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): May 08, 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 May 8, 2023 SAB Biotherapeutics, Inc., a Delaware corporation (the “Company”) made available an updated corporate strategy presentation (the "Presentation") on the Investor Relations section of the Company’s website. The Presentation will provide an overview of the Company's platform, the Fast Track Designation and Breakthrough Therapy Designation for SAB-176 anti-influenza. A copy of the Presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 8.01, 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	Corporate Presentation
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: May 12, 2023

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

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ADVANCING A POWERFUL NEW CLASS OF THERAPEUTIC IMMUNOGLOBULIN (hIgG)

May 2023

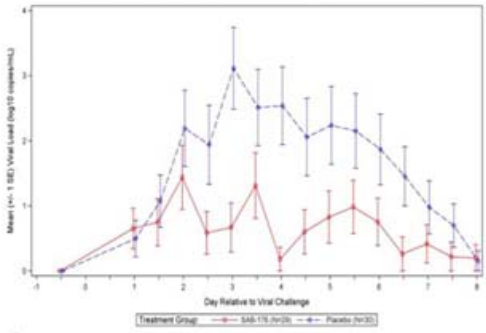
SAB-176 & SAB-185 Designations & Announcements – April 2023

- Granted **Breakthrough Therapy Designation (BTD) and Fast Track designation by the FDA** 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
  - **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).
  - **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.
- 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.
- **Positive Data in COVID Phase III: SAB-185** demonstrated significant benefit in sustained symptom resolution over 2 and 4 consecutive days (p= 0.021 and 0.01 respectively) in study participants with COVID-19 caused by Omicron as compared to participants who received a monoclonal antibody combination, REGEN-COV®

Established Proof-of-Concept for SAB-176: Met Primary Endpoint of Viral Load Reduction in Phase 2a Challenge Study

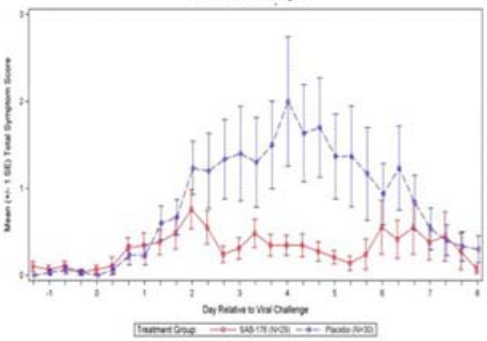
Achieved Statistically Significant (p = 0.026) Reduction in Viral Load

Mean Viral Load by Nasal Samples qRT-qPCR by Day Relative to Viral Challenge



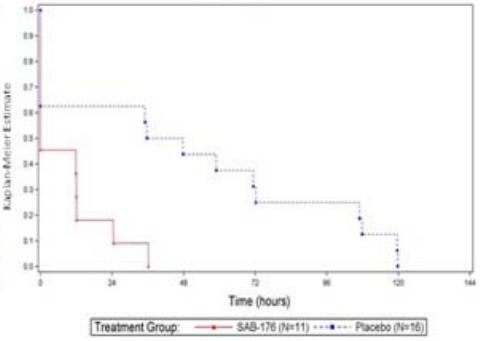
SAB-176 Achieved Statistically Significant (p = 0.013) Improvement in Symptoms at Day 4

Mean Total Symptom Score by Day Relative to Viral Challenge



SAB-176 Shortened Time of Viral Shedding as Measured by Lack of Culturable Virus

Time to Resolution of Positive Viral Cultures Following First Positive Culture Starting 2 Days After Intranasal Viral Challenge



SAB-176 not specifically targeted to pH1N1 strain used in challenge study

Statistically significant reduction in virus load confirms high cross reactivity to pandemic strain (not targeted with immunogen)

Reinforces ability to generate broadly neutralizing immunoglobulins to viral variants

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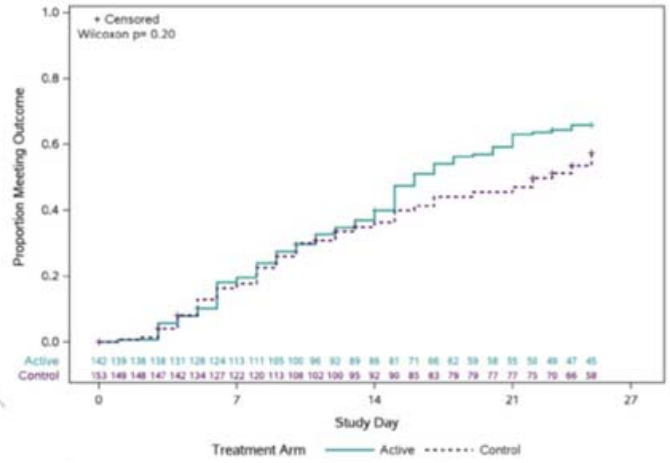
SAB-185 Phase III: Time (days) to All Targeted Symptoms Absent for 4 Consecutive Days

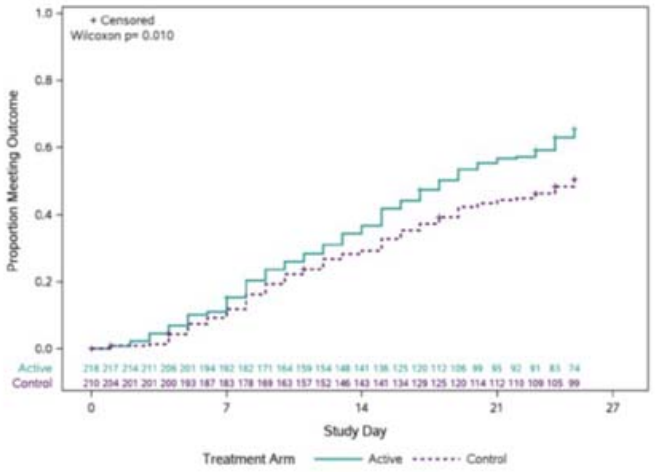
Non-OMICRON Population



Time (days) Estimate (95% CI) by Treatment Arm		
	Active	Control
Q1	9.0 (8.0, 11.0)	9.0 (8.0, 12.0)
Median	15.0 (15.0, 20.0)	23.0 (17.0, >25.0)
Q3	>25.0 (>25.0, >25.0)	>25.0 (>25.0, >25.0)

Percent Estimate (95% CI) by Treatment Arm			
	Active	Control	Difference
By Day 25	34.1% (28.2%, 40.1%)	42.6% (34.8%, 50.6%)	-8.5% (-16.9%, 0.0%)

