

**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): September 23, 2022**

**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 September 23, 2022, SAB Biotherapeutics, Inc. (the “Company” or “SAB”) made available an updated corporate strategy presentation (the “Presentation”) on the Investor Relations section of the Company’s website. A copy of the Presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The foregoing (including Exhibit 99.1) is being furnished pursuant to Item 7.01 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 “Securities Act”), or the Exchange Act. 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 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-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 8.01 Other Events.**

On September 23, 2022, SAB Biotherapeutics, Inc. (the “Company” or “SAB”) issued a press release announcing that the Company will present new data on its fully-human polyclonal antibody platform’s ability to maintain its efficacy against multiple variants of several highly mutating viruses at the Options for Control of Influenza (OPTIONS XI) conference, which is hosted by the International Society for Influenza and other Respiratory Virus Diseases (ISIRV) in Belfast, Northern Ireland, from Sept. 26-29, 2022.

A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits. The exhibits listed on the Exhibit Index are incorporated herein by reference.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Presentation dated September 23, 2022</a>
99.2	<a href="#">Press Release of the Company, dated September 23, 2022</a>
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: September 23, 2022

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

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# ADVANCING A POWERFUL NEW CLASS OF IMMUNOTHERAPEUTIC ANTIBODIES

September 2022

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# 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



# Advancing a New Class of Immunotherapies



Robust, growing clinical-stage pipeline spanning multiple therapeutic areas



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



Leveraged advanced genetic engineering & antibody science to develop Tc bovine-derived fully-human polyclonal antibodies



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 polyclonal antibodies**

# 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.

# Versatile Antibody Platform with Ability to Capture Multiple Modalities



*Human Antibody Discovery & Product Development Engine, New Source for Novel Treatments*

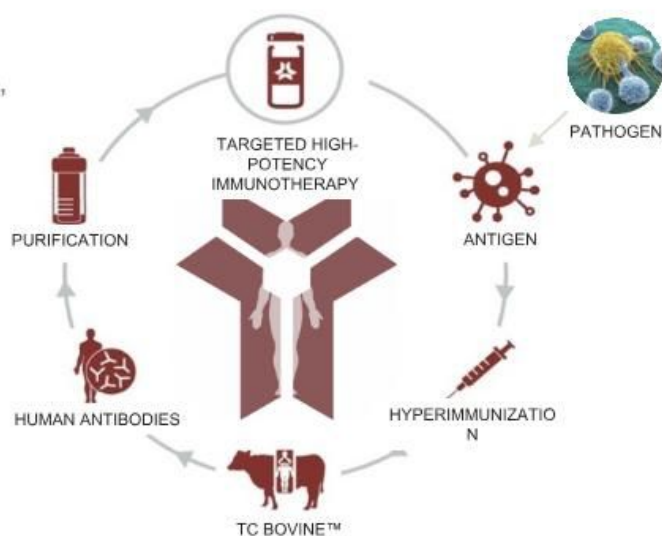




## DiversitAb™ Platform

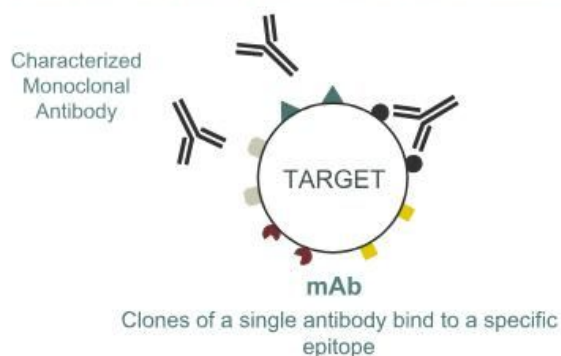
*Advancing a new class of fully-human polyclonal Tc bovine-derived antibodies without the need for human serum*

- Reliable, controlled, consistent production of diverse, high-titer, high-avidity, fully-human polyclonal antibodies
- Generated antibodies behave similarly to human-derived with ability to specifically target
- Proprietary immunization strategies and robust immune response drive extremely high potency
- Well-established and understood regulatory path as biologic through FDA-CBER
- Vertical integration enabling rapid, scalable development and production of multivalent products



# Polyclonals: Broader Spectrum Efficacy Valuable in Range of Indications

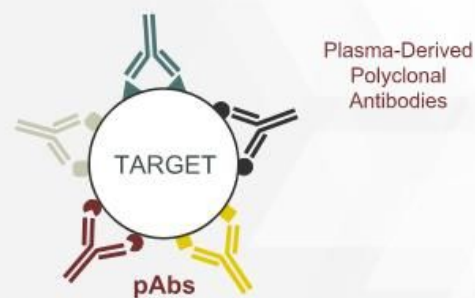
FDA: CENTER FOR **DRUG** EVALUATION & RESEARCH (CDER) FDA: CENTER FOR **BIOLOGICS** EVALUATION & RESEARCH (CBER)



## Monoclonal Approach

- Highly-targeted with specific activity
- Iterative Ab identification and selection process
- Selected and cloned *in vitro*
- May promote escape mutants via selective pressure
- Resistance may develop as pathogen/target mutates
- Current cocktail trend to address resistance

