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): November 21, 2022

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 November 21, 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 (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 8.01 Other Events.

As previously disclosed, on October 5, 2022, the Company received a written notification from The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that it was not in compliance with Nasdaq Listing Rule 5450(a)(1), as the closing bid price for the Company’s common stock was below the $1.00 per share requirement for the 30 consecutive business days preceding the written notification.

On November 21, 2022, the Company received a written notification from Nasdaq notifying the Company that Nasdaq has determined that for ten (10) consecutive business days, from November 7, 2022 to November 18, 2022, the minimum closing bid price for the Company’s common stock was at least $1.00 per share. Accordingly, Nasdaq has determined that the Company has regained compliance with Listing Rule 5450(a)(1) and it has indicated that the matter is now closed.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Presentation dated November 21, 2022
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: November 21, 2022

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

EXHIBIT 99.1

SAb BIOTHERAPEUTICS

ADVANCING A POWERFUL NEW CLASS OF IMMUNOTHERAPEUTIC ANTIBODIES

November 2022

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

SAb BIOTHERAPEUTICS

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.

Human Polyclonal Antibodies Produced in Transchromosomic Bovine

Tc Bovine™ contain all the human immunoglobulin genes

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

Tc Bovine™

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

Versatile Antibody Platform with Ability to Capture Multiple Modalities

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

Polyclonal Antibody Development

–Fully-human, targeted, high-potency
–Multivalent, multi-targeted

Human Immunoglobulin

–Specifically targeted
–Large-scale, consistent, managed donor pool, genetically representing single human donor

Monoclonal Antibody Discovery

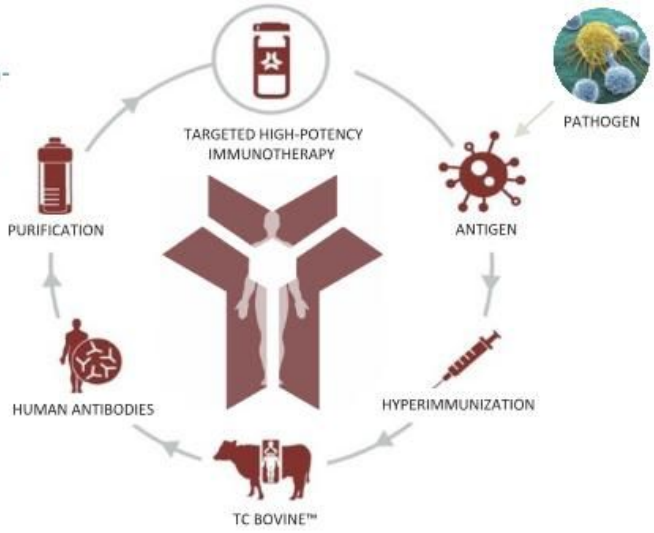
–Larger volume of antibodies
–Greater diversity; higher affinity
–Robust (ruminant) immune response

- **Robust pipeline across multiple therapeutic areas**
- **Potential to capture monoclonal, hIVIG, animal polyclonal markets and address unmet needs**
- ***In vivo* data demonstrating comparability to approved subcutaneous product and potential benefits over human-derived**
- **Multiple ongoing global pharma collaborations**

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

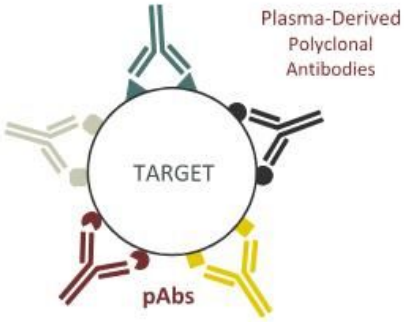


SAB Polyclonal Antibodies: Next Generation of Biologics

Key Product Differentiators:

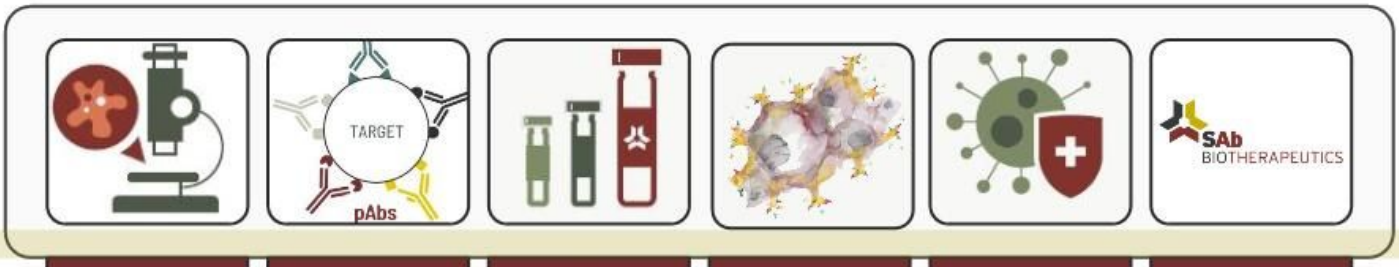
- Multi-target capability in a single therapeutic
  - ✓ Natural multi-epitope targeted pAb selected and produced *in vivo*
  - ✓ Ability to target multiple antigens to disease
- Specifically driven high-potency antibody titers and avidity
- Naturally activates cellular immunity
- Effective against escape mutants with reduced possibility for resistance
- Ability to target human antigens

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



Natural mixture of many **human** antibodies that bind to multiple epitopes

SAB Biotherapeutics Fact Sheet



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

DiversitAb™ Platform is Clinically Validated Across Several Targets

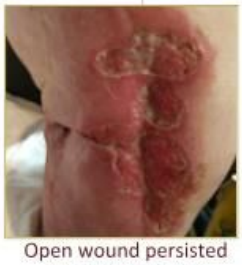
3 INDs & 1 CTA	Filed in US and ex-US
7 Clinical Trials	Span from Phase 1 to Phase 3 across 3 indications
Public Collaborations	DoD, BARDA, NIH NIAID, Naval Medical Research Center, USAMRIID
Academic Collaborations	Brigham and Women's Hospital, Harvard, University of South Dakota, University of Pittsburgh

Referenced Trials:

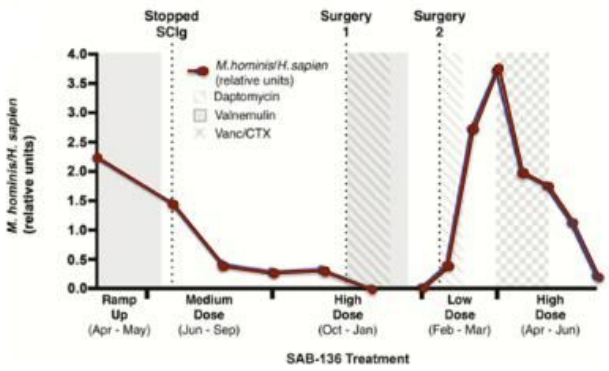
- Safety, Tolerability, and Pharmacokinetics of SAB-176 in Healthy Participants – Full Text View - ClinicalTrials.gov
- Study of SAB-176 in Healthy Adult Participants - Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-185 in Healthy Participants – Full Text View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

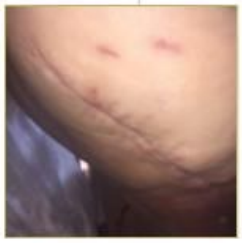
Demonstrated Human Safety and Efficacy in Multi-Dosing Regimen

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

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

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 TRANSCHROMOSOMAL BOVINE FOR PERSONALIZED ANTIMICROBIAL THERAPY, CLINICAL INFECTIOUS DISEASES, VOLUME 66, ISSUE 7, 1 APRIL 2018, PAGES 1116–1119