OMICRON Population



Consecutive Days

Time (days) Estimate (95% CI) by Treatment Arm		
	Active	Control
Q1	10.0 (8.0, 12.0)	12.0 (9.0, 15.0)
Median	18.0 (16.0, 21.0)	25.0 (20.0, >25.0)
Q3	>25.0 (>25.0, >25.0)	>25.0 (>25.0, >25.0)

Percent Estimate (95% CI) by Treatment Arm			
	Active	Control	Difference
By Day 25	34.4% (28.1%, 40.8%)	49.5% (42.4%, 56.2%)	-15.1% (-24.5%, -5.6%)

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SAB-185: Key Symptom Data Recovery

Table 5: Symptom Outcomes through Day 28

	Non-Omicron Population			Omicron Population		
	SAB-185 (N=142)	C+I (N=153)	Superiority p-value[A] Difference (95% CI)[B]	SAB-185 (N=218)	C+I (N=210)	Superiority p-value[A] Difference (95% CI)[B]
Symptom Improvement for at least 2 days						
Median (quartiles), days	11 (5, 24)	13 (5, 23)	0.80	12 (5, 19)	13 (7, 25)	0.07
RMST, days	13.4	14.0	-0.6 (-3, 2) days	12.9	14.5	-1.6 (-3, 0) days
% not meeting endpoint	20%	19%	0.6 (-9, 10) %	15%	22%	-6.5 (-14, 1) %
Symptom Resolution for at least 2 days						
Median (quartiles), days	15 (8, >27)	19 (8, >27)	0.20	17 (9, >27)	23 (10, >27)	0.021
RMST, days	16.2	17.6	-1.4 (-4, 1) days	16.9	18.8	-1.9 (-4, 0) days
% not meeting endpoint	26%	38%	-11.7 (-23, -1) %	29%	42%	-13.3 (-22, -4) %
Symptom Resolution for at least 4 days						
Median (quartiles), days	16 (9, >25)	23 (9, >25)	0.20	18 (10, >25)	25 (12, >25)	0.010
RMST, days	16.3	17.6	-1.3 (-3, 1) days	17.2	18.8	-1.6 (-3, 0) days
% not meeting endpoint	34%	43%	-8.5 (-20, 3) %	34%	50%	-15.1 (-25, -6) %

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SAB-142:

Fully Human Anti-Thymocyte Globulin for the Prevention of Type 1 Diabetes (T1D)

SAB-142 has Strong Potential in Two Attractive T1D Markets

Stage 2 Prevention Market

Tzield (teplizumab-mzwv)

Projected to reach >$1B in WW sales[1] by 2028

In the US, only family relatives are screened for T1D (<10% of patients), but screening programs are expanding

SANOFI

$2.9B Sanofi acquisition of Provention Bio illustrates **value of prevention market**

Stage 3 Recent Onset Market

64k

64k patients are diagnosed with T1D in the US every year[2]

With insulin as the only treatment option, patients lose residual beta-cell function over time

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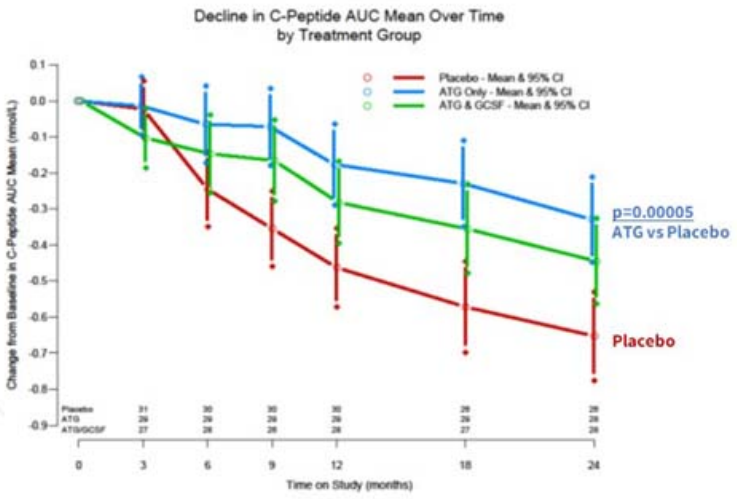
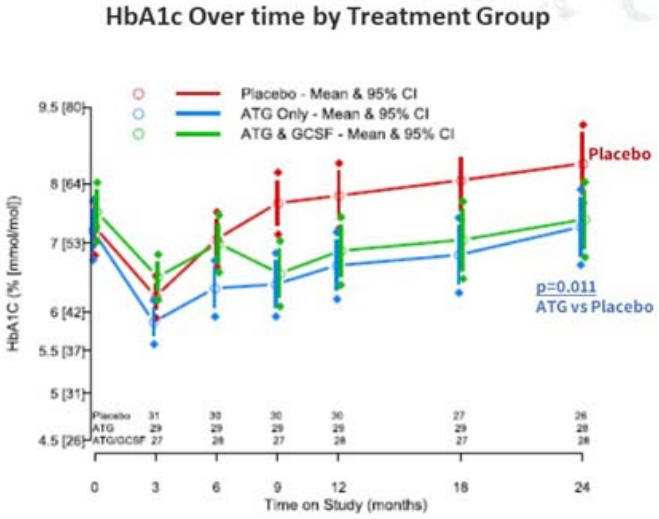
SAB-142 is positioned to **quickly advance to the clinic** to address unmet need in recent onset patients

1. Source: Analyst consensus forecast (Evaluate Pharma)
2. Source: BMC Med . 2017 Nov 8;15(1):199. doi: 10.1186/s12916-017-0958-6

SAB-142: MoA Clinically Validated by 3rd Party Compound

2 Years: Low-Dose ATG Preserved C-Peptide in New Onset T1D*





*RABBIT ATG FROM SANOFI – NOT SAB-142 (HUMAN TC-BOVINE DERIVED ATG)

Haller et al. Diabetes. 2019. June, 68(6):1267-1276

Anti-Thymocyte Globulin (ATG) Demonstrates Strong Efficacy In T1D

Anti-Thymocyte Globulin

Polyclonal Ab that restrains the immune system by targeting T-lymphocytes

Two marketed ATG products indicated for organ transplant and aplastic anemia

Thymoglobulin
Anti-thymocyte Globulin (Rabbit)

ATGAM
Horse anti-T-lymphocyte immunoglobulin

2015

Established T1D pilot study
After 12 months C-peptide was ~75% higher in ATG-treated patients vs. placebo

2024

Recent onset T1D DRF
Ongoing MELD-ATG study to optimize dose in recent onset patients

Academic Low-Dose ATG Trials (Rabbit ATG)

