CLOSER LOOK

MEMORANDUM

SAB BIO 1Q26 – FDA confirms C-peptide as surrogate endpoint; $218 million in cash supports ongoing progress for SAB-142 in T1D – May 12, 2026

Executive Summary

- **Florida-based SAB BIO reported its 1Q26 results today** on a call led by CEO Mr. Samuel Reich – see the webcast and press release.
- **The company,** which was founded in 2014 and aims to develop disease-modifying immunotherapy for T1D, continues to advance SAB-142, its fully human anti-thymocyte immunoglobulin. For reference, SAB-142 aims to delay T1D progression by preventing the immune system from attacking insulin-producing pancreatic beta cells. Enrollment in the phase 2b SAFEGUARD trial (n=159) remains on track for completion by the end of 2026, with topline data expected in 2H27. The company will review its phase 1 data at ADA 2026 in June.
- **The FDA confirmed that C-peptide may be a surrogate endpoint for accelerated approval** in a written correspondence. This confirmation gives the company greater certainty as it executes the SAFEGUARD trial and plans its path to market.
- **SAB BIO ended 1Q26 with $218 million in cash and cash equivalents,** representing a 17-fold increase from 1Q25 and a 1.5-fold increase from 4Q25. The increase in cash and cash equivalents was supported by a $95 million public offering completed in March 2026. Management believes this will provide operational runway through 2028.

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1. Enrollment for phase 2 SAFEGUARD trial for SAB-142 in T1D on track to complete by end of 2026; topline results expected in 2H27

The company continues to advance SAB-142, its fully human anti-thymocyte immunoglobulin for T1D. Enrollment for the phase 2b SAFEGUARD trial (n=159) remains on track for completion by the end of 2026, with topline data expected in 2H27. The company will present additional data at ADA 2026 in June.

- **Part A (n=12) is a dose-ranging study for adults with new-onset stage 3 T1D.** The study will evaluate the efficacy, safety, and tolerability of SAB-142 in new-onset stage 3 T1D. Enrollment for Part A has been completed in 1Q26.
- **Part B (n=147) was initiated in 1Q26 and examines the efficacy and safety of high- and low-dose SAB-142** compared to placebo in pediatric, adolescent, and adult participants. The study Data Monitoring Committee has approved the first stepdown to include patients aged 12 and older.

Management emphasized the urgent need for T1D therapies beyond insulin. SAB-142 aims to fill this gap through targeted immune modulation redosing that delays autoimmune destruction of beta cells.

In April 2026, SAB BIO announced additional data from the phase 1 HUMAN trial (n=6), in which SAB-142 demonstrated C-peptide preservation, improvement in glycemic control, and T-cell exhaustion in adults with established T1D. Among the four treated participants, mean Time in Range improved from 73% at baseline to 85% at Day 120 without an increase in exogenous insulin use, which, although for a very small group, was impressive. Three participants were "super responders" with C-peptide levels at or above baseline at Day 120.

2. Greater regulatory confidence following FDA correspondence confirming C-peptide may serve as a surrogate endpoint for accelerated approval

The company received written correspondence from the FDA confirming that C-peptide may serve as a surrogate endpoint for accelerated approval. This confirmation gives the company greater certainty as it executes the SAFEGUARD trial and plans its path to market. The company developed a clinical trial design and a broader clinical-regulatory plan in alignment with FDA expectations. There is a drive toward using C-peptide that we have seen of late – CGM metrics will also be helpful to see alongside this measure.

