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): February 6, 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 February 6, 2023, SAB Biotherapeutics, Inc. (the "Company" or "SAB") presented an overview of its DiversitAb™ platform (the "Presentation) at the BIO CEO and Investor Conference.

The Presentation highlighted the latest innovations and treatment pathways in immunology, including an overview of the Company's novel DiversitAb™ platform, and data from completed clinical trials that indicate the Company's polyclonal antibody therapies can provide long-lasting efficacy against numerous highly mutating pathogens or multiple targets or pathways at once. A copy of the Presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference. Additionally, the Company made an audio recording of the Presentation available on the Company's investor relations website prior to the BIO CEO and Investor Conference at https://ir.sab.bio/.

The foregoing (including Exhibit 99.1) is being furnished pursuant to Item 7.01 of Form 8-K and will not be deemed to be filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise be subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended. The information contained in the Presentation is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements the Company may make by press release or otherwise from time to time.

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, including the development and efficacy of our influenza program, C. diff. program, Type 1 Diabetes program, and other discovery programs, the likelihood that a patent will issue from any patent application, the results, including timing, of the development of SAB-176, SAB-185 and SAB-195 (including any IND filing or proposed clinical trials), financial projections and future financial and operating results (including estimated cost savings and cash runway), the outcome of and potential future government and other third-party collaborations or funded programs (including negotiations with the DoD).

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 SEC, 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	Presentation dated February 6, 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: February 7, 2023

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

Exhibit 99.1

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Next Generation Biologics in Immunology

Solution for Complex Diseases

BIO CEO and Investor Conference| February 2023

Eddie J. Sullivan, PhD
President and CEO

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.

The SAB logo and other trademarks of SAB appearing in this presentation are the property of SAB. All other trademarks, services marks, and trade names in this presentation are the property of their respective owners.

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SAB Biotherapeutics Fact Sheet

2
Years or less from concept to IND filing

11
Anti-infective assets with proven efficacy in Discovery or Development stages

90
Percent success rate from concept to IND and beyond

700
Subjects treated with SAB therapeutics in clinical trials across DIVERSITAB platform

0
Assets to date that lost efficacy to escape mutants

1
Only company to produce unlimited supply of fully-human broadly neutralizing pAbs without need for human donors

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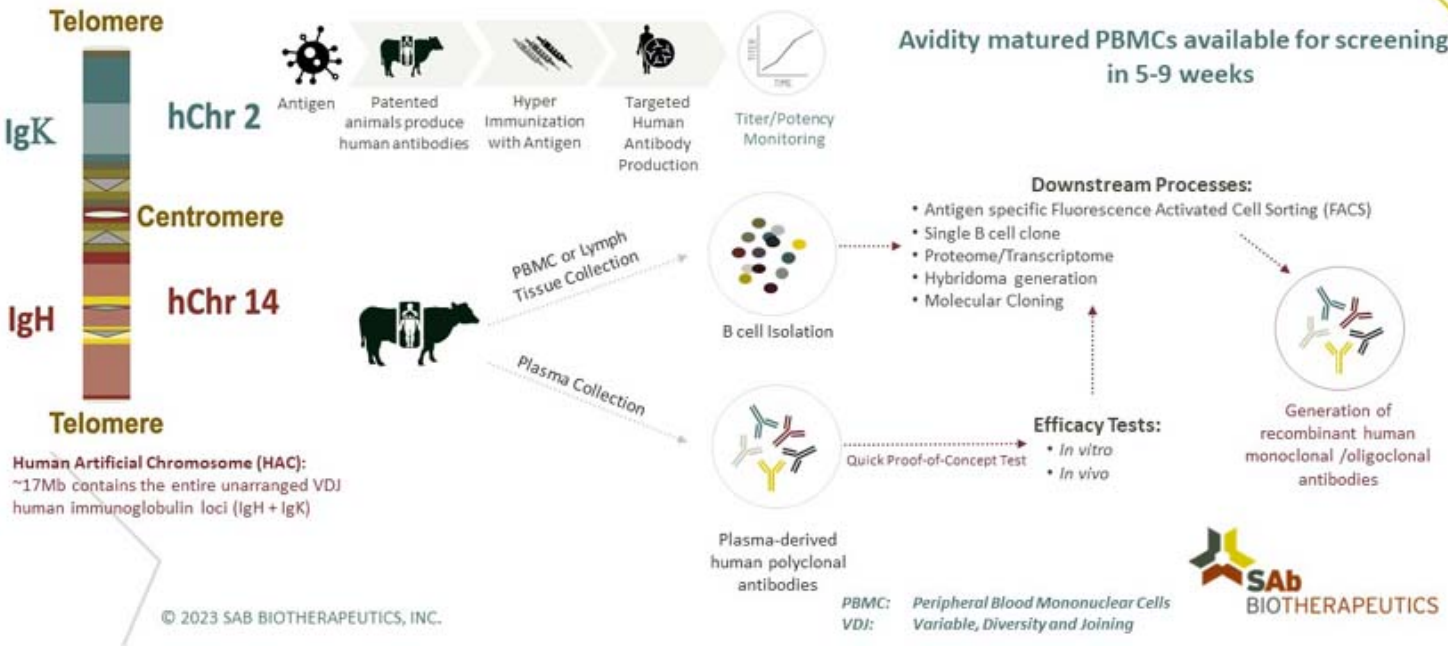
Demonstrated as a Novel Discovery Platform for Human Monoclonal and Polyclonal Antibodies