Recent onset T1D phase 2
After 24 months C-peptide was 2-fold higher in ATG-treated patients vs. placebo

2019

Phase 2 prevention study
Ongoing study to test efficacy of ATG in preventing T1D onset

2029

Clinicians and KOLs in the T1D community are deeply invested in advancing ATG as an immunotherapy for T1D

Note: Dates represent top-line results, or publication of study outcomes
Source: J Clin Invest . 2015 Jan;125(1):448-55. doi: 10.1172/JCI78492. Epub 2014 Dec 15.; Diabetes . 2019 Jun;68(6):1267-1276. doi: 10.2337/db19-0057. Epub 2019 Apr 9.; MELD-ATG trial (NCT04509791); STOP-T1D trial (NCT04291703)

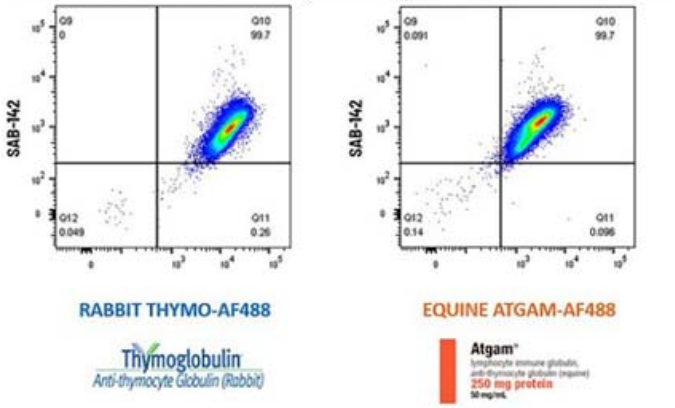
SAB-142 vs rATG and Teplizumab

Projected favorable risk/benefit profile compared to other treatments

	Teplizumab (Tzield)	rATG	SAB-142
Nature of the antibody	Humanized mAB	Rabbit pAbs	Human pAbs
MoA	Binds to CD3	Multifactorial: Binds across ~40 markers	Multifactorial: Shown to bind to similar cell lineages
Indications	Stage 2 (Q1 2023)	Not approved	Targeting Stage 2 & Stage 3
Efficacy	**63% effect o**n C-peptide AUC after year 2	**103% effect** on C-peptide AUC after year 2	• For 1st dosing course, anticipated to be comparable to rATG • Unlike rATG/teplizumab, **maintenance of C-peptide preservation can be achieved by safe re-dosing**
Immunogenicity: **- ADA** **- Neutralizing ADA**	• 57% of treated patients have ADA • 46% of whom having neutralizing ADAs	• 68% of treated patients	• ADA and nAbs are projected low/none • 0% of subjects dosed at or below 25mg/kg had ADA, across multiple clinical-stage compounds
T1/2	4.5 days	<14 days	21-28 days
Safety		Up to 78% of serum sickness	Lower/no probability of serum sickness
Dosing	IV daily for 14 days	IV over 2 days	IV over 1-2 days
Repeated dosing	Challenging due to high % of nAbs	Safety/efficacy impacted by nAbs	High probability of safe redosing due to fully human nature of pAbs

SAB-142 has an Identical MoA to rATG with Several Distinct Advantages

Tc Bovine Human-PB-ATG - SAB-142, Rabbit THYMO-AF488, and Equine ATGAM-AF488



RABBIT THYMO-AF488

Thymoglobulin
Anti-thymocyte Globulin (Rabbit)

EQUINE ATGAM-AF488

Atgam®
250 mg protein

	Thymoglobulin Anti-thymocyte Globulin (Rabbit)	SAb BIOTHERAPEUTICS
Safety	Majority of patients develop **grade 3 serum sickness**	**No serum sickness** expected due to fully human product
Efficacy	Lower half-life and **inability to re-dose** due to anti-drug antibodies	Improved PK and **opportunity to re-dose**

Forward-Looking Statements

The material in this presentation has been prepared by SAB Biotherapeutics, Inc. ("SAB") and is general background information about SAB's activities current as of the date of this presentation. This information is given in summary form and is not intended to be complete. Information in this presentation, including financial forecasts, should not be considered advice or a recommendation to investors or potential investors in relation to holding, purchasing, or selling securities or other financial products or instruments and does not take into account any particular investment objectives, financial situation or needs.

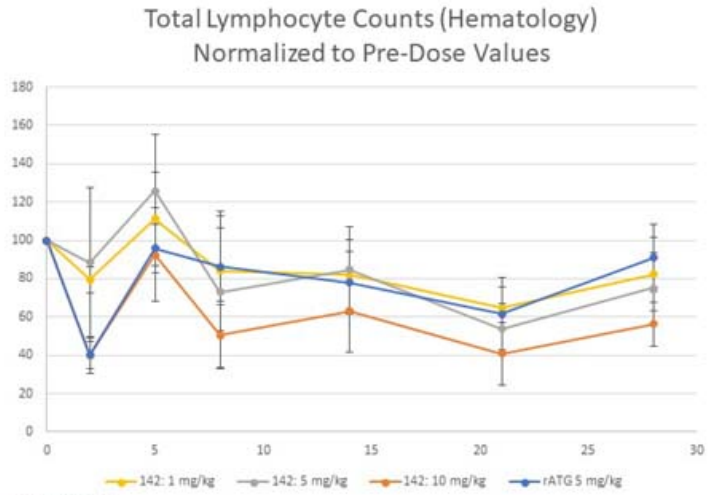
This presentation may contain forward-looking statements including statements regarding our intent, belief, or current expectations with respect to SAB's businesses and operations, market conditions, results of operations and financial condition, capital adequacy, specific provisions, and risk management practices. Readers are cautioned not to place undue reliance on these forward-looking statements. SAB does not undertake any obligation to update any information herein for any reason or to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof to reflect the occurrence of unanticipated events unless required by law. While due care has been used in the preparation of forecast information, actual results may vary in a materially positive or negative manner and the presentation may contain errors or omissions. Forecasts and hypothetical examples are subject to uncertainty and contingencies outside SAB's control. Past performance is not a reliable indication of future performance. The forward-looking statements contained or implied in this presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in SAB's most recent Annual Report on Form 10-K with the Securities and Exchange Commission (the "SEC") and in other filings that SAB makes with the SEC.

Unless otherwise specified, information is current at the date hereof.

