

**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): January 09, 2023**

**SAB BIOTHERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

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

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

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

**2100 East 54th Street North**  
**Sioux Falls, South Dakota**  
(Address of Principal Executive Offices)

**57104**  
(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 January 9, 2023, SAB Biotherapeutics, Inc. (the "Company" or "SAB") issued a press release announcing that the Company will present an overview of the its DiversitAb™ platform and data from completed trials (the "Presentation") on January 10, 2023 at the Biotech Showcase held in San Francisco. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

The Presentation will highlight 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 99.2 and is incorporated herein by reference. Additionally, the Company will make an audio recording of the Presentation available on the Company's investor relations website prior to the Biotech Showcase Presentation at <https://ir.sab.bio/>.

The foregoing (including Exhibits 99.1 and 99.2) are 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, or the Exchange Act. The information contained in each of the press release and the Presentation is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission 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 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of the Company, dated January 9, 2023</a>
99.2	<a href="#">Presentation dated January 10, 2023</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: January 9, 2023

By: /s/ Eddie J. Sullivan

Eddie J. Sullivan

Chief Executive Officer

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## **SAB Biotherapeutics' CMO Alexandra Kropotova to Deliver Presentation on Next Generation Biologics in Immunology at Biotech Showcase**

SIOUX FALLS, S.D., January 9, 2023 (GLOBE NEWSWIRE) – SAB Biotherapeutics (Nasdaq: SABs), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, high-avidity, fully-human polyclonal antibodies without the need for human donors, announced today that Alexandra Kropotova, MD, Executive Vice President and Chief Medical Officer, will deliver a presentation at the Biotech Showcase in San Francisco on Tuesday, Jan. 10 at 2:30 p.m. PST

Dr. Kropotova's presentation, titled: ***Next Generation Biologics in Immunology: Solution for Complex Diseases***, will discuss the latest innovations and treatment pathways in immunology, including an overview of SAB's novel DiversitAb™ platform. DiversitAb™ is the only platform in the world that produces fully-human, broadly neutralizing, polyclonal antibodies utilizing transchromosomal cows. Dr. Kropotova will also present data from completed clinical trials that indicate SAB's polyclonal antibody therapies can provide long-lasting efficacy against numerous highly mutating pathogens or multiple targets or pathways at once.

"SAB's approach is to develop treatments designed to address multiple dysregulated pathways, multiple disease targets, and multiple epitopes in one powerful treatment," said Dr. Kropotova. "SAB's groundbreaking DiversitAb™ therapeutic platform and its promising pipeline developments in influenza, Clostridioides difficile, type 1 diabetes and other complex disease states with high unmet patient need is setting a promising new standard for immunology."

During the Biotech Showcase, potential partners, collaborators, and investors who are registered and attending the conference may request one-on-one appointments with the Company through the Biotech Showcase partnering platform: <https://informaconnect.com/biotech-showcase/>

To schedule an in-person or virtual meeting during J.P. Morgan week, regardless of attendance or registration, please contact: [SABIR@westwick.com](mailto:SABIR@westwick.com)

To learn more about partnering opportunities with SAB Biotherapeutics, visit: <https://www.sab.bio/partnering-opportunities/>

### **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 Transchromosomal (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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**CONTACTS:**

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# Next Generation Biologics in Immunology

## *Solution for Complex Diseases*

**Biotech Showcase Conference | January 2023**

Alexandra Kropotova, MD  
Executive Vice President & Chief Medical Officer

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## 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.

