# 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): January 10, 2023**

# SAB BIOTHERAPEUTICS, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-39871** | **85-3899721** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **2100 East 54th Street North Sioux Falls, South Dakota** | | **57104** |
| **(Address of Principal Executive Offices)** | | **(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 January 10, 2023, SAB Biotherapeutics, Inc. (the "Company" or "SAB") issued a press release announcing the successful completion of an IND-enabling GLP-Tox study for SAB-142, further progressing the therapeutic as a way to prevent and/or delay onset and progression of Type 1 Diabetes and potentially other T-cell mediated autoimmune diseases.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

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 (the “Exchange Act”), 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.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release of the Company, dated January 10, 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: January 10, 2023

By: */s/ Eddie J. Sullivan*
Eddie J. Sullivan
Chief Executive Officer

# SAB Biotherapeutics Successfully Concludes IND-Enabling GLP Toxicology Study for SAB-142, a Novel Immunotherapeutic for Type 1 Diabetes

*Study shows SAB's fully-human polyclonal therapeutic that has potential to delay the onset or progression of type 1 diabetes is well tolerated; next step is investigational new drug (IND) filing*

SIOUX FALLS, S.D., January 10, 2023 (GLOBE NEWSWIRE) – SAB Biotherapeutics (Nasdaq: SABS), ("SAB"), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, high-avidity, fully-human polyclonal antibodies (hpAB) without the need for human donors, today announced the successful completion of an IND-enabling GLP-tox study for SAB-142, further progressing the therapeutic as a way to prevent and/or delay onset and progression of type 1 diabetes (T1D) and potentially other T-cell mediated autoimmune diseases. The study assessed the toxicity and pharmacodynamic effects of SAB-142 against an FDA-approved T-cell depleting therapeutic at varying doses and found it to be well tolerated and showed a desired dose-dependent pharmacologic effect. SAB will submit the IND filing within approximately 12 months.

SAB-142 is the first fully-human anti-thymocyte hpAB therapeutic currently being developed for delaying the progression and onset of type 1 diabetes, among other autoimmune indications. Commercially available products for T-cell mediated autoimmune diseases, such as fully-animal antibodies and other monoclonal lymphodepletion therapeutics, require re-dosing and often induce immune-mediated reactions such as serum sickness. As a fully-human polyclonal antibody therapeutic, SAB-142 may be administered multiple times without causing these immune-related adverse reactions, a desired factor when treating life-long diseases such as type 1 diabetes.

"The completion of this GLP-tox study is an early, but significant milestone in the development of SAB-142 that enables a successful IND submission," said Alexandra Kropotova, MD, Chief Medical Officer of SAB. "We are eager to continue progressing this therapeutic, which we believe has the potential to impact the lives of millions of patients with varying autoimmune diseases, including those with type 1 diabetes."

In the study, SAB-142 was dosed at 1, 5, and 10 mg/kg and commercially available anti-thymocyte globulin was dosed at 5 mg/kg. The study results showed that both SAB-142 and its active control, FDA-approved animal-derived polyclonal anti-thymocyte immunoglobulin, induced transient lymphodepletion confirming the SAB-142 mechanism of action. The dynamics of the depletion appeared to be more prolonged in the cohort with SAB-142 treatment, which could create the opportunity for an optimized dosing regimen.

**About SAB Biotherapeutics**

SAB Biotherapeutics, Inc. (SAB) is 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. It 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.

**CONTACTS**
**Investor Relations:**
SABIR@westwicke.com
**Media Relations:**
SABPR@westwicke.com