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SELECTED PIPELINE PROGRAMS

Robust 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						

Clinical Development Programs: Focus Over the Next 4+ Years

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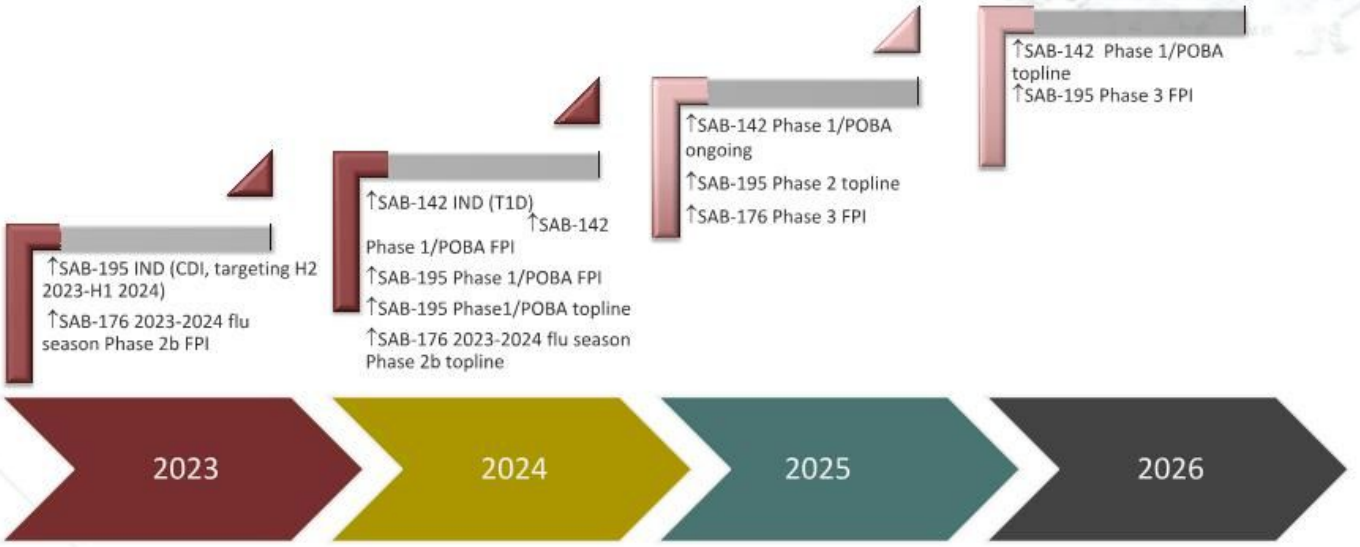

FPI: *First Patient In*
POBA: *Proof of Biological Activity*
HV: *Healthy Volunteers*
CDI: *Clostridioides Difficile Infection*
T1D: *Type 1 Diabetes*

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SAB-176:

First-In-Class Biologic Anti-Influenza Treatment

Unmet Need of Seasonal Influenza

CDC; 2018-19 FLU SEASON

Devastating health and economic impacts

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

No current effective treatment for seasonal influenza

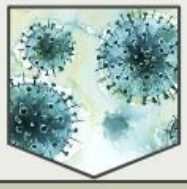
- Current antiviral has a 48-hour window
- Approved antiviral small molecule treatments may shorten duration of fever and symptoms, but not effective against clinically meaningful endpoints or neuraminidase mutation; limited efficacious window

Value Proposition: SAB-176

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

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: Oseltamivir Resistant (OR) H1N1pdm Virus Challenge Model

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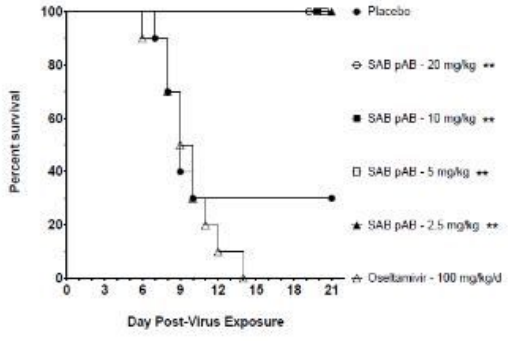
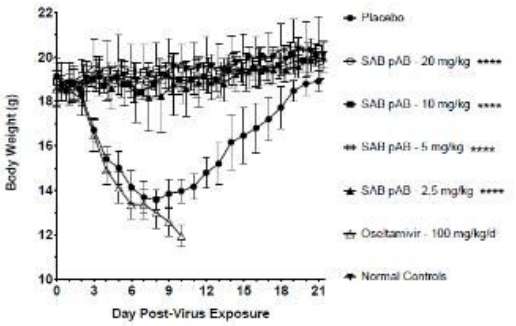
SAB-176 Showed 100% Protection at All Dose Levels From Mortality