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## Polyclonal Approach

- Diversity of antibodies with multiple modalities
- Naturally selected and produced *in vivo*
- Effective against escape mutants
- Reduced possibility of resistance
- Activates cellular immunity
- Synergistic properties not duplicated by mono- or oligoclonals

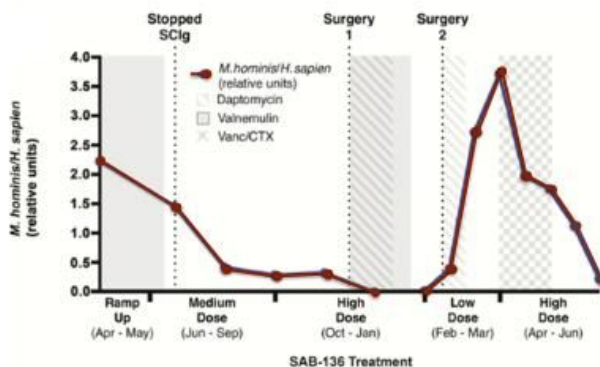
# Demonstrated Human Safety and Efficacy in Multi-Dosing Regimen



High-dose therapy resulted in improved clinical parameters associated with reduced *M. hominis* burden following two subsequent infections



Open wound persisted ~7 years prior to treatment



Same area following treatment with SAB - 136



JARED N SILVER, CAMERON D ASHBAUGH, JACOB J MILES, HUA WU, GREGORY T MARECKI, JOYCE K HWANG, JIN-AN JIAO, MARK ABRAMS, EDDIE J SULLIVAN, DUANE R WESEMANN, DEPLOYMENT OF TRANSCROMOSOMAL BOVINE FOR PERSONALIZED ANTIMICROBIAL THERAPY, CLINICAL INFECTIOUS DISEASES, VOLUME 66, ISSUE 7, 1 APRIL 2018, PAGES 1116-1119

# DiversitAb™ Platform is Clinically Validated Across Several Targets



### 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](#)



# SELECTED PIPELINE PROGRAMS

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# Robust Biologic Pipeline with Broad Polyclonal Therapeutic Reach

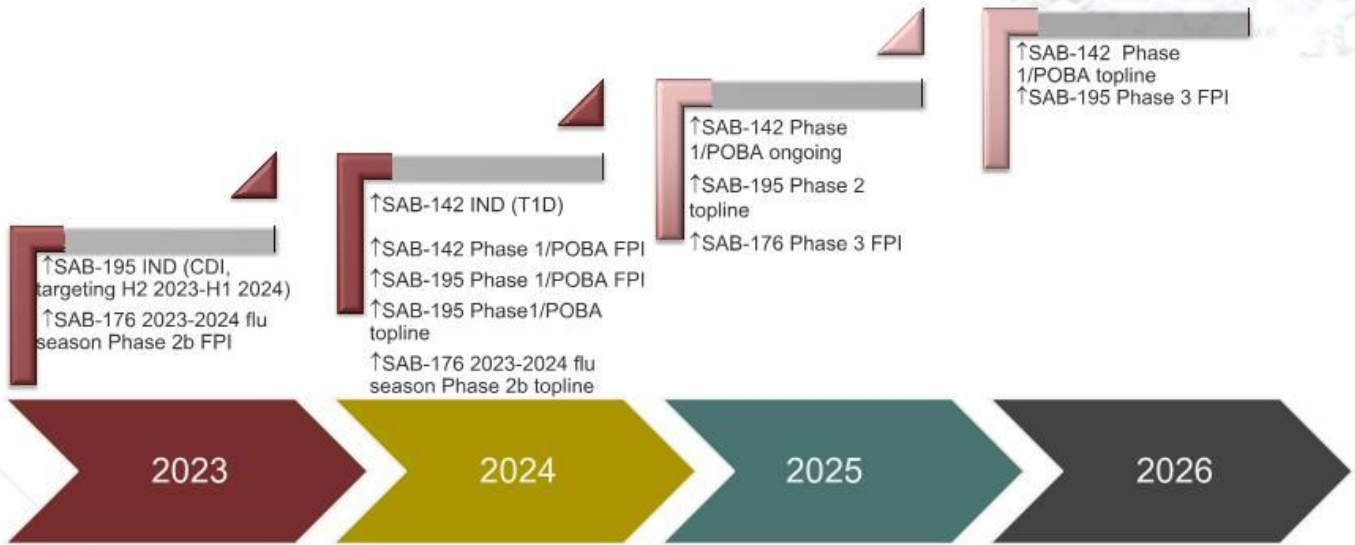
## Ongoing discovery programs in oncology, autoimmune, infectious and anti-idiotypic diseases

	PRODUCT	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL
GASTROINTESTINAL	SAB-195	CLOSTRIDIODES DIFFICILE	[Progress bar]					
RESPIRATORY	SAB-176	SEASONAL INFLUENZA	Phase 1 Trial & Phase 2a Challenge Study Top line results available					
IMMUNOLOGY	SAB-142	TYPE 1 DIABETES	[Progress bar]					
	SAB-142	IMMUNOLOGY	[Progress bar]					