SAB-142: GLP Tox Study Results Enable IND Submission

Results:

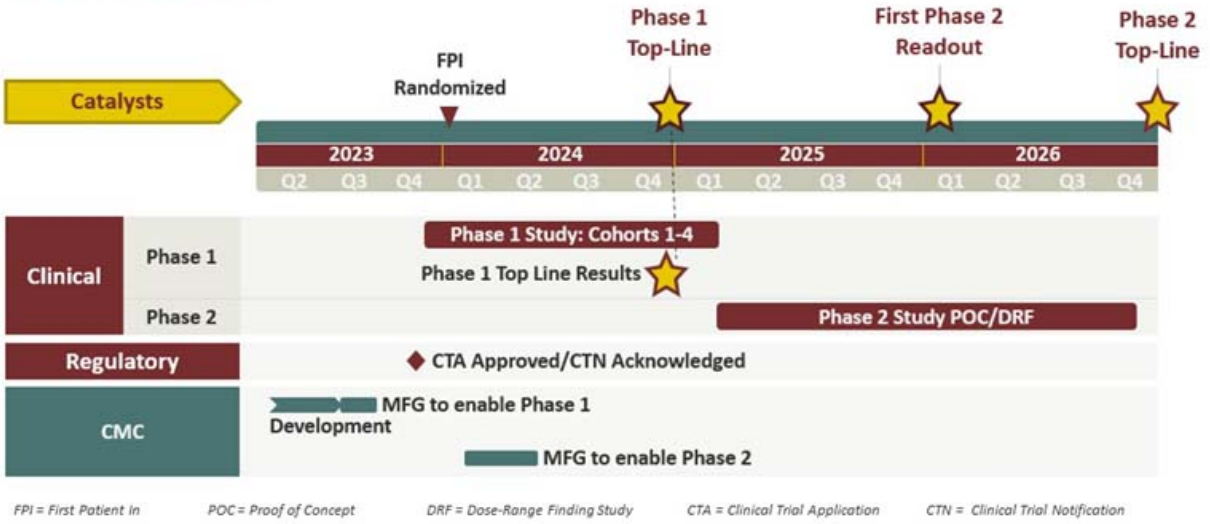
- GLP-tox study demonstrated SAB-142 is well tolerated at escalating doses tested
- Both SAB-142 and its active control, an FDA-approved rabbit-derived ATG, showed anticipated pharmacodynamic impact on the mature total lymphocytes as well as key lymphocyte subsets.
- The dynamics of such lymphocyte impact are dose-depended and appear to be more prolonged with SAB-142 treatment



SAB-142: Clinical Development Plan T1D

	Phase 1: Stable T1D in adults	**Phase 2:** New Onset T1D in Adults and Adolescents (Stage 3)
STUDY DESIGN	Phase 1: Single Ascending Dose, open label design, SS=18 patients with stable T1D	Phase 2: R, DB, PBO-controlled design in patients with New onset T1D (Stage 3) and C-peptide ≥ 0.2, SS= 48 patients • 0.1-2.5 mg/kg range (MELD-ATG driven dose range; final MRSD and dosing range recommendations will be based off allometric scaling and comparative potency) • Safety/Biomarker-driven escalation on acute safety Plus CD4+, CD8+ cells, Tregs
ENDPOINTS	**Phase 1:** • **Primary: acute (serum sickness, CRS) and long-term (rate of infections) safety** • **Major outcomes:** • **Anticipate 0% of serum sickness based on existing safety database of >700 patients (vs. up to 100% with rATG)** • **Validates MoA of SAB-142 vs rATG, clinically established and preferred tmt for Stage 3 T1D** • Secondary: pharmacokinetics, pharmacodynamics, immunogenicity/ADA • Proof of Biological Activity (POBA): change vs baseline in CD3, CD8, CD4, CD8/CD4 ratio, Tregs	Phase 2: • **Primary efficacy**: **AUC for C-peptide at 12 months** • Secondary efficacy end point: **HbA1C, expected to be better effects vs teplizumab** • Immunogenicity/ADA: **important for potential redosing**

SAB-142 Catalysts



FPI = First Patient In *POC = Proof of Concept* *DRF = Dose-Range Finding Study* *CTA = Clinical Trial Application* *CTN = Clinical Trial Notification*

Phase 1 / Phase 2 Major Outcomes:

- ✓ *0% serum sickness*
- ✓ *0% ADA/nADA*
- ✓ *Superior efficacy vs TZIELD on C-peptide*
- ✓ *Superior efficacy vs TZIELD on HbA1C*

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SELECTED PIPELINE PROGRAMS

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SAB-176: (Expanded)

First-In-Class Biologic Anti-Influenza Treatment

Unmet Need of Seasonal Influenza

CDC; 2018-19 FLU SEASON

Devastating health and economic impacts

- Estimated 30,000 - 50,000 deaths/year U.S. with 290,000 - 650,000 globally
- ~500,000 hospitalizations annually in U.S.
- Average US hospital stay: $8,000 - $9,000/day; 4-8 days/stay
- Often 30% - 70% failure rate for vaccine; vaccine ineffective in at-risk sub-populations

No current effective treatment for seasonal influenza

- Current antiviral has a 48-hour window
- Approved antiviral small molecule treatments may shorten duration of fever and symptoms, but not effective against clinically meaningful endpoints or neuraminidase mutation; limited efficacious window

Value Proposition: SAB-176

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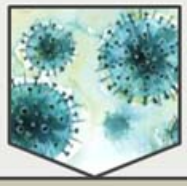
First-in-class fully-human immunoglobulin treatment aimed to provide superior long-lasting efficacy for prophylaxis and management of influenza in high-risk patients

Key Differentiators

First and only broadly neutralizing immunoglobulin for prophylaxis and treatment of influenza in high-risk patients



Adaptive and cross-reactive to multiple influenza strains

Multiprong Mechanism of Action

- Neutralizing activity targeting multiple epitopes of Influenza A and B virus
- Antibody-Dependent Cellular Cytotoxicity (ADCC)

Established Proof-of-Concept in the well-established validated influenza challenge model

Only SAB-176 Provides Potential for "EVERGREEN" Influenza Biologic with Low Risk of Escape Mutants

First-in-class fully-human immunoglobulin treatment aimed to provide superior long-lasting efficacy for prophylaxis and management of influenza in patients at high-risk

	Oseltamivir	Baloxavir marboxil	Broadly neutralizing human polyclonal SAB-176
Mechanism of Action (MoA):			
• Neuraminidase inhibitor	✓	☒	☒
• Polymerase acidic (PA) endonuclease inhibitor	☒	✓	☒
• Blocks virus from entering the host cell: neutralization of their infectivity	☒	☒	✓
• Opsonization, Complement activation, ADCC of the virus	☒	☒	✓
Single Dose	☒	✓	✓
• Extended protection against viral shedding, recrudescent infection, or new infection with another influenza strain	☒	☒	✓
Low risk of antiviral resistance/escape mutants while being treated	☒	☒	✓
Potential to treat patients infected with anti-viral resistant strains	☒	☒	✓