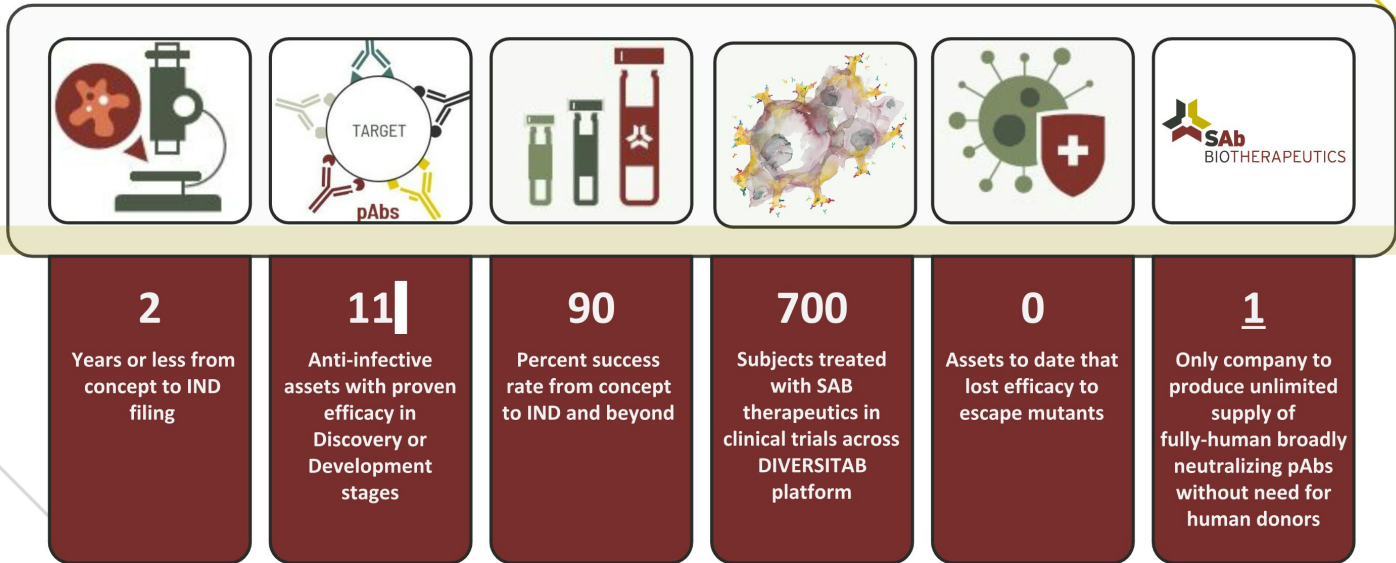
Unless otherwise specified, information is current at the date hereof.

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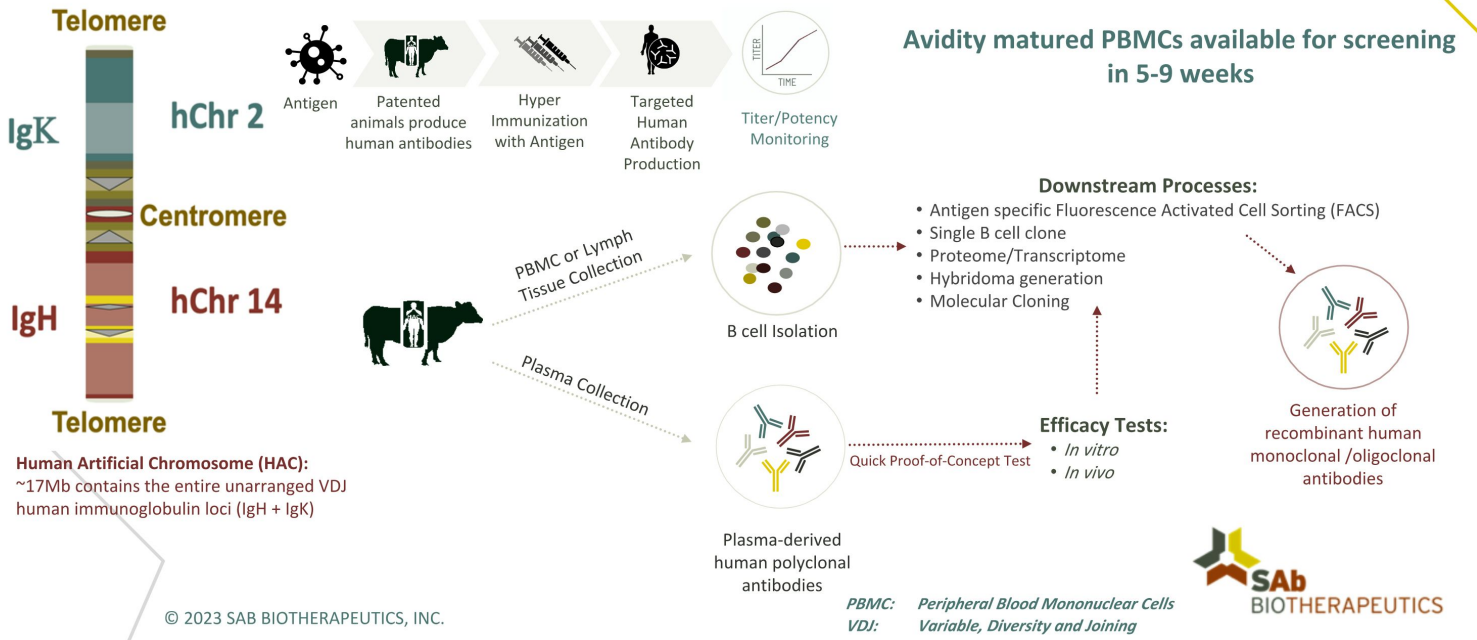