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



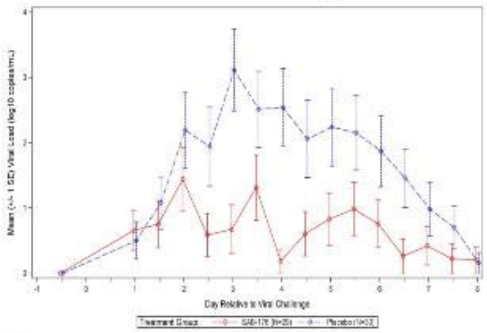
SAB-176 Protected Mice from Weight Loss While Oseltamivir Didn't



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

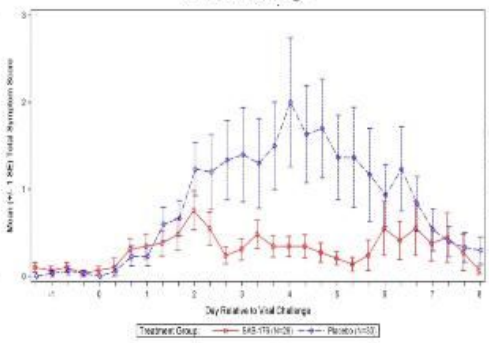
Achieved Statistically Significant (p = 0.026) Reduction in Viral Load

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



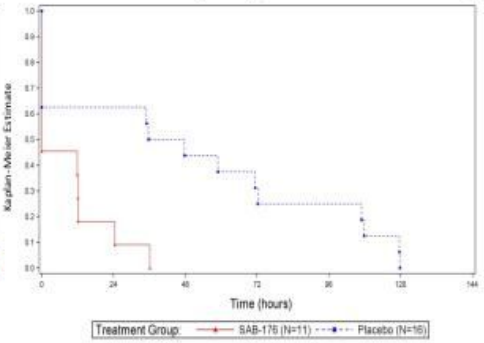
SAB-176 Achieved Statistically Significant (p = 0.013) Improvement in Symptoms at Day 4

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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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	• Randomized, double-blind, placebo-controlled • 27 healthy volunteers • Single ascending dose study • 1, 10, 25 and 50 mg/kg	• 60 total participants • 60 randomized to SAB-176 or control (30-30) • Challenge strain: H1N1 California (pandemic)	• 300-600 participants • High-risk of serious influenza with symptoms < 4 days • SAB-176 and standard of care vs standard of care • Dose ranging	• ~1,000 participants (TBD) • High-risk of serious influenza with symptoms ≤ 3-4 days • SAB-176 and standard of care vs standard of care
ENDPOINTS	• Primary: safety • Secondary: pharmacokinetics, pharmacodynamics, anti-drug antibodies	• Primary: safety and viral load reduction • Secondary: sign/symptom reduction	• Primary: time to onset of clinically significant influenza • Reduction of risk developing influenza symptoms	• Primary: hospitalization and ICU days and death • Secondary: multiple
TIMING	• All participants reached end-of-study • Data being analyzed for final report • Readout expected mid-2021	• Study start 2Q2021 • Readout reported 4Q2021	• Multi-site: Northern hemisphere and/or Southern hemisphere	• Multi-site: Northern hemisphere and/or Southern hemisphere

SAB-176 Development Timelines

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SAB-185: COVID-19

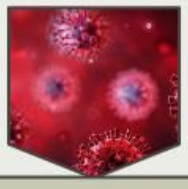
Value Proposition: SAB-185

First-in-class fully-human broadly neutralizing polyclonal antibody treatment designed to reduce risk of losing efficacy to escape mutants for high-risk COVID-19 patients

Key Differentiators

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

Only biologic treatment showing neutralizing activity against mAb escape mutants



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

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

SAB-185 Protects Recombinant hACE2 Hamsters from Mortality and/or Severe Morbidity from SARS CoV-2 Variants Including Omicron