## Government-funded Phase 3 clinical-stage program

RESPIRATORY	SAB-185	COVID-19	Phase 3 Trial (NIH ACTIV-2)					
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# Clinical Development Programs: Focus Over the Next 4+ Years





# **SAB-195:** Clostridioides difficile Infections: Fast to Proof-of-Concept

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# 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<sup>1</sup>
  - ~ 30,000 deaths per year in the US<sup>1</sup>
- CDI infection is associated with significant costs: Up to \$4.8 billion each year in excess health care costs for acute care facilities alone<sup>1</sup>
- Patients with the first CDI recurrence have a risk of subsequent recurrence from 25% to 40% and higher<sup>1, 2</sup>
- 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<sup>2</sup>
- 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 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



Only treatment with dual mode of action:

- Unlike bezlotoxumab, SAB-195 targets surface antigen on CDI as well as multiple toxins
- Unlike antibiotics, SAB-195 targets several CDI toxins responsible for severity of the disease



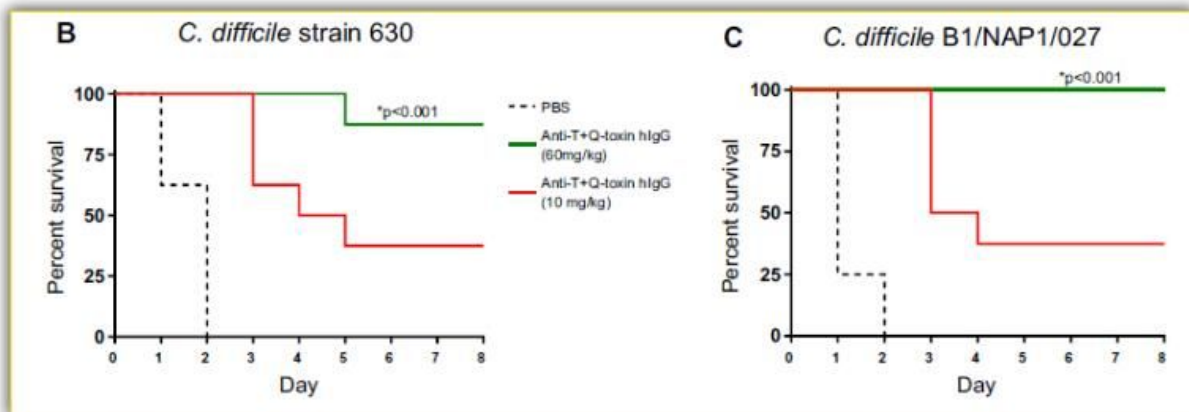
SAB-195 is a target-specific treatment targeting only CDI while fully preserving good microbiome



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**

# SAB-195: Clinical Development Plan CDI: Two Indications

## Phase 1/Proof of Biological Activity (POBA)

Phase 1 in adult healthy volunteers (HVs), followed by subjects meeting high-risk criteria and patients with CDI

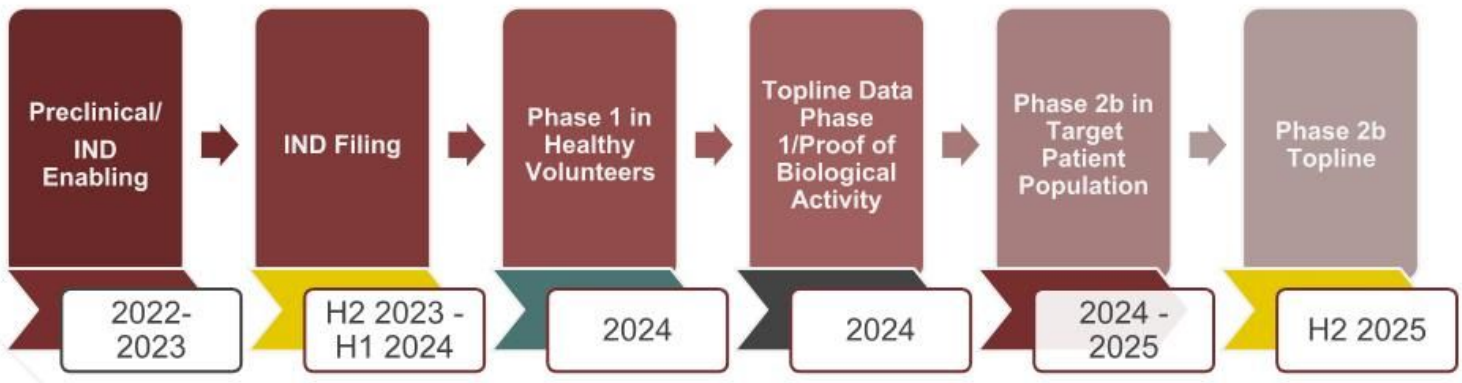
## Phase 2b - 3:

Adult patients with moderate to severe CDI at risk for recurrent CDI

STUDY DESIGN	Phase 1/Proof of Biological Activity (POBA)	Phase 2b - 3:
ENDPOINTS	<ul style="list-style-type: none"> <li>• Randomized, double-blind, placebo-controlled single ascending dose first-in in HVs, followed by expansion cohorts in subjects meeting high-risk for CDI recurrence criteria and in patients with CDI</li> <li>• Study populations:               <ul style="list-style-type: none"> <li>= HVs for single ascending dose SAB-195 study (Phase 1)</li> <li>= Subjects meeting high-risk criteria:                   <ul style="list-style-type: none"> <li>&gt;65-years old, pharmacokinetic (PK), anti-drug antibody (ADA) immunocompromised, Phase 1</li> </ul> </li> <li>= Patients with mild-moderate CDI (Proof of Biological Activity)</li> </ul> </li> <li>• XXX mg/kg (determined based preclinical in vitro and in-vivo data)</li> </ul>	<ul style="list-style-type: none"> <li>• Randomized, double-blind, placebo-controlled Phase 2b dose-range efficacy trial with 3 dose levels of SAB-195 (high, medium, low) vs. standard of care (SOC).</li> <li>• Followed by randomized, double-blind, placebo-controlled Phase 3 trial(s)</li> <li>• Active comparators vary by indication: antibiotics for treatment of CDI-associated diarrhea; bezlotoxumab for reduction of CDI recurrence</li> <li>• Study population: Patients &gt;18 years old who are at a high risk for CDI recurrence</li> </ul>
	<ul style="list-style-type: none"> <li>• Primary for Phase 1: acute and long-term safety</li> <li>• Primary Proof of Biological Activity: proportion of CDI patients with clinical cure at Days 14-16</li> <li>• Secondary Phase 1: pharmacokinetics (PK), pharmacodynamics, anti-drug antibody (ADA), healthy microbiome impact</li> <li>• Secondary Proof of Biological Activity: proportion of CDI patients with clinical cure at Days 30 &amp; 60</li> </ul>	<ul style="list-style-type: none"> <li>• Co-primary end points:               <ul style="list-style-type: none"> <li>= Treatment of CDI: proportion of patients with clinical cure at Day 14-16 (Indication 1)</li> <li>= Reduction of CDI recurrence: sustained clinical response rate vs standard of care (SOC) at 12 weeks (Indication 2)</li> </ul> </li> <li>• Secondary end points:               <ul style="list-style-type: none"> <li>= Safety, pharmacokinetic (PK), anti-drug antibody (ADA), microbiome impact</li> </ul> </li> </ul>



# SAB-195 Development Timelines





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

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# Unmet Need of Seasonal Influenza



**35,500,000**  
ILLNESSES

**34,200**  
DEATHS

**1 of 1,000**  
INFECTIONS  
RESULTED  
IN DEATH

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



**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 biologic for management of influenza in high-risk patients



Adaptive and cross-reactive to multiple influenza strains



Fully human polyclonal antibodies uniquely positioned to manage influenza course in high-risk patients including but not limited to:

- Immunocompromised
- Immunosenescent patients
- Patients in long-term care facilities



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

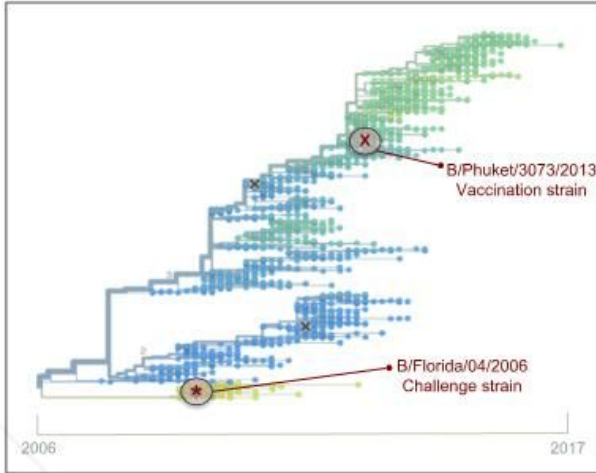


# Efficacy Against Mutational Drift

*Adaptive & Cross Reactive to Mutating Strains*

## Highly-Mutational Influenza Virus

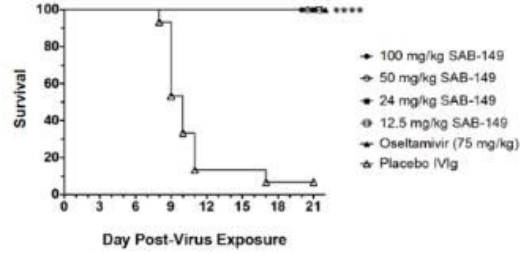
BYAM PHYLOGENIC TREE



SOURCE: NEXTFLU AT [HTTPS://NEXTFLU.ORG/VIC/12Y/](https://nextflu.org/vic/12y/)

