the need for human donors or convalescent plasma, to treat and prevent immune and autoimmune disorders. The company's lead asset, SAB-142, targets type 1 diabetes (T1D) with a disease-modifying therapeutic approach that aims to change the treatment paradigm by delaying onset and potentially preventing disease progression. Using advanced genetic engineering and antibody science to develop Transchromosomal (Tc) Bovine™, the only transgenic animal with a human artificial chromosome, SAB's DiversitAb™ drug development production system is able to generate a diverse repertoire of specifically targeted, high-potency, fully-human IgGs that can address a wide range of serious unmet needs in human diseases without the need for convalescent plasma or human donors. For more information on SAB, visit: <https://www.SAB.bio/>.

Forward-Looking Statements

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