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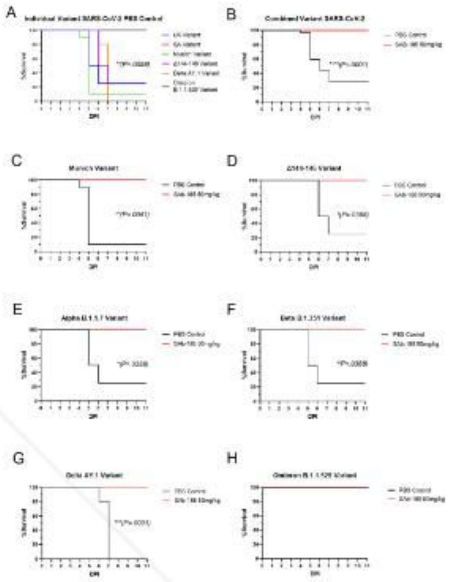
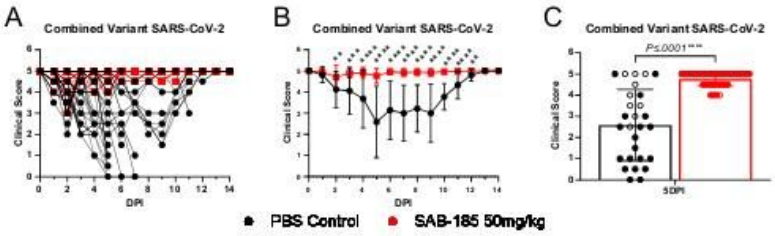
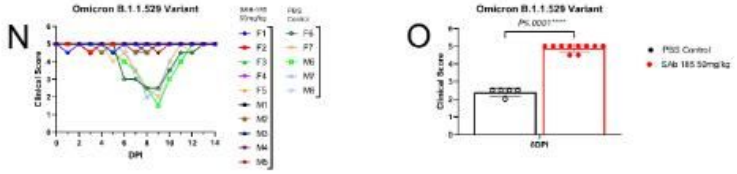
SAB-185 protection from mortality in hamsters challenged with six variant SARS CoV-2 isolates



SAB-185 protection from clinical signs in hamsters challenged with six variant SARS CoV-2 isolates



SAB-185 protection from clinical signs in hamsters challenged with Omicron variant



University of Pittsburgh

UtahState University

Phase 2 Data from NIH ACTIV-2 Trial Confirms SAB-185 Met Virology Endpoints for Graduation to Phase 3

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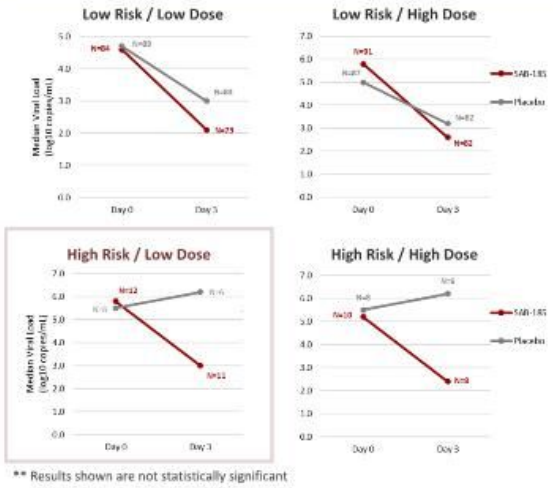
Viral load reductions of ≥0.5 log_{10} for both lower and higher dose at Day 3

INTERIM ANALYSIS

	LOW-DOSE (3,840 UNITS/KG)	HIGH-DOSE (10,240 UNITS/KG)
Difference from PBO for RNA level (log_{10} copies/ml)	1.48	0.67
Minimum RNA level difference (log_{10} copies/ml)	0.5	0.5
Minimum Posterior Probability	0.6*	0.6*
Actual Posterior Probability	0.91	0.75

*. The choice of 0.6 for this Bayesian probability indicates that there is a 3 to 2 odds of the agent being better than placebo by the desired amount (≥0.5 log_{10} /ml) for the outcome measure.