## 100% Protection at All Dose Levels in Influenza Mouse Challenge

Antibodies produced to B/Phuket/3073/2013 protected against B/Florida/04/2006





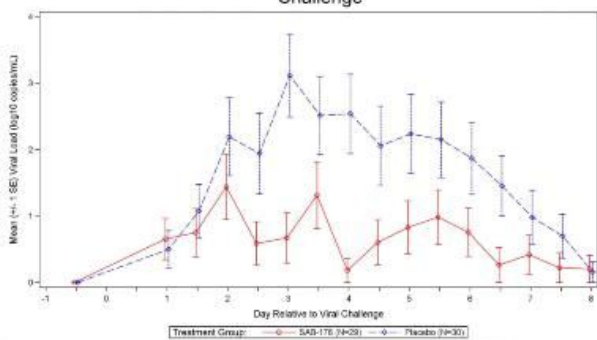
# Established Proof-of-Concept for SAB-176:

# Met Primary Endpoint of Viral Load Reduction in Phase 2a Challenge Study

## Study

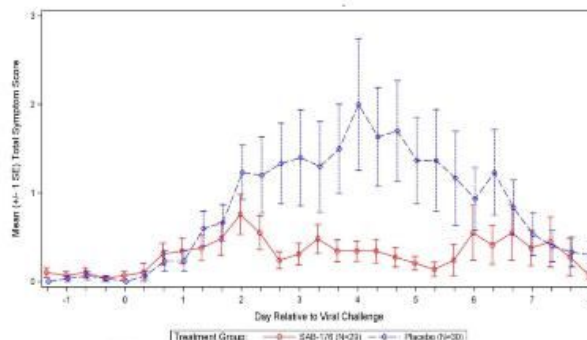
**Achieved Statistically Significant ( $p = 0.026$ ) Reduction in Viral Load**

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



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

Mean Total Symptom Score by Day Relative to 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

# SAB-176: Clinical Development Plan

	Phase 1: Healthy Volunteers	Planned Phase 2a Challenge Study: Healthy Volunteers	Planned Phase 2b and Phase 3 Designs	
STUDY DESIGN	<ul style="list-style-type: none"> <li>Randomized, double-blind, placebo-controlled</li> <li>27 healthy volunteers</li> <li>Single ascending dose study</li> <li>1, 10, 25 and 50 mg/kg</li> </ul>	<ul style="list-style-type: none"> <li>60 total participants</li> <li>60 randomized to SAB-176 or control (30-30)</li> <li>Challenge strain: H1N1 California (pandemic)</li> </ul>	<ul style="list-style-type: none"> <li>300-600 participants</li> <li>High-risk of serious influenza with symptoms &lt; 4 days</li> <li>SAB-176 and standard of care vs standard of care</li> <li>Dose ranging</li> </ul>	<ul style="list-style-type: none"> <li>~1,000 participants (TBD)</li> <li>High-risk of serious influenza with symptoms ≤ 3-4 days</li> <li>SAB-176 and standard of care vs standard of care</li> </ul>
ENDPOINTS	<ul style="list-style-type: none"> <li>Primary: safety</li> <li>Secondary: pharmacokinetics, pharmacodynamics, anti-drug antibodies</li> </ul>	<ul style="list-style-type: none"> <li>Primary: safety and viral load reduction</li> <li>Secondary: sign/symptom reduction</li> </ul>	<ul style="list-style-type: none"> <li>Primary: time to onset of clinically significant influenza</li> <li>Reduction of risk developing influenza symptoms</li> </ul>	<ul style="list-style-type: none"> <li>Primary: hospitalization and ICU days and death</li> <li>Secondary: multiple</li> </ul>
TIMING	<ul style="list-style-type: none"> <li>All participants reached end-of-study</li> <li>Data being analyzed for final report</li> <li>Readout expected mid-2021</li> </ul>	<ul style="list-style-type: none"> <li>Study start 2Q2021</li> <li>Readout reported 4Q2021</li> </ul>	<ul style="list-style-type: none"> <li>Multi-site: Northern hemisphere and/or Southern hemisphere</li> </ul>	<ul style="list-style-type: none"> <li>Multi-site: Northern hemisphere and/or Southern hemisphere</li> </ul>

# SAB-176 Development Timelines





# **SAB-142:** Type 1 Diabetes (T1D) Prevention

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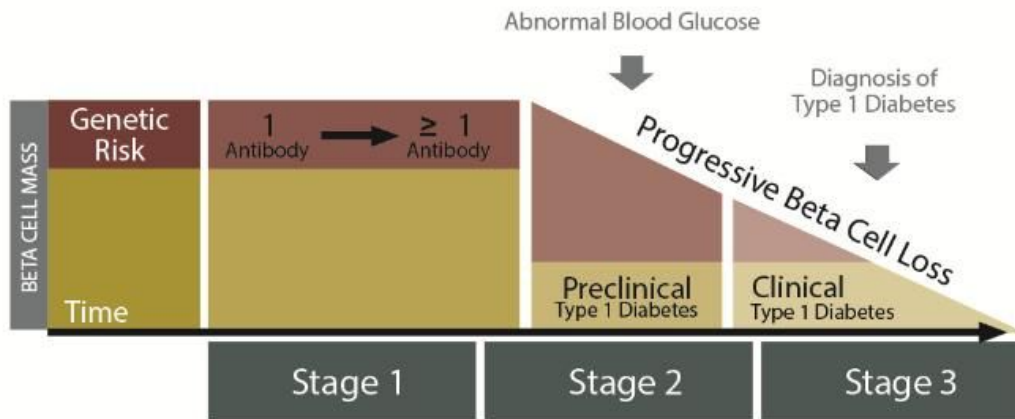
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# Type 1 Diabetes