# SAB Biotherapeutics Fact Sheet





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



# Significant Gains in R&D Efficiency with SAB hpAb Discovery & CMC Production

## Traditional mAbs therapeutics: Sequential discovery and CMC production process



## Traditional mAbs Discovery to IND filing: 4-6 years

## SAB hpAb therapeutics: Simultaneous "discovery" and CMC production in Tc Bovine

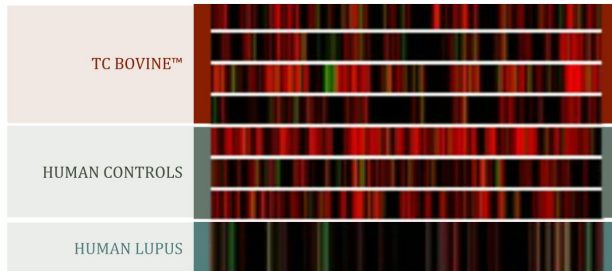


## Tc hpAbs Discovery to IND filing: 1-2 years

# Fully-Human, Diverse Repertoire, & Functional Antibodies

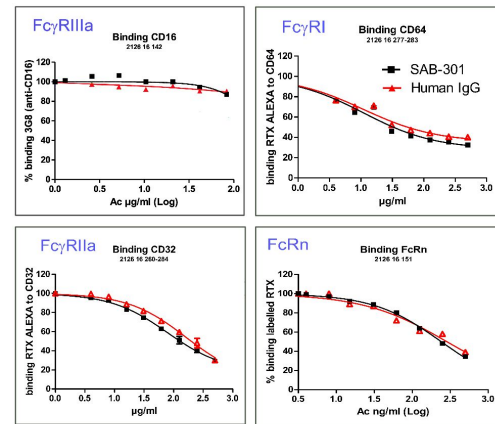
## Rich Antibody Diversity

VDJ repertoire usage mimics human-derived diversity in variable region



## Highly-Functional Fc Region

Matches full activation of effector cells and functional glycosylation / post translational modification