Sub-analysis** of viral load reduction shows pronounced impact in small subset of high-risk patients given either lower or higher dose



** Results shown are not statistically significant

NIH NIAID (ACTIV) IN COLLABORATION WITH THE AIDS CLINICAL TRIALS GROUP (ACTG)

SAb BIOTHERAPEUTICS

SAB-195:

Clostridioides difficile Infections: Fast to Proof-of-Concept

High Unmet Medical Needs Remain

High Morbidity, Mortality, and Costs

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

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

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

Value Proposition: SAB-195

First-in-class fully-human 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:

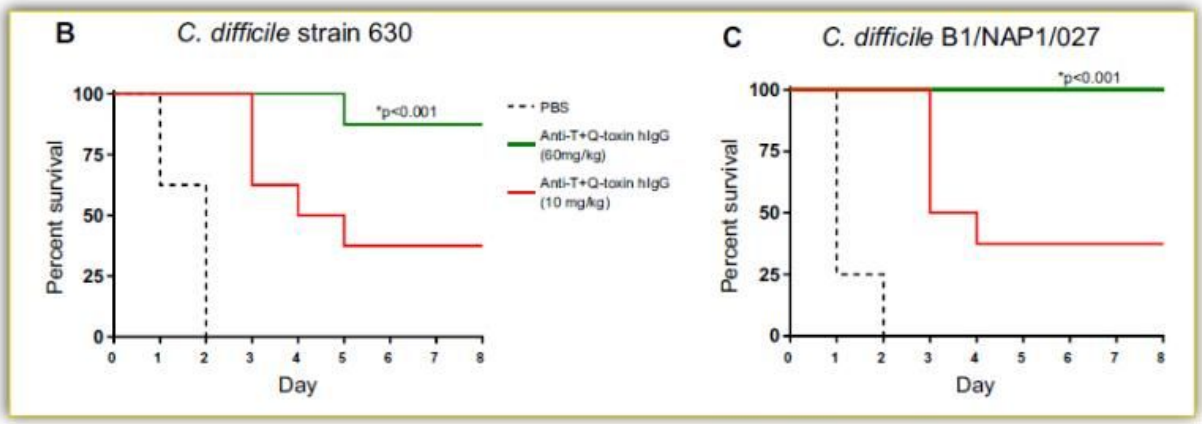
- Unlike bezlotoxumab, SAB-195 targets surface antigens on C. diff bacteria and spores
- Unlike antibiotics, SAB-195 targets several C. diff toxins responsible for severity of the disease

SAB-195 is a target-specific treatment targeting only C. diff bacteria 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)



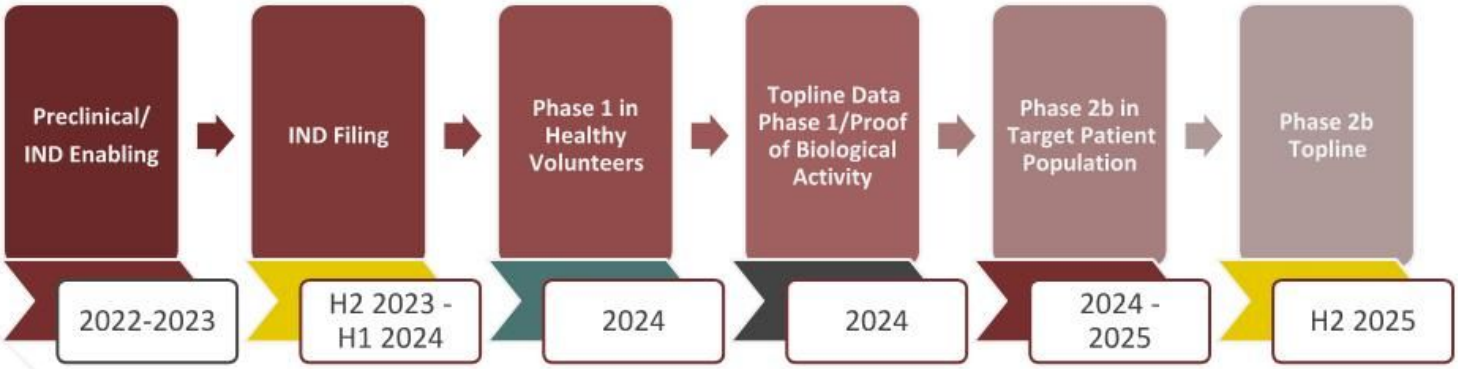
Tc bovine-derived anti-quadrivalent toxin hIgG provided 90% to 100% protection in hamsters against CDI strain 630 or more virulent epidemic strain NAP1