*High Unmet Medical Needs Drive High Level of Competition*

- Disease-modifying treatments in late-stage development:
  - >100 active interventional trials with small molecules, biologics, and cell therapies in Type 1 Diabetes



## Value Proposition: 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 (T1D)**

### Key Differentiators



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

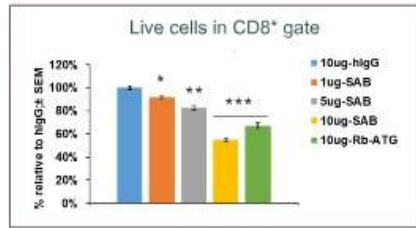


Validated Mechanism of Action by a 3rd party ATG demonstrating reduction in loss of C-peptide vs. placebo (Haller, 2019)

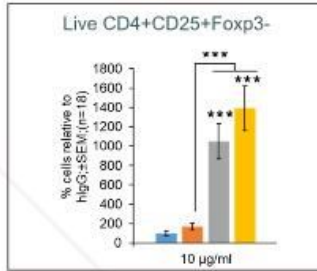
# SAB-142: Similar Activity to Approved Rabbit Anti-Thymocyte Globulin (ATG) Targets CD8 and Protects T-Regulatory Cells



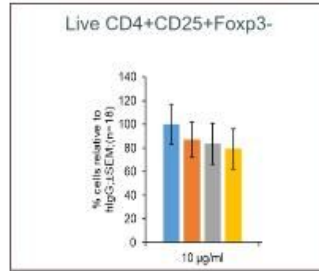
## CD8 T Cells



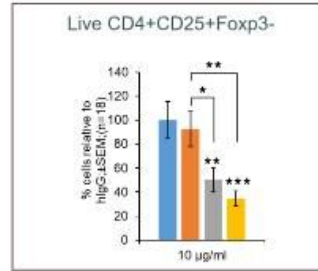
## Treg Cells



## Activated CD4 T Cells



## Naïve CD4 T Cells

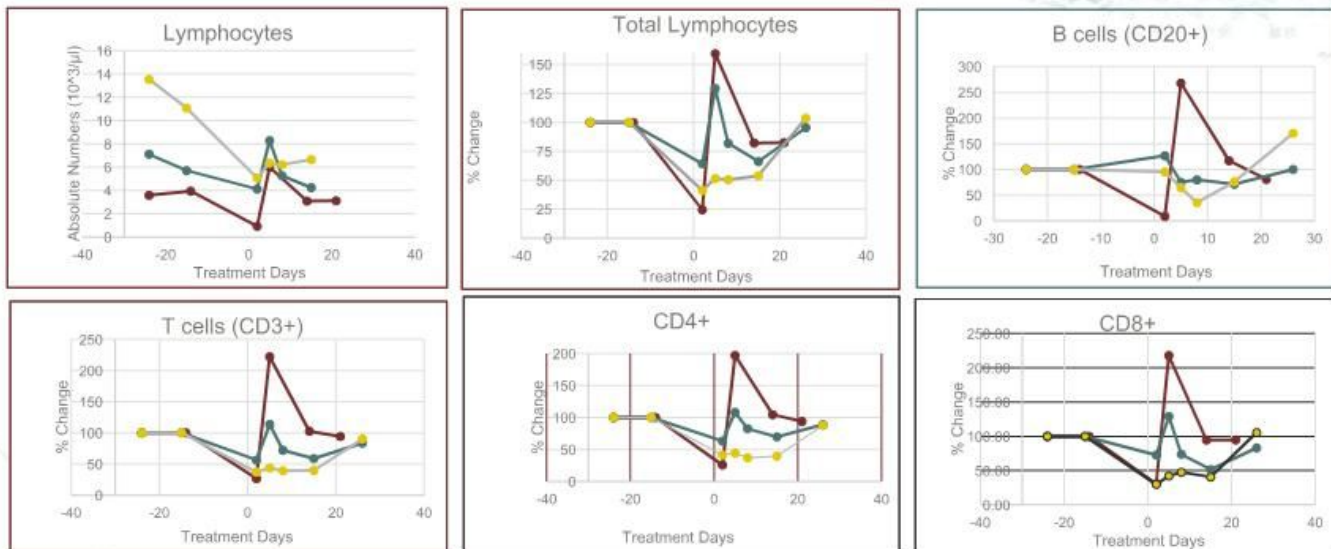


■ hlgG  
 ■ Ho-ATG  
 ■ Rb-ATG  
 ■ SAB-ATG



# SAB-142 Preclinical Data Continued

## Major Subsets of Peripheral Blood Lymphocytes



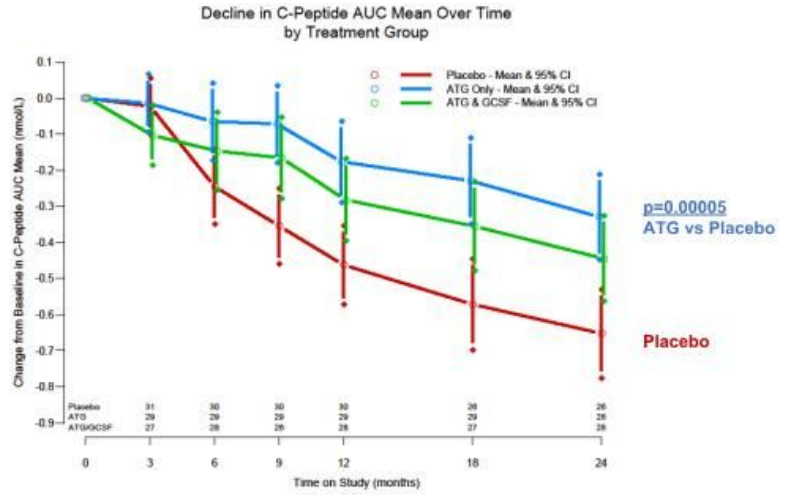
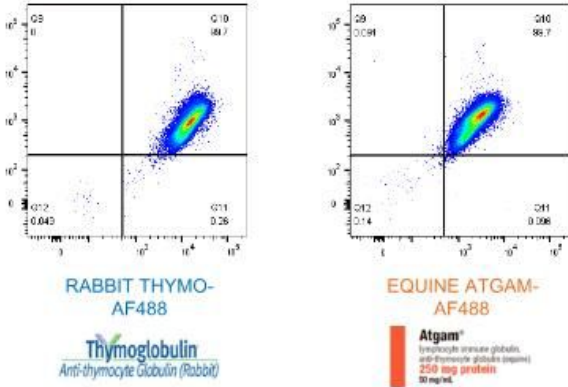
Changes in major subsets of peripheral blood lymphocytes (total lymphocytes, T and B cells, CD4+ and CD8+ T helpers and killers, respectively) following SAB-142 and ATG treatments. Red: 5 mg/kg ATG; Blue: 1 mg/kg SAB-142; Grey: 5 mg/kg SAB-142