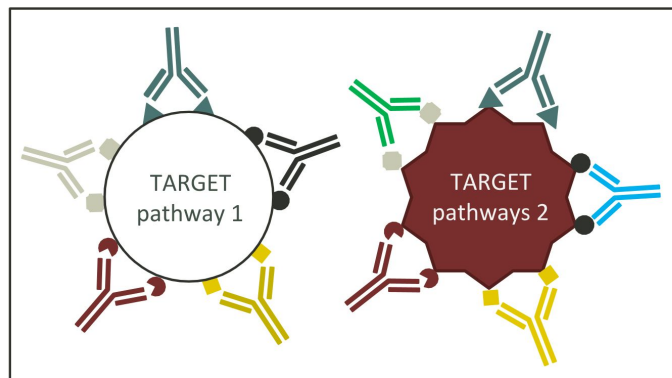


## Key Product Differentiators vs Monoclonal Antibodies:

- 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

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



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

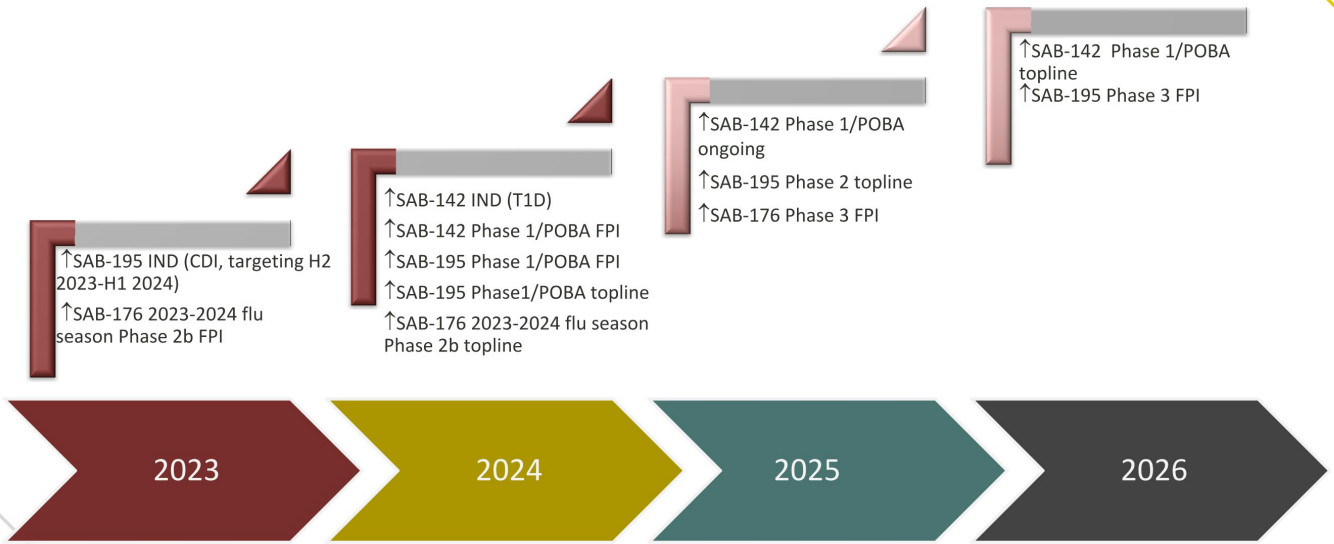


# Biologic Pipeline with Broad Polyclonal Therapeutic Reach

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	CLOSTRIDIODES 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						



# 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



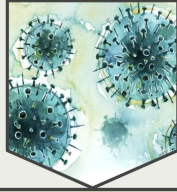
# Value Proposition: SAB-176

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

## Key Differentiators



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



Adaptive and cross-reactive to multiple influenza strains



Multiprong Mechanism of Action

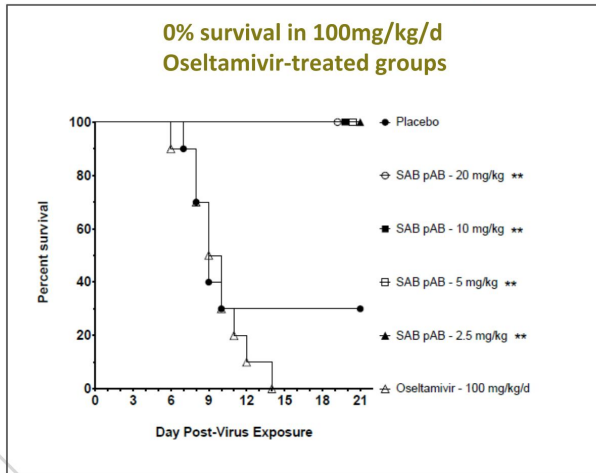
- Neutralizing activity targeting multiple epitopes of Influenza A and B virus
- Antibody-Dependent Cellular Cytotoxicity (ADCC)