PBMC: *Peripheral Blood Mononuclear Cells*
VDJ: *Variable, Diversity and Joining*

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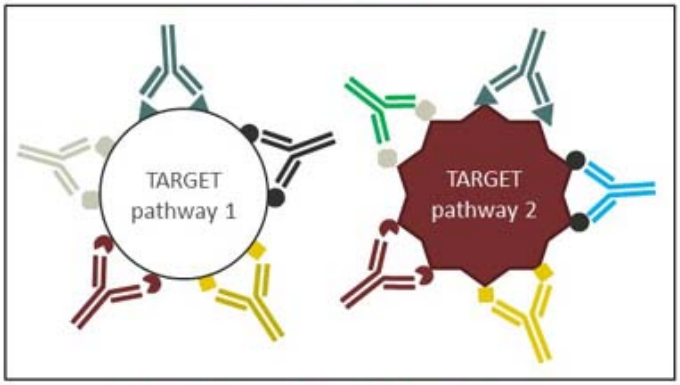
SAB Human Polyclonal Antibodies: Next Generation of Biologics

Key Product Differentiators vs Monoclonal Antibodies:

- Multi-target capability in a single therapeutic
  - ✓ Natural multi-epitope targeted pAb selected and produced *in vivo*
  - ✓ Ability to target multiple disease pathways at once increase potential for superior efficacy
- Specifically driven high-potency antibody 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** antibodies
that bind to multiple epitopes is regulated as a single product

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Biologic Pipeline with Broad Polyclonal Therapeutic Reach

R&D PIPELINE

	PRODUCT	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
RESPIRATORY	SAB-185	COVID-19	Phase 3 Trial (NIH ACTIV-2)				
	SAB-176	PAN INFLUENZA	Phase 1 Trial & Phase 2a Challenge Study Top line results available				
GASTROINTESTINAL	SAB-195	CLOSTRIDIOIDES DIFFICILE					
IMMUNOLOGY	SAB-142	TYPE 1 DIABETES					
	SAB-142	ORGAN TRANSPLANT REJECTION OR APLASTIC ANEMIA					
	ANTI-IDIOTYPE SERIES	SYSTEMIC LUPUS ERYTHEMATOSUS, TYPE 1 DIABETES, RHEUMATOID ARTHRITIS					
ONCOLOGY	SAB-162						

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Clinical Development Programs: Asset Progress

FPI: First Patient In
POBA: Proof of Biological Activity
HV: Healthy Volunteers
CDI: Clostridioides Difficile Infection
T1D: Type 1 Diabetes

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

First-in-class fully-human polyclonal antibody 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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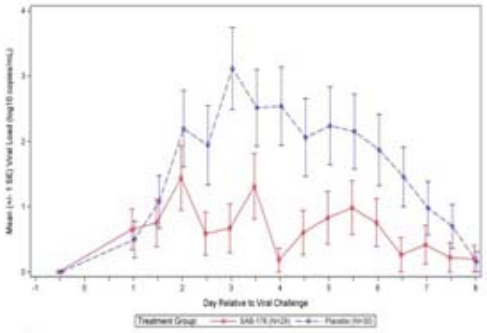
Established Proof-of-Concept for SAB-176: Met Primary Endpoint of Viral Load Reduction in Phase 2a Challenge Study