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

# SAB-142: Clinical Development Plan Type 1 Diabetes (T1D)

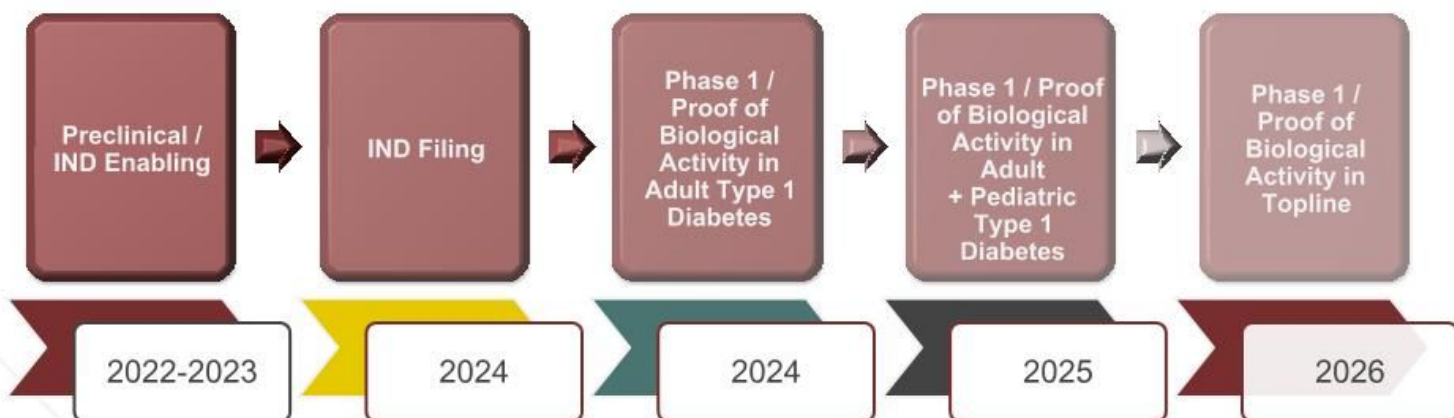


**Phase 1-2:**  
Early Onset T1D in Adults, followed by adults and adolescents at C-peptide interim analysis

**Phase 3:**  
New and Recent Onset T1D in Adults and Children (Study 1)  
At Risk Adults and Children (Study 2)

STUDY DESIGN	<ul style="list-style-type: none"> <li>• Open-label</li> <li>• Teplizumab or anti-thymocyte globulin more likely to be a control</li> <li>• XX participants</li> <li>• Ascending dose SAB-142 study</li> <li>• XXX mg/kg (preclinical NHP data will adjust)</li> <li>• Biomarker-driven escalation with adaptive randomization based on Safety + CD4, CD8+ cells and Tregs</li> </ul>	<ul style="list-style-type: none"> <li>• Randomized, blinded, placebo and teplizumab controlled</li> <li>• 90 (45:45), a control is either anti-thymocyte globulin or teplizumab</li> <li>• SAB-142 vs anti-thymocyte globulin / teplizumab</li> </ul>
ENDPOINTS	<ul style="list-style-type: none"> <li>• Primary: acute and long-term safety</li> <li>• Primary Proof of Biological Activity: C-peptide</li> <li>• Secondary: pharmacokinetics, pharmacodynamics, hypersensitivity (anti-drug antibody), C-protein, HbA1c, T regs, CD3, CD8/CD4 and other markers.</li> </ul>	<p><b>New and Recent Onset T1D in Adults and Children (Study 1):</b></p> <ul style="list-style-type: none"> <li>• Primary: improvement/control of T1D disease</li> <li>• Secondary: safety, pharmacokinetics, pharmacodynamics, hypersensitivity and serum sickness (anti-drug antibody), C-protein, HbA1c, CD3, CD8/CD4 and other markers.</li> </ul> <p><b>At Risk Adults and Children (study 2):</b></p> <ul style="list-style-type: none"> <li>• Primary: time to onset of clinical stage (Stage 3) T1D</li> <li>• Secondary: safety, pharmacokinetics, pharmacodynamics, hypersensitivity and serum sickness (anti-drug antibody), C-protein, HbA1c, CD3, CD8/CD4 and other markers.</li> </ul>

# SAB-142 Type 1 Diabetes Development Timelines



## Summary

- **Executive Management:** Proven team with biotech startup, rapid drug development, and entrepreneurial experience.
- **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.
- **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-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-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 submission expected in 2024.



# APPENDIX

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# Multi-Pronged Business Strategy Powered by Novel Proprietary Platform

*Opportunity to Create New Class of Immunotherapies*



# Intellectual Property

## Regulatory Exclusivity

Reference Product Exclusivity (RPE) prevents licensure of aBLA for biosimilar SAB-176 (2040 + 6 mo PED<sup>1</sup>)

Reference Product Exclusivity (RPE) prevents licensure of aBLA for biosimilar SAB-CDI (2041 + 6 mo PED<sup>1</sup>)