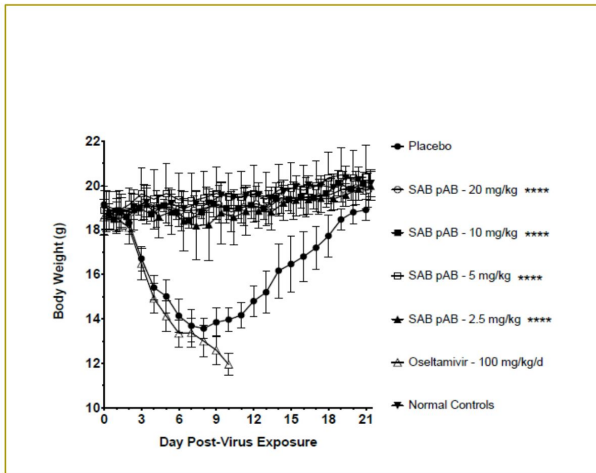
Established Proof-of-Concept in the well-established validated influenza challenge model

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

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



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

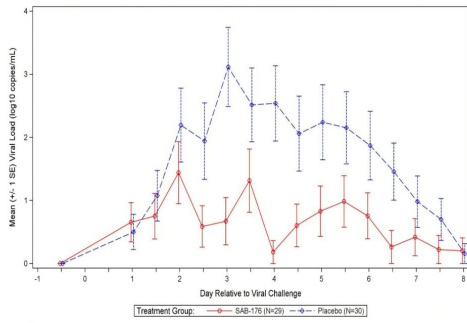




# Established Proof-of-Concept for SAB-176: Met Primary Endpoint of Viral Load Reduction in Phase 2a Challenge Study

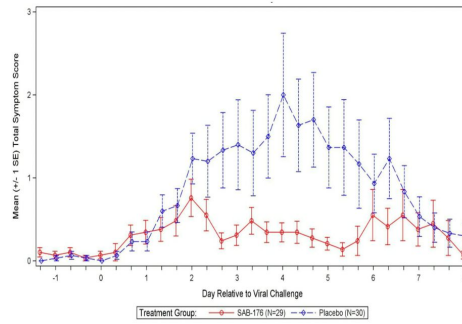
**Achieved Statistically Significant ( $p = 0.026$ ) Reduction in Viral Load**

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



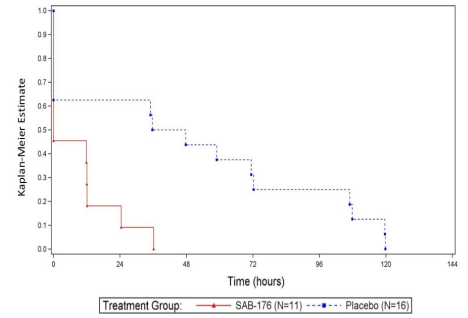
**SAB-176 Achieved Statistically Significant ( $p = 0.013$ ) Improvement in Symptoms at Day 4**

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



# Only SAB-176 Provides Potential for “EVERGREEN” Biologic with Low Risk of Escape Mutants

Comprehensive approach to treating high-risk patients with influenza by broadly neutralizing fully-human pAb immunotherapeutic with several anti-viral mechanisms

	Osetamivir	Baloxavir marboxil	Broadly neutralizing human polyclonal SAB-176
<b>Mechanism of Action (MoA):</b>			
• 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	✗	✗	✓
<b>Single Dose</b>	✗	✓	✓
• Extended protection against viral shedding, recrudescence infection, or new infection with another influenza strain	✗	✗	✓
<b>Low risk of antiviral resistance/escape mutants while being treated</b>	✗	✗	✓
<b>Potential to treat patients infected with anti-viral resistant strains</b>	✗	✗	✓



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

## Key Differentiators



First-in-class fully human polyclonal antibody 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