- 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-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	• 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 • Study populations: = HVs for single ascending dose SAB-195 study (Phase 1) = Subjects meeting high-risk criteria: >65-years old, pharmacokinetic (PK), anti-drug antibody (ADA) immunocompromised, Phase 1 = Patients with mild-moderate CDI (Proof of Biological Activity) • XXX mg/kg (determined based preclinical in vitro and in-vivo data)	• 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). • Followed by randomized, double-blind, placebo-controlled Phase 3 trial(s) • Active comparators vary by indication: antibiotics for treatment of CDI-associated diarrhea; bezlotoxumab for reduction of CDI recurrence • Study population: Patients >18 years old who are at a high risk for CDI recurrence
ENDPOINTS	• Primary for Phase 1: acute and long-term safety • Primary Proof of Biological Activity: proportion of CDI patients with clinical cure at Days 14-16 • Secondary Phase 1: pharmacokinetics (PK), pharmacodynamics, anti-drug antibody (ADA), healthy microbiome impact • Secondary Proof of Biological Activity: proportion of CDI patients with clinical cure at Days 30 & 60	• Co-primary end points: = Treatment of CDI: proportion of patients with clinical cure at Day 14-16 (Indication 1) = Reduction of CDI recurrence: sustained clinical response rate vs standard of care (SOC) at 12 weeks (Indication 2) • Secondary end points: = Safety, pharmacokinetic (PK), anti-drug antibody (ADA), microbiome impact