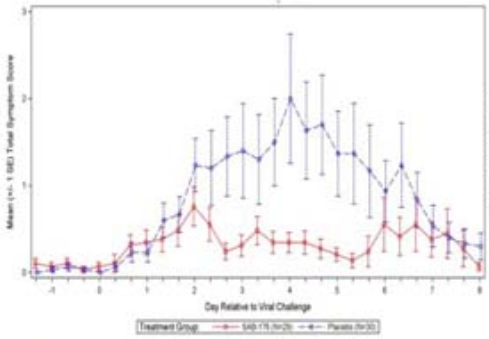
Achieved Statistically Significant (p = 0.026) Reduction in Viral Load

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



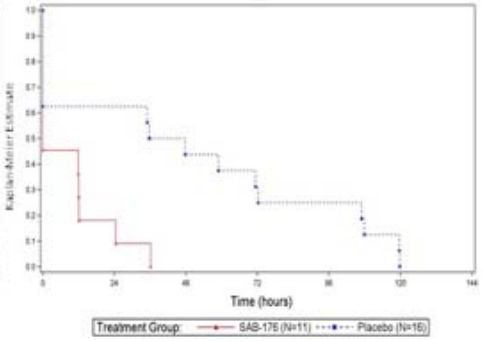
SAB-176 Achieved Statistically Significant (p = 0.013) Improvement in Symptoms at Day 4

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 antibodies to viral variants

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

First-in-class fully-human polyclonal antibody 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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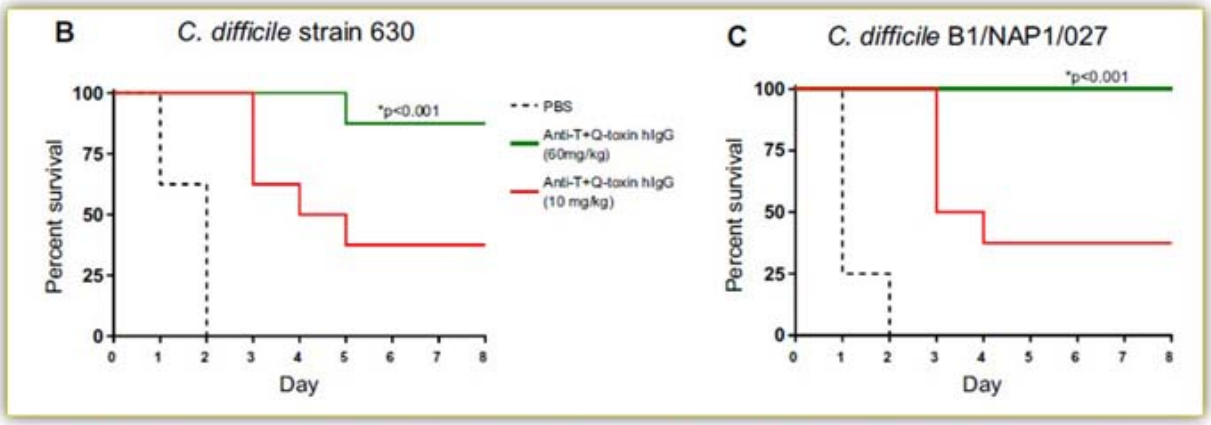
SAB-195 Preclinical Data

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/28669616/#:~:text=Vaccine,33(%3A4079%2D4087

SAB-142: Only Fully-Human Polyclonal Anti-Thymocyte Immunoglobulin

First-in-class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 Type 1 Diabetes (T1D)

	Teplizumab	Low Dose ATG	SAB-142
Mechanism of Action (MoA):			
• Anti-CD3	✓	☒	☒
• Anti-thymocyte	☒	✓	✓
Modality			
• Monoclonal Ab	✓	☒	☒
• Polyclonal Abs	☒	✓	✓
Fully-human	☒	☒	✓
Short dosing regimen	☒	✓	✓
Potential for redosing	✓	☒	✓

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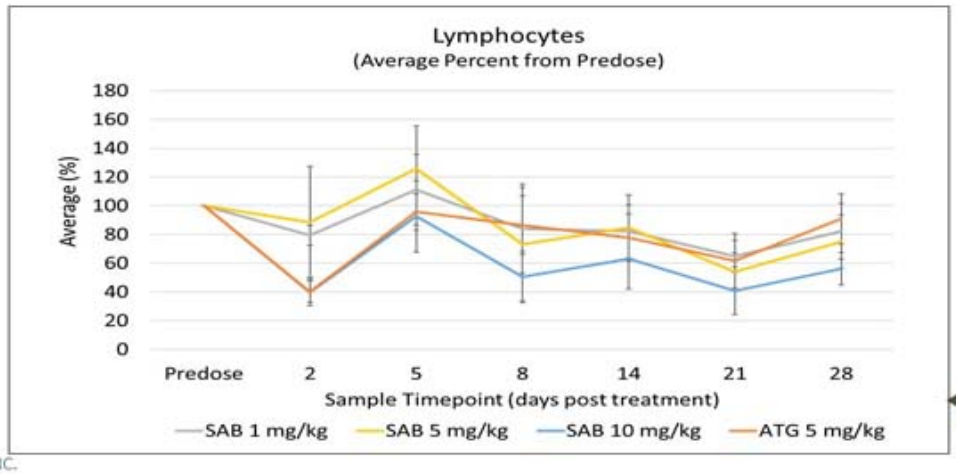
SAB-142: GLP Tox Study Results Enable IND Submission