3. Multi-year partnership with Emergent BioSolutions expands manufacturing capacity for SAB-142

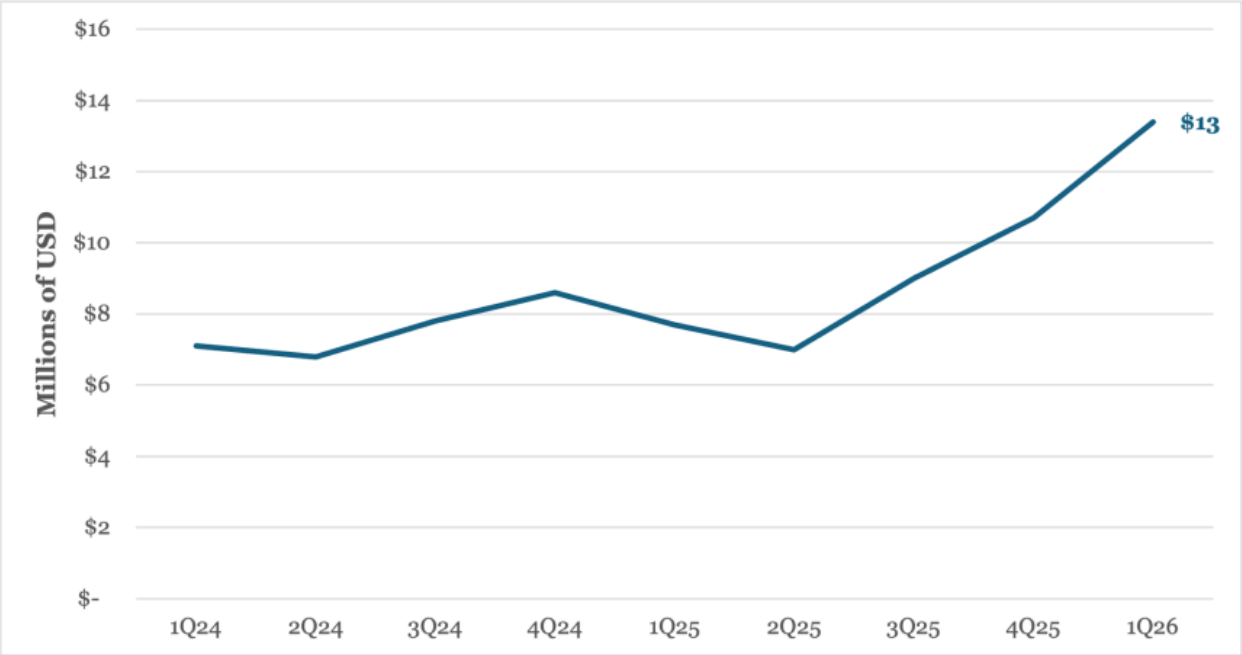
In April 2026, SAB BIO entered into a multi-year strategic manufacturing agreement with Emergent BioSolutions to support clinical and commercial production of SAB-142. Management emphasized that Emergent BioSolutions's facility in Winnipeg, Canada, brings expertise in plasma-derived and complex biologics. The agreement provides a durable manufacturing capacity for SAB-142's path toward commercialization and ensures the company can meet anticipated demand if the therapy is approved. The partnership is valued at $50 million, with $36 million of the deal dependent on regulatory approval and milestones of SAB-142.

4. Significant investments made in 1Q26, with strong cash position of $200-plus million in cash and cash equivalents; runway expected through 2028

SAB BIO ended 1Q26 with $218 million in cash and cash equivalents, representing a 17-fold increase from 1Q25 and a 1.5-fold increase from 4Q25. The increase in cash and cash equivalents was supported by a $95 million public offering completed in March 2026. Management believes this will provide operational runway through 2028.

In terms of investments in 1Q26, R&D spending totaled $13.4 million, up 74% from $7.7 million in 1Q25, reflecting continued investment in the registrational phase 2b SAFEGUARD trial (n=159) of SAB-142. See the graph below for SAB BIO's R&D spending since 1Q24. Net loss for the quarter was nearly $19 million, up substantially from just over $5 million in 1Q25 and reflecting significant investment throughout many parts of the company.

SAB BIO R&D Spending 1Q24-1Q26



Source: SAB BIO

Close Concerns' Questions

1. With written FDA confirmation that C-peptide may serve as a surrogate endpoint for accelerated approval, what additional data, analyses, or regulatory interactions will be required to support a potential approval for SAB-142?
2. How does the partnership with Emergent support SAB BIO's long-term supply needs, including potential six-month redosing?
3. How does SAB BIO plan to prioritize its $218 million in cash across clinical development, regulatory preparation, and manufacturing scale-up for SAB-142?

--by Kayla Mathieu, Kat Moon, and Kelly Close