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Efficacy Against Mutational Drift: Oseltamivir Resistant (OR) H1N1pdm Virus Challenge Model

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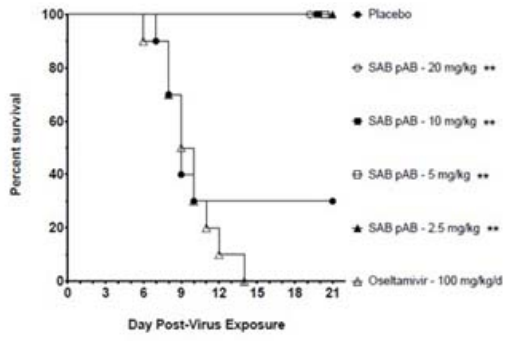
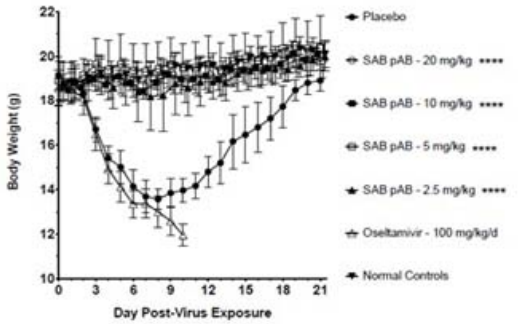
SAB-176 Showed 100% Protection at All Dose Levels From Mortality

0% survival in 100mg/kg/d Oseltamivir-treated groups



SAB-176 Protected Mice from Weight Loss While Oseltamivir Didn't



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SAB-185: (expanded)

SARS-CoV2 Infections

Investment Thesis

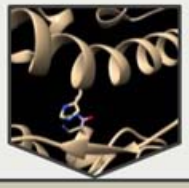
- SAB Biotherapeutics is a next generation antibody platform company with human data in > 700 patients, recent receipt of Breakthrough Therapy and Fast Track designations, focused on Type 1 diabetes.
- MoA of SAB-142 in T1D is a proven therapeutic approach with support and enthusiasm from clinicians, opinion leaders and Juvenile Diabetes Research Foundation (JDRF)
- Expecting to file IND/ CTA for SAB-142 within 12 months; de-risked development plan is designed with JDRF
- Phase 1 data expected by YE 2024 with goal of demonstrating safety advantage over rATG (zero serum sickness and ADA) due to fully human nature of antibody
- Phase 2 to begin 1Q25; Ph 2 is focused on demonstrating efficacy seen with existing rabbit ATG
- Competitive Target Product Profile: zero serum sickness/zero ADA plus equivalent or better efficacy vs. existing rabbit ATG. Zero ADA will enable re-dosing
- Value for new drugs for prevention of Type 1 diabetes is demonstrated by Sanofi's acquisition of Provention for $2.9B, another company sponsored by JDRF
- Other assets include: SAB-176 for influenza (Breakthrough Therapy & Fast Track Designations), SAB-185 for COVID-19, SAB-195 for C. Diff, and other preclinical assets to be developed with partnership funding.

SAB-185 Potential Value to Patients

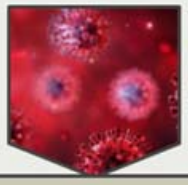
Only biologic with sustained efficacy across non-Omicron and Omicron variants in high-risk and low-risk patients
Only antibody treatment designed to reduce risk of losing efficacy to escape mutants for high-risk COVID-19 patients

Key Differentiators

First-in-class fully human broadly-neutralizing IgG1 antibody treatment for COVID-19



Only biologic treatment showing neutralizing activity against mAb escape mutants



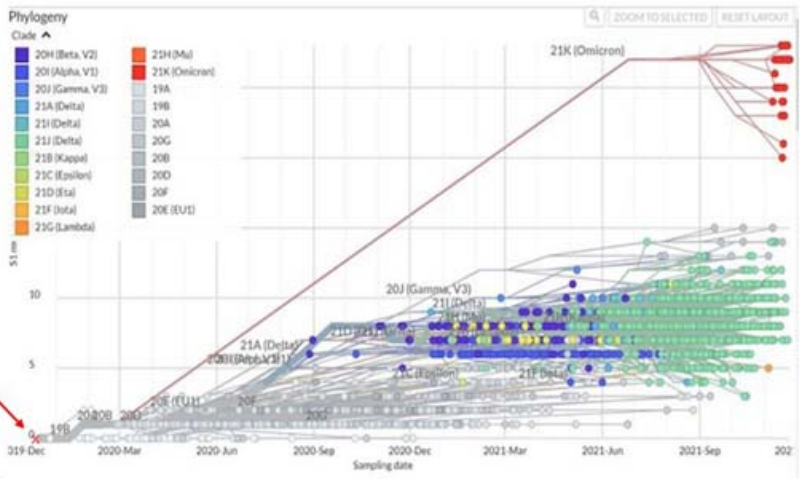
Clinical and preclinical *in-vivo* and *in-vitro* data demonstrate efficacy against all tested SARS-CoV-2 variants to date

Preclinical and clinical data support potential for competitive efficacy in high-risk COVID-19 patients

SARS-CoV2 Variants Associated with Ph2/3 ACTIV Trials

Omicron was a strain shift event and evolved during SAB-185 Ph3 enrollment

SAB-185 Immunization Strain Wu Han 2019



Haseltine W. Birth Of The Omicron Family: BA.1, BA.2, BA.3. Each As Different As Alpha Is From Delta. Online Forbes Article

	Ph2 Variants	Ph3 Variants
Omicron BA.1		√
Omicron BA.2		√
Omicron BA.3		
Alpha	√	
Beta		
Gamma		
Delta	√	√
Lambda		

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SAB-195:
Clostridioides difficile Infections

High Unmet Medical Needs Remain

High Morbidity, Mortality, and Costs

Clostridioides difficile Infection (CDI) is a bacterial infection of the large intestine (colon). A spectrum of clinical disease ranges from mild diarrhea to severe. CDI is characterized by abdominal pain, fever, diarrhea, nausea, and vomiting. Complications of severe CDI include kidney failure, toxic megacolon, bowel perforation, and death.