Reference Product Exclusivity (RPE) prevents licensure of aBLA for biosimilar SAB-142 (2041 + 6 mo PED<sup>1</sup>)

## Patent Exclusivity

Human Artificial Chromosome Vector (11/17/30)

Chromosome Engineering to Produce Human Abs (8/5/33)

System to Produce pAbs (11/25/36)

New Antigen / Indication Specific pAb filings (2H 2043) + potential PTE for each pAb approved (14yr cap)

Trade secrets (e.g. manufacturing), proprietary materials (e.g., cell lines)



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

<sup>1</sup>Potential Pediatric Exclusivity + 6 months



# Scaled Infrastructure & Capacity: Tc Bovine & Plasma Production Facility



# Scaled Infrastructure & Capacity: Laboratory & Manufacturing



**SAB Biotherapeutics to Present New Data at ISIRV OPTIONS XI Conference  
on SAB-176 Phase 2a Influenza Trial and SAB-185's Effectiveness  
Against Multiple COVID-19 Variants**

SIOUX FALLS, S.D., Sept. 23, 2022 (GLOBE NEWSWIRE) – SAB Biotherapeutics (Nasdaq: SABS), ("SAB"), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, fully-human polyclonal antibodies without the need for human donors, announced today that the Company will present new data on its fully-human polyclonal antibody platform's ability to maintain its efficacy against multiple variants of several highly mutating viruses at the Options for Control of Influenza (OPTIONS XI) conference, which is hosted by the International Society for Influenza and other Respiratory Virus Diseases (ISIRV) in Belfast, Northern Ireland, from Sept. 26-29, 2022.

SAB will conduct an oral presentation, titled **"Efficacy and Safety of SAB-176, a Novel Anti-Type A and B Influenza Immunotherapeutic: A Phase 2a, Randomized, Double-Blind Trial in H1N1 Challenged Adults,"** on Thursday, Sept. 29, at 11: 24 AM BST.

Additionally, SAB will present a poster, titled **"Transchromosomal Bovine-Derived Human Anti-SARS-CoV-2 Polyclonal Antibodies Protect hACE2 Transgenic Syrian Hamsters Against Multiple SARS CoV-2 Variants,"** on Tuesday, Sept. 27, from 5:30-7 PM BST.

"We look forward to highlighting the power of polyclonal antibodies to neutralize highly mutating viruses and the differentiation of SAB's novel therapeutic products at the upcoming ISIRV conference," said Eddie Sullivan, co-founder, President, and Chief Executive Officer of SAB.

To view the OPTIONS XI program online, please visit: <https://www.optionsxi2022.org.uk/programme>.

**About SAB Biotherapeutics, Inc.**

SAB Biotherapeutics, Inc. (SAB) We are 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**

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.

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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-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.

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