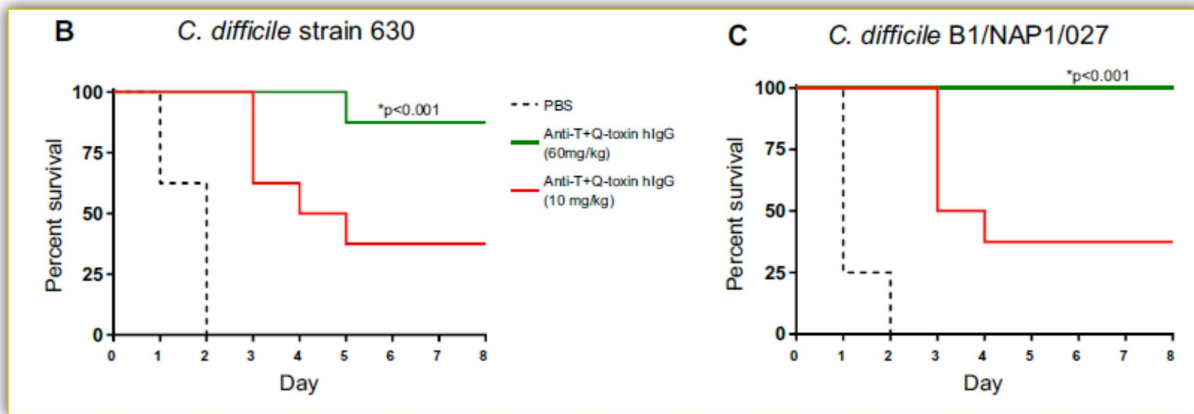
SAB-195 is a target-specific treatment targeting only C. diff bacteria/spores/toxins while fully preserving good microbiome



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

## 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 hlgG 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 <sup>a</sup>, Gregory Glenn <sup>a</sup>, David Flyer <sup>a</sup>, Bin Zhou <sup>a</sup>, Ye Liu <sup>a</sup>, Eddie Sullivan <sup>b</sup>, Hua Wub, James F. Cummings <sup>a</sup>, Larry Ellingsworth <sup>a</sup>, Gale Smith
- <https://pubmed.ncbi.nlm.nih.gov/28669616/#:~:text=Vaccine,33%63A4079%2D4087>



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

Comprehensive approach to treating patients with CDI addresses the entire life cycle of the C. diff pathogen and disease pathophysiology

	Antibiotics	Monoclonal Antibodies (bezlotoxumab)	Polyclonal Broadly Neutralizes C. diff Specific Antibody SAB-195
<b>Mode of Action (MoA) Targets:</b>			
• C. diff Spores	✗	✗	✓
• C. diff Bacteria	✓	✗	✓
• Toxin A	✗	✗	✓
• Toxin B	✗	✓	✓
• Binary toxin CDT	✗	✗	✓
<b>Single Dose</b>	✗	✓	✓
<b>Indications:</b>			
• 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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**First-in-class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 Type 1 Diabetes (T1D)**

**Key Differentiators**



**First-in-class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset and progression of clinical Stage 3 T1D**

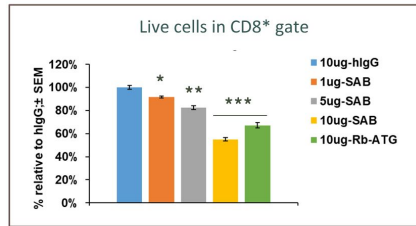


**Validated Mechanism of Action by a 3rd party ATG demonstrating reduction in loss of C-peptide vs. placebo (Haller, 2019)**

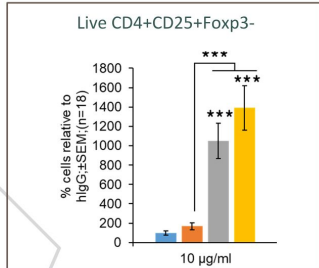
# SAB-142 Demonstrates Similar Activity to Approved Rabbit Anti-Thymocyte Globulin (ATG)

