

**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): March 30, 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 2.02. Results of Operations and Financial Condition.

On March 31, 2023, SAB Biotherapeutics, Inc., a Delaware corporation (the “Company”) issued a press release announcing its financial results for the year ended 2022. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information furnished pursuant to this “Item 2.02 - Results of Operations and Financial Condition”, including Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”) or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by us under the Exchange Act or Securities Act of 1933, as amended, regardless of any general incorporation language in any such filing, except as shall be expressly set forth by specific reference in such filing.

Item 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

On March 30, 2023, the audit committee (the “Audit Committee”) of the board of directors of the Company, and the Company’s management concluded that the Company’s previously issued audited financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 (the “Prior Year Financial Statements”), and the Company’s previously issued interim financial statements included in the Company’s Quarterly Reports on Forms 10-Q for the three months ended March 31, 2022, the six months ended June 30, 2022, and nine months ended September 30, 2022 (the “Prior Period Interim Financial Statements”), should no longer be relied upon as a result of the following accounting errors:

- The Company concluded that it did not correctly account for a financed insurance premium whereby a third-party lender prepaid the Company’s annual insurance premiums to our insurance companies in exchange for a short-term interest bearing note (the “Insurance Financing Agreement”). The Company previously recognized, on its consolidated balance sheet, a current prepaid asset for the amount paid by the Company under the Insurance Financing Agreement in excess of the total amortized value of the prepaid insurance policy. The Company reassessed its accounting for the Insurance Financing Agreement and determined that the Insurance Financing Agreement should be classified as a current note payable with the full amount of the insurance premium recognized as current prepaid asset at the time the Company entered into the Insurance Financing Agreement.
- The Company concluded that the Insurance Financing Agreement and corresponding payment to the third-party lender constitutes a constructive receipt and disbursement of cash. As a result, the Company determined the cash flows from financing activities contained within the Prior Year Financial Statements is understated—this error is accompanied by a corresponding overstatement in cash flows from operating activities due to an understated prepaid asset.
- Similar to the above assessment, the Company concluded that the cash payments to the third-party lender should be presented within cash flows from financing activities. As a result, the Company determined the cash flows from financing activities contained within the Prior Period Interim Financial Statements are overstated—this error is accompanied by a corresponding understatement in cash flows from operating activities due to the derecognition of the previously unrecognized prepaid asset.

Accordingly, investors should no longer rely upon the Prior Year Financial Statements or the Prior Period Interim Financial Statements.

The Company is restating its financial results for the fiscal year ended December 31, 2021 in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and intends to file an amendment to the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 to restate the Prior Year Financial Statements.

The Audit Committee and management of the Company have discussed the matters disclosed in this Item 4.02(a) with Mayer Hoffman McCann P.C., the Company’s independent registered public accounting firm.

Cautionary Note Regarding 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, the timing of completion of the restatements and revisions and any anticipated conclusions of the Company, the Audit Committee or the Company’s management. Other factors that could cause our actual results, performance or achievements to differ materially from our expectations include: the ongoing review of our financial statements, accounting, accounting policies and internal control over financial reporting; the preparation of, and the audit or review, as applicable, of restated filings; and the subsequent discovery of additional adjustments to our previously issued financial statements.

These statements are based on the current expectations of the Company 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 the Company’s control. Actual events and circumstances are difficult or impossible to predict, and these risks and uncertainties may cause the Company’s or its industry’s 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 the Company’s most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q, and other filings with or submissions to, the SEC, which are available at <https://www.sec.gov/>. Except as otherwise required by law, the Company 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 of the Company, dated March 31, 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: March 31, 2023

By: /s/ Eddie J. Sullivan

Eddie J. Sullivan

Chief Executive Officer

SAB Biotherapeutics Provides Company Update for Full Year 2022

SIOUX FALLS, S.D., March 31, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SAB), (SAB), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, fully-human immunoglobulin (hIgG) antibodies, also known as fully-human polyclonal antibodies, without the need for human donors, today reported financial results for the full year ended December 31, 2022, and provided a company update.

“I am pleased to share the meaningful progress SAB has made this past year advancing our groundbreaking, proprietary immunotherapy platform, a powerful approach and the only one in the world that generates targeted and fully-human immunoglobulin antibodies without the need for human donors. We continue to use this platform to create first-of-its-kind approaches and set new standards in developing differentiated treatments for a myriad of complex diseases. SAB’s clinically validated platform has the potential to deliver new treatments for patients with unmet medical needs, including potential for a highly desired disease-modifying approach in difficult-to-treat chronic autoimmune disorders, where we’ve made tremendous progress in our type 1 diabetes program. Our *Clostridioides difficile* Infection, or *C. diff*, investigational product is the first and only to deliver a multi-targeted approach to the entire complex lifecycle of the *C. diff* pathogen. *C. diff* is a devastating disease recognized by the CDC as an urgent antibiotic resistance threat,” said Eddie J. Sullivan, Ph.D., Co-Founder, President, and Chief Executive Officer of SAB Biotherapeutics. “Our focus remains on enhancing patient outcomes while also generating long-term value for our shareholders.”