- CDI infection is one of the most prevalent health care–associated bacterial infections in the US and developed world
  - ~ 500,000 infections per year in the US[1]
  - ~ 30,000 deaths per year in the US[1]
- CDI infection is associated with significant costs: Up to $4.8 billion each year in excess health care costs for acute care facilities alone[1]
- Patients with the first CDI recurrence have a risk of subsequent recurrence from 25% to 40% and higher[1, 2]
- CDI-attributable median length of stay and costs (in US$) increased from 7 (4-13) days and $13,168 ($7,525-$24,456) for patients with primary CDI only to 15 (8-25) days and $28,218 ($15,050-$47,030) for patients with recurrent CDI[2]
- The risk of death for patients with recurrent CDI is 33% higher compared to those patients without recurrence

References:
1. CDC. Atlanta, GA: U.S. Department of Health and Human Services. Accessed 6/27/2022 Nearly half a million Americans suffered from Clostridium difficile infections in a single year | CDC Online Newsroom | CDC
2. Economic burden of primary compared with recurrent Clostridium difficile infection in hospitalized patients: a prospective cohort study.. J Hosp Infection. 2016 Jul;93(3):286-9

Value Proposition: SAB-195

First-in-class fully-human immunoglobulin treatment with dual mechanism of action designed to treat severe CDI and reduce CDI recurrence in high-risk patients

Key Differentiators

First-in-class fully human immunoglobulin treatment targeting C. diff spores, bacteria, and toxins

Only treatment with dual mode of action:

- Unlike bezlotoxumab, SAB-195 targets surface antigens on C. diff bacteria and spores
- Unlike antibiotics, SAB-195 targets several C. diff toxins responsible for severity of the disease

SAB-195 is a target-specific treatment targeting only C. diff bacteria/spores/toxins while fully preserving good microbiome

Preclinical data supports potential for competitive efficacy as first-line immunoglobulin therapy for severe CDI in patients who are at high risk for CDI recurrences

Only SAB-195 Can Target Multiple C. diff Antigens and Toxins in One Therapeutic

First-in-class fully-human immunoglobulin treatment with dual mechanism of action designed to treat severe CDI and reduce CDI recurrence in high-risk patients

	Antibiotics	Monoclonal Antibodies (bezlotoxumab)	Polyclonal Broadly Neutralizes C. diff Specific Antibody SAB-195
Mode of Action (MoA) Targets:			
• C. diff Spores	☒	☒	✓
• C. diff Bacteria	✓	☒	✓
• Toxin A	☒	☒	✓
• Toxin B	☒	✓	✓
• Binary toxin CDT	☒	☒	✓
Single Dose	☒	✓	✓
Indications:			
• To treat Clostridioides difficile-associated diarrhea (CDAD)	✓	☒	✓
• To reduce recurrence of Clostridium difficile infection (CDI) in patients at high risk for CDI recurrence	☒	✓	✓

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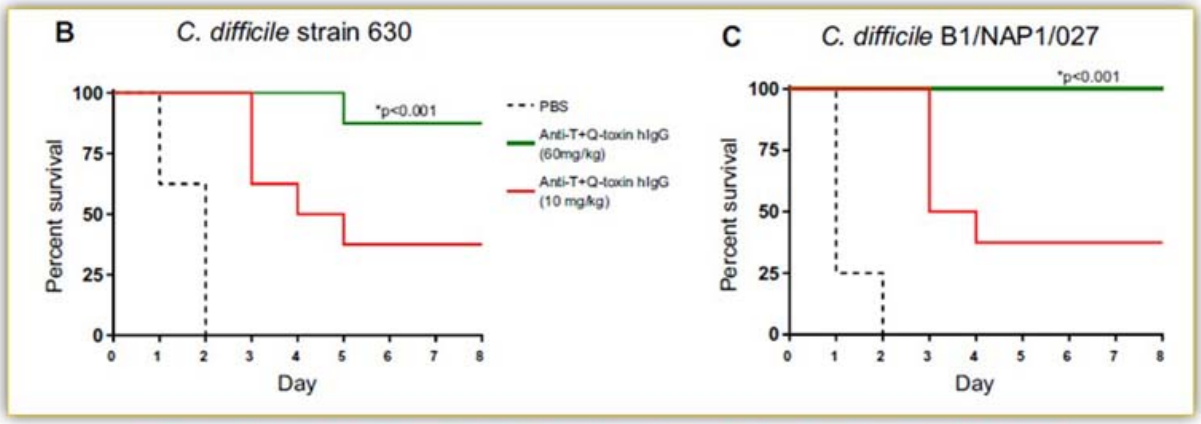
SAB-195 Preclinical Data

Tc bovine Immunized with Antigen Fusion Proteins Constructed from Receptor Binding Domain of C. diff Toxin A (TcdA), C. diff Toxin B (TcdB)(630) and (TcdB)(027) and Binary Toxin (CDT)



Tc bovine-derived anti-quadrivalent toxin hIgG provided 90% to 100% protection in hamsters against CDI strain 630 or more virulent epidemic strain NAP1

- Clostridium difficile chimeric toxin receptor binding domain vaccine induced protection against different strains in active and passive challenge models.. Jing-Hui Tian a, Gregory Glenn a, David Flyer a, Bin Zhou a, Ye Liu a, Eddie Sullivan b, Hua Wub, James F. Cummings a, Larry Ellingsworth a,¶, Gale Smith
- https://pubmed.ncbi.nlm.nih.gov/29669616/#:~:text=Vaccine,33(%3A4079%2D4087

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APPENDIX

Human Immunoglobulin G Produced in Transchromosomic Bovine

Tc Bovine™ contain all the human immunoglobulin genes

Human Artificial Chromosome (HAC) ~17Mb contains the entire unarranged VDJ human immunoglobulin loci (IgH + Igκ)

Tc Bovine™

- Only transgenic animal that carries the entire human immunoglobulin (Ig) heavy and light (κ) chain loci.
- HAC is subject to mitosis along with the other 60 Tc Bovine™ chromosomes.
- HAC present in the Tc Bovine™ allows for the highest production of human immunoglobulin repertoire most similar to humans.