## SAB-142 Targets CD4+, CD8+ and Protects T-Regulatory Cells

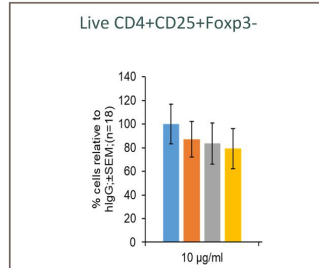
### CD8 T Cells



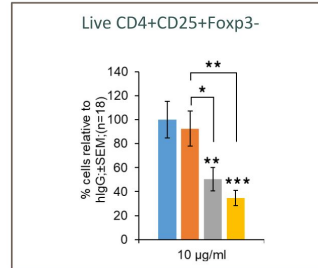
### Treg Cells



### Activated CD4 T Cells



### Naïve CD4 T Cells



■ hlgG  
■ Ho-ATG  
■ Rb-ATG  
■ SAB-ATG



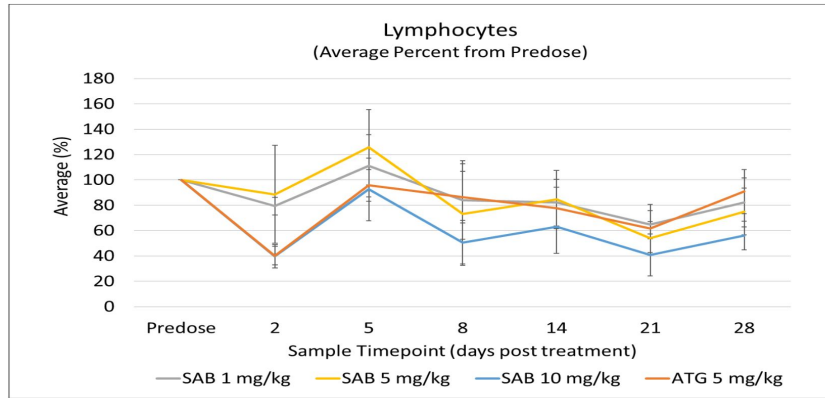
## SAB-142: GLP Tox Study Results Enable IND Submission

### 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

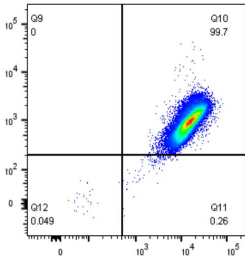




# SAB-142: MoA Clinically Validated by 3<sup>rd</sup> Party Compound

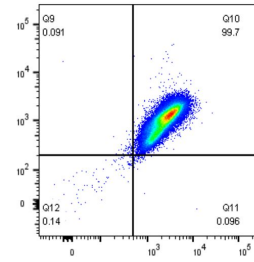
2 Years: Low-Dose ATG\* Preserved C-Peptide in New Onset T1D

Tc Bovine Human-PB, Rabbit THYMO-AF488, Equine ATGAM-AF488 and Anti-CD3-APC



RABBIT THYMO-AF488

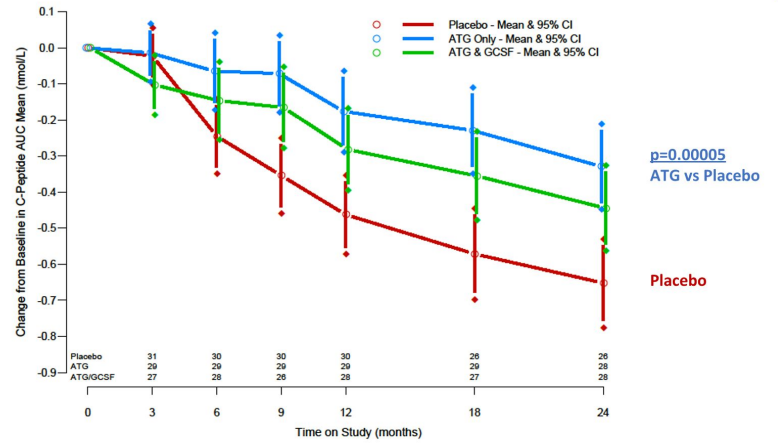
**Thymoglobulin**  
Anti-thymocyte Globulin (Rabbit)



EQUINE ATGAM-AF488

**Atgam**<sup>®</sup>  
lymphocyte immune globulin,  
anti-thymocyte globulin (equine)  
**250 mg protein**  
50 mg/mL

Decline in C-Peptide AUC Mean Over Time by Treatment Group



\*RABBIT ATG FROM SANOFI – NOT SAB-142 (HUMAN TC-BOVINE DERIVED ATG)  
*Haller et al. Diabetes. 2019. June, 68(6): 1267-1276*



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

Comprehensive approach to treating Stage 2/3 T1D with fully-human pAb anti-thymocyte immunotherapeutic

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



## 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.