Pipeline Milestones and Updates

SAB continues to execute its strategy to build a proprietary immunology pipeline addressing complex immune disorders and respiratory and gastrointestinal diseases that disproportionately affect immunocompromised patients, including the elderly. Below are some key highlights and milestones from the year 2022:

- Advanced our SAB-142 type 1 diabetes program and completed numerous pre-clinical activities, including an IND-enabling GLP toxicology study, which was completed in early 2023.
- Expanded our pipeline with SAB-195, a new, differentiated research program to treat *C. diff*, a potentially terminal gastrointestinal infectious disease with few effective treatments.
- Announced new clinical data for SAB’s Influenza Phase 2a challenge trial, validating SAB-176’s proof of concept in reducing viral load and improving symptoms of influenza, while also reinforcing the ability to generate broadly neutralizing antibodies to H1N1 pandemic strain as well as all tested viral variants of influenza A and B.
- Presented new pre-clinical data for SAB-185 demonstrating the therapeutic candidate to be effective against the majority of SARS-CoV-2 variants, including Omicron.
- Announced results from a project collaborating with global biotechnology leader CSL (ASX: CSL), confirming that SAB’s DiversitAb™ polyclonal platform can generate functional and fully-human anti-idiotypic polyclonal antibodies to effectively target and neutralize autoantibodies associated with autoimmune diseases.
- Forged an exclusive manufacturing services agreement with Emergent BioSolutions Inc. to provide contract development and manufacturing services to produce SAB’s fully-human IgG antibody products.
- Welcomed Alexandra Kropotova, M.D., to be the company’s new Chief Medical Officer. Dr. Kropotova brings to SAB more than 20 years of experience in all phases of global clinical development, translational medicine and medical affairs. Prior to joining SAB, Dr. Kropotova was the Therapeutic Area Head of Global Specialty R&D at Teva Pharmaceuticals, where she led innovative drug development focused on delivering on a broad portfolio of immunology, respiratory, and immuno-oncology assets spanning from pre-IND to BLA/NDA filing of biologics and complex drug-device combination products and was instrumental in clinical development of Dupixent at Sanofi.
- Announced the appointment of Rear Admiral (RADM), retired, Scott Giberson, a former Assistant U.S. Surgeon General and two-star admiral with the U.S. Public Health Service and current President of AMI Health to SAB’s Board of Directors
- Negotiated settlement with the US Government in October 2022 and received first payment of \$8.6 million in November 2022, with a second and final payment of \$8.2 million in January 2023, to close out work for manufacturing of SAB-185, the company’s clinical stage therapeutic candidate for COVID-19.
- Raised \$7.9 million in a private placement of common stock to advance our pipeline of first-in-class therapeutic candidates and fund working capital.
- Presented an overview of the Company’s DiversitAb™ Platform and data showing benefits of fully-human IgG antibody products derived from cows vs. human-derived plasma and highlighted data on SAB-176 for seasonal and pandemic influenza and SAB-185 for COVID-19 at the 2022 Plasma Product Biotechnology Conference in Cyprus.
- Presented “Novel Biologic Therapeutics for Infectious Diseases,” focusing on SAB-176, a novel pan-influenza immunotherapeutic, SAB-195, an immunotherapeutic for *Clostridioides difficile* Infection, and SAB-185, a broadly neutralizing COVID-19 treatment, at the Pharma Partnering Conference in Boston.

Financial Guidance

- Financial Guidance: Based on its current operating plans, SAB reaffirms that it expects its existing business plan, cash and cash equivalents, and anticipated cash flows will be sufficient to fund its operating expenses and capital expenditure requirements through December 2023.
- Cash Position: Cash and cash equivalents were \$15.0 million as of December 31, 2022, compared to \$33.2 million on December 31, 2021.
- The company reduced its annualized anticipated net cash consumption from \$60 million to \$18 million.

Restatement of 2021 Financial Results

The Company will restate its previously issued consolidated financial statements for the fiscal year ended December 31, 2021. The Company determined that it is necessary to correct the presentation of a financed insurance premium resulting in offsetting increases to current assets, current liabilities, and the associated presentation on the Company's statement of cash flows. Investors should no longer rely upon the Company's consolidated financial statements contained in its Form 10-K for the year ended December 31, 2021, and the Company's previously issued interim financial statements included in the Forms 10-Q for the 2022 fiscal year. The Company will restate its prior period financial results in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Such restatement is an error related to accounting presentation; as such it will not result in any net increase or reduction in the Company's income, nor adjustment in historical or anticipated cash flows.

As previously disclosed by SAB in a Form 12b-25 filed with the Securities and Exchange Commission on March 31, 2023, SAB has delayed filing its Form 10-K because SAB and its independent auditors require additional time to complete procedures surrounding the restatement of prior period financials.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics, Inc. (SAB) We are 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 Transchromosomal (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, SAB-142 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.

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