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 18, 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 18, 2023, SAB Biotherapeutics, Inc., a Delaware corporation (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has granted Breakthrough Therapy Designation ("BTD") 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.

BTD is designed to expedite the development and review of a medicine that is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over therapies currently available on a clinically significant endpoints.

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 Breakthrough Therapy designation, and the outcome of 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 18, 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 19, 2023

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

SAB Biotherapeutics Announces U.S. FDA Grants Breakthrough Therapy Designation to SAB-176 Influenza Immunotherapy

SAB-176 has now received both Breakthrough and Fast Track designations from FDA – signifying its potential to fundamentally improve influenza treatment and prophylaxis

Influenza therapeutic now eligible for intensive guidance from FDA for an efficient development program

SAB-176 is the first fully-human multi-epitope binding broadly neutralizing immunoglobulin antibody therapeutic being developed for treatment of high-risk patients and for post-exposure prophylaxis of Type A and Type B influenza

SIOUX FALLS, S.D., April 18, 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, or fully human polyclonal) antibodies, without the need for human donors, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to SAB-176, an investigational therapeutic, for post-exposure prophylaxis for Type A and Type B influenza illness in high-risk patients, including those who have anti-viral resistant strains. On April 13, SAB announced that the FDA had granted Fast Track designation to SAB-176, and that the company had 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.

The FDA's Breakthrough Therapy designation process is designed to expedite the development and review of a medicine that is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over therapies currently available on a clinically significant endpoint(s). Products that qualify for Breakthrough Therapy designation receive more benefits than Fast Track products.

"Influenza continues to pose considerable health concerns both in the U.S. and on a global scale. This Breakthrough Therapy designation signifies an important step forward in our fight against this disease," said Eddie Sullivan, PhD, co-founder, President & CEO of SAB Biotherapeutics. "Even though both designations can be requested early in development, the requirements for Breakthrough Therapy designation are higher than those for the Fast Track program. For Breakthrough Therapy designation, the improvement demonstrated must be substantial. We are proud that based on generated preclinical and clinical evidence, SAB-176 has received both Breakthrough and Fast Track designations, a combination rarely seen. These designations further assure us that SAB-176 has a clear regulatory and clinical development path to progress this important therapeutic."

SAB-176 is being developed for several influenza indications, including treatment of high-risk patient populations, as well as pre- and post-exposure prophylaxis. The FDA's Breakthrough Therapy designation confirms that the multi-epitope targeting modality of SAB-176 has a clear differentiation vs. monoclonal antibodies (mAb) that bind to a single epitope, and SAB's treatment can sustain its efficacy over viral mutations and prevent or reduce the risk of emerging treatment-resistant influenza strains. Virus evolution driven by vaccines or treatments is a serious challenge and the use of therapeutics can create "escape mutants" or versions of a virus that have changed to escape pressure on virus survival driven by an antiviral treatment, whether it is a small molecule or monoclonal antibody modality.

Clinical evidence for SAB-176 generated in the SAB-176-201 clinical trial showed a significantly shorter time to resolution of positive viral culture vs. the control group. SAB's DiversitAb™ platform data also showed that the multi-epitope binding modality of SAB's biologic treatments reduces risk for emergence of treatment-resistant viruses. Preclinical evidence of *in vivo* efficacy of SAB-176 in the treatment-resistant strains further supports the scientific foundation for this Breakthrough designation.

SAB-176 is a highly potent immunotherapy that is grounded in fundamentals of the natural immune response to neutralize Type A and Type B influenza viruses by generating endogenous multi-epitope binding antibodies. 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 (CDI or C. diff), autoimmune disorders, such as type 1 diabetes, and cancers.

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 across seasonal and pandemic strains of Influenza A and lineages of influenza B including strains that were not specifically targeted in the manufacturing of the therapeutic. At the same time, the FDA guidance and regulatory alignment received by the company paves the way for changing the strains that are specifically targeted by the product over time to potentially ensure that the product maintains efficacy as the virus mutates over time.

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 the 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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Investor Relations:
SABIR@westwicke.com

Media Relations:
SABPR@westwicke.com