Objectives:

- Determine the potential toxicity of SAB-142 vs. an anti-thymocyte globulin (ATG) when given by single intravenous infusion to non-human primates
- Characterize mechanism of action, toxicokinetic & immunogenicity profile of SAB-142

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, induced transient and prolonged lymphodepletion for the duration of the study. The dynamics of such depletion appears to be more prolonged with SAB-142 treatment in a dose-dependent manner



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DiversitAb™ Platform Anti-ID Proof of Principle in Autoimmune Disease

Multi-target capability in a single therapeutic
Ability to target multiple autoantibodies at once increase potential for superior efficacy

Known mAb autoantibodies were selected and used as antigens for hyperimmunization

IgG1 isotype (mAbG1)

IgG4 isotype (mAbG4)

pAbs generated by hyperimmunization with selected mAbs showed binding to the variable region and blocked in vitro functional effects

Anti-IgG1 pAbs

mAbG1

Anti-IgG4 pAbs

mAbG4

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DiversitAb™ Anti-Variable/Anti-ID hpAbs are Specific to the Variable Region

100X Excess
Competitive Ab/Fragments

Tc bovine sample	mAbG1 (TcBovine Antigen)	mAbG4-like Fab Fragment	mAbG1-like Fc Fragment	mAbG1-like framework
Pre-Immunization	-2.3	-4.7	3.9	-8.6
V3 hIgG	**99.9**	13.6	19.3	15.5
V4 hIgG	**100.0**	10.2	10.7	4.8
V5 hIgG	**100.0**	16.0	22.2	11.2

100X Excess
Competitive Ab/Fragments

Tc bovine sample	mAbG4 (TcBovine Antigen)	mAbG4-like Fab Fragment	mAbG4-like Fc Fragment	mAbG4-like framework
Pre-Immunization	3.1	-3.8	6.9	6.1
V3 hIgG	**99.8**	**99.7**	-12.7	-8.9
V4 hIgG	**99.9**	**99.0**	14.6	10.0
V5 hIgG	**99.9**	**99.5**	10.0	7.8

- Pretreatment with various antibodies or variable region fragments
- Analyzed using bridging immunoassays
- Data shown is percent inhibition, indicating specificity of binding to variable regions

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Comparison of Treatments for System Lupus Erythematosus (SLE)

	Immunosuppressive Therapies (i.e., anti-malarial drugs, corticosteroids, immunosuppressants)	Biologics (i.e., mAb Belimumab: anti-B-lymphocytic stimulator)	SAB's Anti-ID Polyclonal Antibodies
Mechanism of Action (MoA):			
• General Immune Suppression	✓	✓	☒
• Suppression of all B cells	✓	✓	☒
• Suppression/elimination of specific autoreactive antibody and its B cell clone	☒	☒	✓
• Activity against related mutated antibodies and B cell clones (somatic hypermutation)	☒	☒	✓
Potential for extended remission without immune suppression	☒	☒	✓
Potential for personalized medicine	☒	☒	✓

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Summary

- **DiversitAb™ Platform:** Innovative DiversitAb™ platform produces a new class of targeted fully-human, highly-potent polyclonal antibodies, with a broad efficacy spectrum in a broad range of indications.
- **Platform** is well-positioned to address complex diseases with targeting multiple epitopes & pathways in one therapeutic; it has potential to exceed industry PTRS and timelines benchmarks
- **SAB-176:** First-in-class fully-human polyclonal antibody treatment aimed to provide superior efficacy for prophylaxis and management of influenza in patients at high-risk, planned initiation of Phase 2b trial in 2H 2023.
- **SAB-195:** Preclinical data supports potential for competitive efficacy as first-line polyclonal antibody therapy for severe CDI in patients who are at a high risk for recurrences, expect to file IND in H2 2023-H1 2024.
- **SAB-142:** First-in-class fully-human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 Type 1 Diabetes. IND-enabling GLP tox successfully completed with IND submission expected in 2023-2024.

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