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): April 13, 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 April 13, 2023, SAB Biotherapeutics, Inc., a Delaware corporation (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track Designation for SAB-176 an investigational therapeutic for Type A and Type B influenza illness in high-risk patients, including those who have anti-viral resistant strains.

Fast Track Designation is intended to facilitate development and expedite the review of drugs that treat serious conditions and fill an unmet medical need so a product can potentially be approved and reach patients more quickly. Fast Track Designation enables the company to have more frequent interactions with the FDA throughout the drug development process and allows for eligibility for priority review and accelerated approval if certain criteria are met, as well as a rolling review. The Fast Track Designation must continue to be met or FDA can withdraw the designation.

In addition to the Fast Track designation, the Company has also received FDA guidance and regulatory alignment on advancing SAB-176 into the next phase of development, including a Phase 2b trial study design. The study will evaluate the safety and efficacy of SAB-176 in high-risk patients with Type A or Type B influenza illness, including those who have anti-viral treatment resistant strains.

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.

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 development and efficacy of our influenza program, C. diff. program, type 1 diabetes program, and other discovery programs, the results, including timing, of the development of SAB-176, SAB-185, SAB-142 and SAB-195, including SAB-176 Fast Track designation and 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, 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.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company, dated April 13, 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: April 14, 2023

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

SAB Biotherapeutics Granted Fast Track Designation from FDA for SAB-176 Influenza Immunotherapy with High Cross-Reactivity to Multiple Strains of Influenza

FDA greenlights advancement of SAB-176 Phase 2b trial and manufacturing approach to address influenza strain change

SAB-176 is the first fully-human broadly neutralizing immunoglobulin antibody therapeutic intended to prevent or reduce severe outcomes of Type A and Type B influenza infection in patients at high risk for severe complications, including in patients who are immunocompromised

SIOUX FALLS, S.D., April 13, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SABS), (SAB), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, fully-human, multi-epitope binding immunoglobulin (hIgG) antibodies, without the need for human donors, announced today that the US Food and Drug Administration (FDA) has granted Fast Track designation for SAB-176, an investigational therapeutic for Type A and Type B influenza illness in high-risk patients, including those who have anti-viral resistant strains. The Fast Track designation is designed to facilitate accelerated development and expedited review of medicines that treat critical illnesses and address an unmet medical need, with the goal of having promising treatments reaching approval and patients as quickly as possible.

SAB also received FDA guidance and regulatory alignment on advancing SAB-176 into the next phase of development through initiation of a Phase 2b dose-range finding efficacy and safety trial in patient populations at high-risk for developing severe disease.

SAB-176 is a novel, highly potent immunotherapy that is grounded in fundamentals of the natural immune response to neutralize Type A and Type B influenza viruses, which mutate rapidly. SAB-176 is also being studied in emerging and mutating pandemic strains by targeting multiple epitopes of the virus rather than a single epitope. The treatment is produced using SAB's proprietary DiversitAb™ platform, which enables—for the first time—rapid, scalable production of highly potent, fully-human polyclonal IgG antibodies, without the need for human donors. The platform is capable of addressing the emergence and diversity of modern health challenges, including seasonal and pandemic influenza, COVID-19, Clostridioides difficile (C. diff), and autoimmune disorders, such as type 1 diabetes, and cancers.

"We are pleased to receive the FDA Fast Track designation for SAB-176. Influenza continues to be one of the biggest public health challenges the world faces on a continuing basis, with an excessively high number of hospitalizations and deaths each year," said Eddie Sullivan, PhD, co-founder, President & CEO of SAB Biotherapeutics. "We are excited about the potential role SAB-176 can play in tackling a highly mutagenic pathogen like influenza."

SAB-176 has undergone multiple clinical and pre-clinical studies, including a Phase 1 trial in healthy volunteers and a Phase 2a challenge study completed last year. The data indicate that SAB-176 offers broad antibody protection against multiple strains of this rapidly mutating virus. In the Phase 2a study, SAB-176 showed broad cross protection that included strains that were not specifically targeted in the manufacturing of the therapeutic.

In addition to the Fast Track designation, SAB Biotherapeutics has also received FDA guidance and regulatory alignment on advancing SAB-176 into the next phase of development, including a Phase 2b trial study design. The study will evaluate the safety and efficacy of SAB-176 in high-risk patients with Type A or Type B influenza illness, including those who have anti-viral treatment resistant strains. In addition, the FDA aligned with SAB's manufacturing approach, which includes a plasma pooling strategy allowing hyperimmunization to address multiple strains of influenza on an annual basis. This paves the way for SAB to address strain changes, similar to how seasonal influenza vaccines are developed.

"SAB-176 has the potential to be a game-changer in the fight against influenza," said Alexandra Kropotova, MD, Chief Medical Officer of SAB Biotherapeutics. "Its multi-pronged mechanism of action, long half-life, and low risk of emergence of resistant strains could make it a superior therapeutic to achieve and sustain efficacy against this ever-evolving virus. We see this Fast Track designation as a testament to the promise of our innovative DiversitAb platform, which is equipped to rapidly respond to mutating infectious diseases like influenza."

The CDC estimates that there are an average of 9 to 41 million cases of influenza each year in the US, with 140,000-710,000 hospitalizations and 12,000-52,000 deaths per year. While Tamiflu® is an effective therapy for treating influenza if used within two days of symptom onset, some patients still develop severe disease and resistant strains of influenza to anti-viral drugs has increased in recent years. SAB-176 offers the potential for an additional treatment for influenza, particularly in higher-risk patients.

The DiversitAb platform is a first-of-its-kind technology capable of producing large amounts of fully-human high-titer, high-avidity multi-epitope binding antibodies across multiple targets without a need for human donors. SAB is leveraging its proprietary platform to discover and develop product candidates with the potential to be first-in-class or best-in-class against complex targets to treat or prevent diseases with significant unmet medical needs. These include infectious respiratory and gastroenterological diseases, immune and autoimmune disorders, and oncology.

More information on SAB-176's influenza therapeutic candidate can be found on the pipeline page of SAB's website: sab.bio/sab-176

About SAB Biotherapeutics, Inc.

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

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