SAB Biotherapeutics Fact Sheet

2	11	90	700	0	1
Years or less from concept to IND filing	Anti-infective assets with proven efficacy in Discovery or Development stages	Percent success rate from concept to IND and beyond	Subjects treated with SAB therapeutics in clinical trials across DIVERSITAB platform	Assets to date that lost efficacy to escape mutants	Only company to produce unlimited supply of fully-human broadly neutralizing hIgG without need for human donors

Experienced Management Team

Samuel J. Reich
EXECUTIVE CHAIRMAN, BOD
- 20 years Biopharma Executive and BOD
- Bioentrepreneur
- Co-founder Acuity Pharmaceuticals, OPKO Health, Biscayne Neurotherapeutics
- Molecular Biologist, Inventor, former PENN

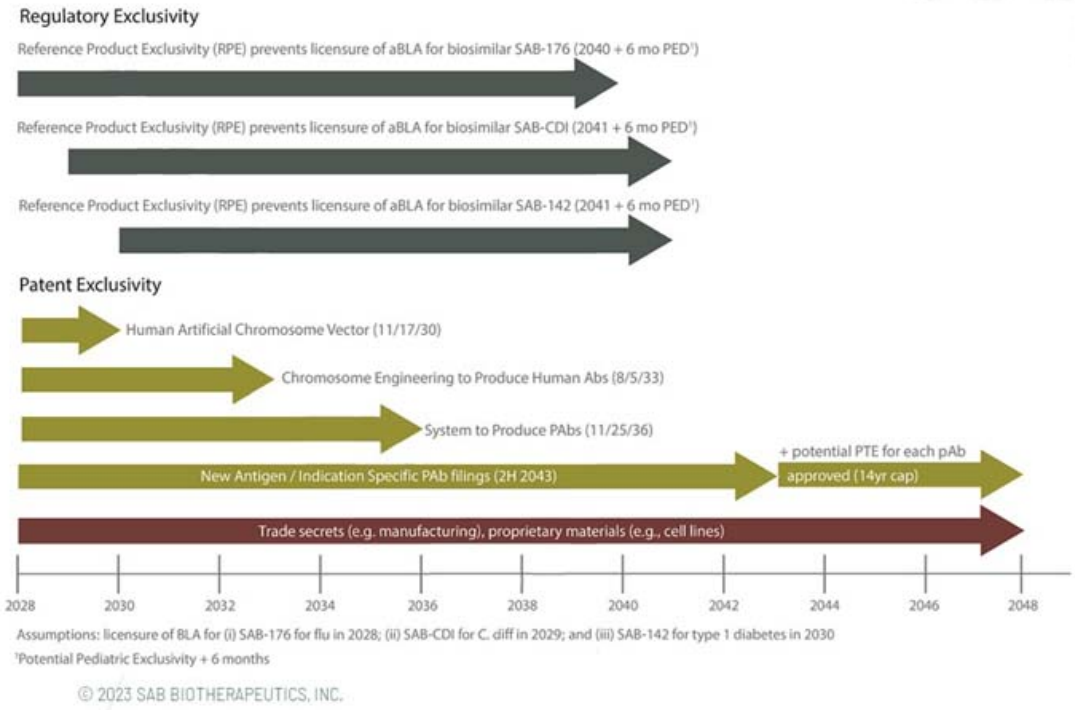
Eddie J. Sullivan, PhD
PRESIDENT & CEO / CO-FOUNDER
- 20 years new technology development
- 25+ years biotech
- Former Japanese pharma
- BIO Executive Committee
- Reproductive physiologist

Russell Beyer, MBA, CMA
EVP & CHIEF FINANCIAL OFFICER
- 25+ years Pharma & Fortune 100
- Country/region CFO at HP, AstraZeneca, Clorox, Amcor
- Track record of driving growth, integrations
- Strategic finance, operations, reporting, planning, IT, Procurement, HR

Christoph Bausch, PhD, MBA
EVP & CHIEF OPERATING OFFICER
- 20+ years research and discovery, biomanufacturing, business development, and platform technology commercialization
- MilliporeSigma (Merck KGaA)
- Stowers Institute for Medical Research Postdoc

Alexandra Kropotova, MD
EVP & CHIEF MEDICAL OFFICER
- 20+ years global clinical development
- Biopharmaceutical R&D leader, Pfizer, Wyeth, Sanofi, Teva Specialty R&D
- Board member, iBio
- Contributed to numerous patents & compounds leading portfolios from Phase I to BLA and NDA approvals

Intellectual Property



Assumptions: licensure of BLA for (i) SAB-176 for flu in 2028; (ii) SAB-CDI for C. diff in 2029; and (iii) SAB-142 for type 1 diabetes in 2030

[1]Potential Pediatric Exclusivity + 6 months

DiversitAb™ Platform is Clinically Validated Across Several Targets

3 INDs & 1 CTA	Filed in US and ex-US
7 Clinical Trials	Span from Phase 1 to Phase 3 across 3 indications
Public Collaborations	DoD, BARDA, NIH NIAID, Naval Medical Research Center, USAMRIID
Academic Collaborations	Brigham and Women's Hospital, Harvard, University of South Dakota, University of Pittsburgh

Referenced Trials:

- Safety, Tolerability, and Pharmacokinetics of SAB-176 in Healthy Participants – Full Text View - ClinicalTrials.gov
- Study of SAB-176 in Healthy Adult Participants - Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-185 in Healthy Participants – Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-185 in Ambulatory Participants With COVID-19 - Full Text View - ClinicalTrials.gov
- ACTIV-2: A Study for Outpatients With COVID-19 - Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-301 in Healthy Adults – Full Text View - ClinicalTrials.gov

Scaled Infrastructure & Capacity: Tc Bovine & Plasma Production Facility

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Competitive Landscape (Immunosuppressive Agents)

	SAB-142	Thymoglobulin Anti-thymocyte Globulin (Rabbit)	Tzield (teplizumab-mzwv)	Alefacept	ORENCIA (abatacept)
Development Stage (T1D)	*Preclinical*	*Phase 2*	*Approved*	*Phase 2*	*Phase 2*
Modality	*Human polyclonal*	*Rabbit polyclonal*	mAb	*mAb*	*mAb*
Impact on C-peptide[1]	*TBD*	+103%	+63%	+36%	+37%
Improvement in HbA1C	*TBD*	YES	STUDY DEPENDENT	NO	YES[3]
Safety Profile[2]	**Expected:** Similar to rATG without serum sickness	CRS (mild/moderate), serum sickness, & Lymphopenia	CRS (mild/moderate), EBV activation, & Lymphopenia	No difference with placebo	No difference with placebo
Administration	2-day IV infusion	2-day IV infusion	14-day IV infusion	Weekly IM for 12 weeks & at 24 weeks	Every 4 weeks
Limitations	Untested in humans	• Serum sickness and CRS • Unclear commercial path forward	• Burdensome 14-day infusion • Limited efficacy in recent onset patients	• Limited efficacy	• Frequent administration

1. 2-year impact on C peptide AUC in recent onset patients relative to placebo
2. Most common treatment associated AEs listed
3. HbA1C was lower at baseline in Abatacept group than placebo at 24 months (unclear if there was meaningful impact of Abatacept at 12-months)

