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

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): October 13, 2026**

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**SAB BIOTHERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39871**  
(Commission File Number)

**85-3899721**  
(IRS Employer  
Identification No.)

**777 W 41st St  
Suite 401  
Miami Beach, Florida**  
(Address of Principal Executive Offices)

**33140**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 305 845-2813**

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

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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:**

| <b>Title of each class</b>                                  | <b>Trading<br/>Symbol(s)</b> | <b>Name of each exchange on which registered</b> |
|-------------------------------------------------------------|------------------------------|--------------------------------------------------|
| Common stock, \$0.0001 par value per share                  | SABS                         | The Nasdaq Stock Market LLC                      |
| Warrants, each exercisable for one share of Common<br>Stock | 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. ☐

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**Item 8.01 Other Events.**

On October 13, 2026, SAB Biotherapeutics, Inc., a Delaware corporation, issued a press release (the “Release”) announcing that the U.S. Food and Drug Administration has granted Fast Track designation to SAB-142, a potentially disease-modifying immunotherapy being developed for the treatment of individuals with new-onset Stage 3 type 1 diabetes (T1D). A copy of the Release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

| <b>Exhibit Number</b> | <b>Description</b>                                                                                      |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| 99.1                  | <a href="#">Press Release issued by SAB Biotherapeutics, Inc. dated October 13, 2026.</a>               |
| 104                   | Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document. |

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## 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: October 13, 2026

By: /s/ Samuel J. Reich

Samuel J. Reich  
Chief Executive Officer

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## SAB BIO Receives FDA Fast Track Designation for SAB-142 in Stage 3 Type 1 Diabetes

*Fast Track designation recognizes the potential of SAB-142 to address an unmet medical need for people with Stage 3 type 1 diabetes*

MIAMI, Oct. 13, 2026 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABBS), a clinical-stage biopharmaceutical company developing a fully human anti-thymocyte immunoglobulin (hATG) for type 1 diabetes (T1D) and other autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SAB-142, a potentially disease-modifying immunotherapy being developed for the treatment of individuals with new-onset Stage 3 T1D.

Fast Track designation is intended to facilitate the development and expedite the review of therapies for serious conditions where there is an unmet medical need and to help bring important new treatments to patients earlier.

"Receiving FDA Fast Track designation is an important regulatory milestone for SAB-142 and reflects the agency's determination that the program has the potential to address an unmet medical need for people diagnosed with type 1 diabetes," said **Samuel J. Reich, Chief Executive Officer of SAB BIO**. "We look forward to continuing to work closely with the FDA as we advance the SAB-142 clinical program. This designation represents meaningful progress toward our goal of bringing SAB-142 to people living with type 1 diabetes as quickly as possible and transforming the meaning of a T1D diagnosis."

SAB-142 is currently being evaluated in the registrational Phase 2b SAFEGUARD study in people within 100 days of a Stage 3 T1D diagnosis, with enrollment expected to be completed in Q4 2026 and topline data anticipated in 2H 2027. The program is further supported by the investigator-led Phase 3 PRISE-hATG study, which is designed to evaluate SAB-142 in people with Stage 3 type 1 diabetes from 100 days to two years following diagnosis.

### About SAB BIO

SAB BIO is a clinical-stage biopharmaceutical company focused on developing multi-specific, high-potency, human immunoglobulin G (hIgG) to treat and prevent immune and autoimmune disorders. Using advanced genetic engineering and antibody science, SAB BIO developed a proprietary technology which holds the potential to generate additional novel therapeutic candidates utilizing the human immune response, without the need for human donors or convalescent plasma. SAB BIO has optimized genetic engineering in the development of transchromosomal cattle, or Tc-Bovine, to produce hIgG. SAB BIO's drug development production system is able to generate a diverse repertoire of specifically targeted, high-potency, hIgGs that can address a wide range of serious unmet needs in human diseases. The Company's lead candidate, SAB-142, targets autoimmune T1D with a disease-modifying therapeutic approach that aims to change the T1D treatment paradigm by delaying onset and potentially preventing disease progression of Stage 3 T1D patients. SAB-142 is currently being evaluated in newly diagnosed Stage 3 autoimmune T1D patients in a registrational Phase 2b clinical trial called SAFEGUARD. For more information, visit [www.sab.bio](http://www.sab.bio).

### Forward-Looking Statements

Certain statements made in this press 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 statements about the FDA Fast Track designation and potential expedited development for SAB-142 to address an area of serious unmet need in Stage 3 T1D; the therapeutic potential of SAB-142 to be a treatment for T1D, the expectations regarding timing for enrollment and topline data, and the overall development of SAB BIO's T1D program.

These statements are based on the current expectations of SAB BIO 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, 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 BIO 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**

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