Note: Green font indicates endpoint was met, red font indicates endpoint was not met

Source: rATG (Diabetes Care 2018;41:1917–1925; Diabetes 2019;68:1267–1), Tzield (Diabetes 2013;62:3766–3774), Alefacept (Lancet Diabetes Endocrinol 2013;1:284–294), Abatacept (Lancet 2011;378:412–419)

Low-Dose rATG Provides the Greatest Relative Preservation of AUC C-peptide

Low-dose ATG treatment is both less costly and more effective relative to other immunotherapies and no treatment for new-onset Type 1 diabetes

	Treatment dose and regimen	*Cost of drug*	*Infusion/ injection costs*	*Premedication costs*	*Costs of managing adverse events*	*Percentage effect on C-peptide AUC after year 1*[5,b]	*Percentage effect on C-peptide AUC after year 2*[5,b]
Low-dose ATG	Total 2.5 mg/kg for 2 days	$900 per 25 mg vial[7]	$1800 ($180/h[24] × 5 h/day × 2 days)	Methylprednisolone[39]: $10	Prednisone[40]: $7 (weight <50 kg), $10 (weight ≥50 kg)	55%	103%
High-dose ATG	Total 6.5 mg/kg for 4 days	$900 per 25 mg vial[7]	$3600 ($180/h[24] × 5 h/day × 4 days)	Methylprednisolone[39]: $60	Prednisone[40]: $7 (weight <50 kg), $10 (weight ≥50 kg)	9%	16%
Abatacept	27 infusions (30 min each) of 10 mg/kg for 2 years	$1170 per 250 mg vial[41]	Year 1: $1260 ($180/h[24] × 0.5 h/day × 14 days) Year 2: $1170 ($180/h[24] × 0.5 h/day × 13 days)	NA	NA	22%	37%
Alefacept	24 injections (15 mg each) for 36 weeks	$1340 per injection[42,a]	$2800 ($118 per visit[25] × 24 visits)	NA	NA	18%	36%
Rituximab	4 infusions on days 1, 8, 15 and 22 each of 375 mg/m[2]	$940 per 100 mg[43]	$1400 ($180/h[24] × 2 h/day × 4 days)	NA	NA	18%	15%
Teplizumab	14 infusions: day 1, 51 mcg/m[2]; day 2, 103 mcg/m[2]; day 3, 206 mcg/m[2]; day 4, 413 mcg/m[2]; days 5–14, 826 mcg/m[2]; repeat dose after 1 year for 77% of patients (23% discontinue treatment after first dose[18])	$100,000 per course[6]	$2500 ($180/h[24] × 1 h/day × 14 days)	NA	NA	48%	63%

2022 Apr;24(4):258-267. Epub 2021 Nov 18.

Cost-Effectiveness of Low-Dose Antithymocyte Globulin Versus Other Immunotherapies for Treatment of New-Onset Type 1 Diabetes

Hai V Nguyen [1], Desmond A Schatz [2], Shweta Mital [1], Laura M Jacobsen [2], Michael J Haller

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Platform Technology

Advancing a New Class of Immunotherapies with Initial Focus on T1D

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Robust, growing clinical-stage pipeline spanning multiple therapeutic areas

Vertical integration enables rapid, scalable development of multi-targeted products

Leveraged advanced genetic engineering & immune science to develop Tc bovine-derived fully-human immunoglobulin (hIgG)

Established proof-of-concept through funded programs & partnerships totaling ~$200MM

Strong corporate position with experienced leadership team and growing infrastructure

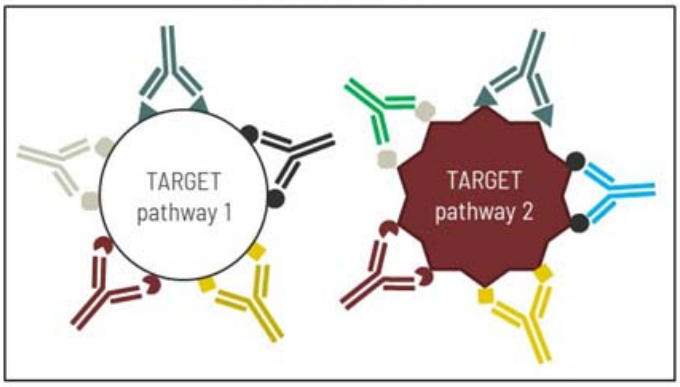
Innovative DiversitAb™ platform produces a new class of targeted fully-human, highly-potent immunoglobulins (hIgG)

SAB Human Immunoglobulin: Next Generation of Biologics

Key Product Differentiators vs Monoclonal Antibodies:

- Multi-target capability in a single therapeutic
  - ✓ Natural multi-epitope targeted hIgG selected and produced *in vivo*
  - ✓ Ability to target multiple disease pathways at once increase potential for superior efficacy
- Specifically driven high-potency titers and avidity
- Effective against escape mutants with reduced possibility for resistance
- Proven ability to target multiple human autoantibodies to treat autoimmune diseases
- More cost and time effective R&D development
- No current risk of biosimilar competition

FDA: CENTER FOR **BIOLOGICS** EVALUATION & RESEARCH (CBER)



Natural mixture of many **human** immunoglobulins that bind to multiple epitopes is regulated as a single product

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SAB Platform has Broad Potential Therapeutic Applications

The Company is currently focusing its resources on the Type 1 Diabetes SAB-142 program; SAB is actively engaging in partnership for further development of other pipeline programs

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PIPELINE

	PRODUCT	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
RESPIRATORY	SAB-185	COVID-19 TREATMENT	Phase 3 Trial (NIH ACTIV-2) Study Top line results available				
RESPIRATORY	SAB-176	INFLUENZA TREATMENT	Phase 1 Trial & Phase 2a Challenge Study Top line results available				
RESPIRATORY	SAB-176	INFLUENZA PROPHYLAXIS					
IMMUNOLOGY	SAB-142	TYPE 1 DIABETES - STAGE 3					
IMMUNOLOGY	SAB-142	ORGAN TRANSPLANT REJECTION OR APLASTIC ANEMIA					
GASTROINTESTINAL	SAB-195	CLOSTRIDIOIDES DIFFICILE					
IMMUNOLOGY	ANTI-IDIOTYPE SERIES	SYSTEMIC LUPUS ERYTHEMATOSUS, TYPE 1 DIABETES, RHEUMATOID ARTHRITIS					

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Positive Clinical Data in Flu and COVID

SAB-176: First-In-Class Biologic Anti-Influenza Treatment

SAB-185: SARS-CoV2 Infections