SAB-195 Development Timelines



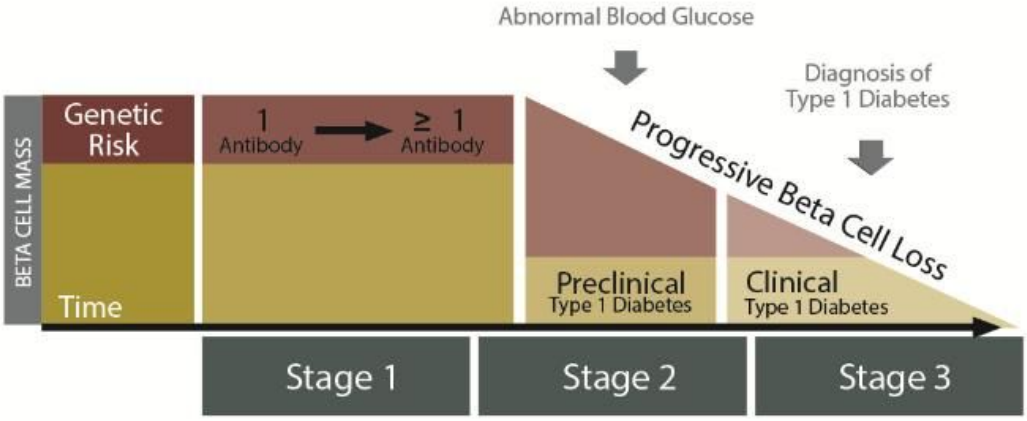
SAb BIOTHERAPEUTICS

SAB-142:
Type 1 Diabetes (T1D) Prevention

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

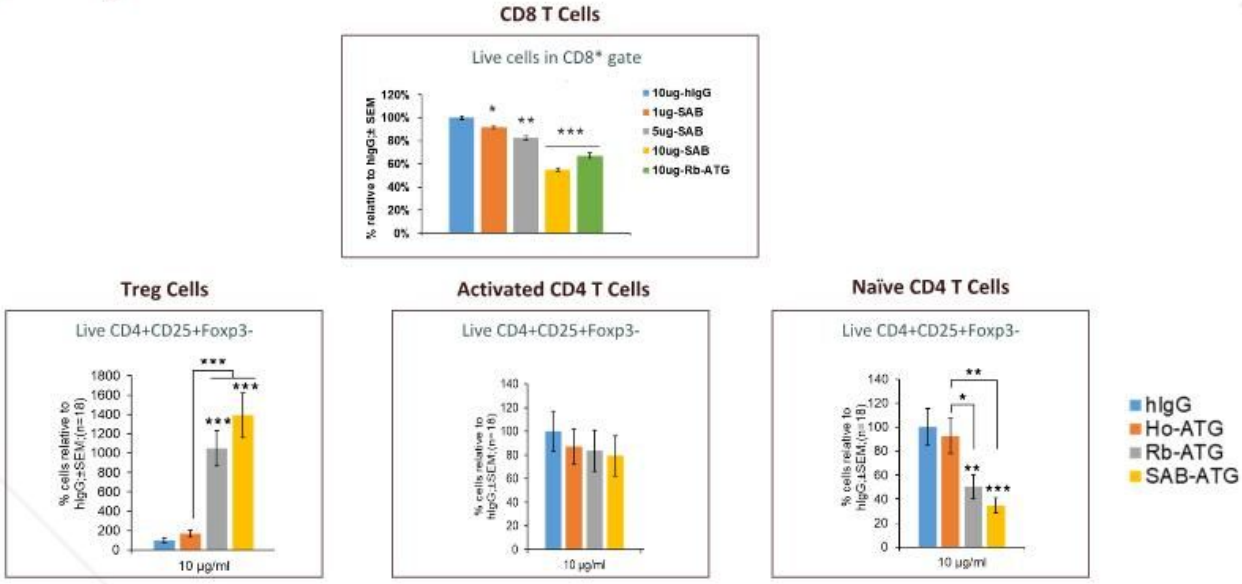
First-in-class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 Type 1 Diabetes (T1D)

Key Differentiators

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

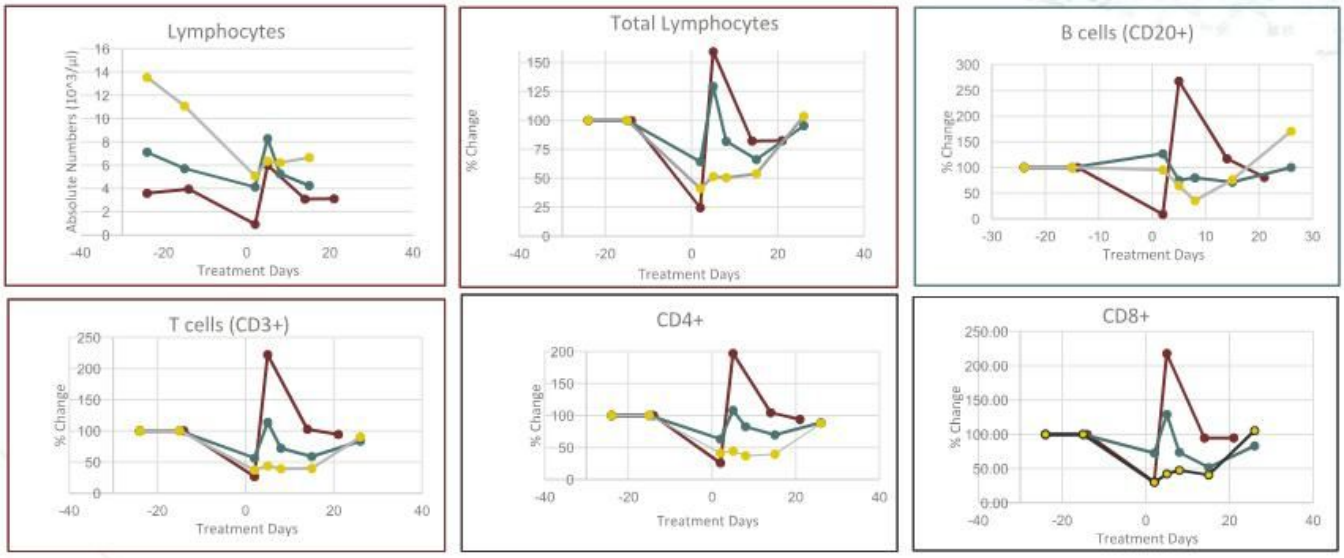
Validated Mechanism of Action by a 3rd party ATG demonstrating reduction in loss of C-peptide vs. placebo (Haller, 2019)

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



SAB-142 Preclinical Data Continued

Major Subsets of Peripheral Blood Lymphocytes



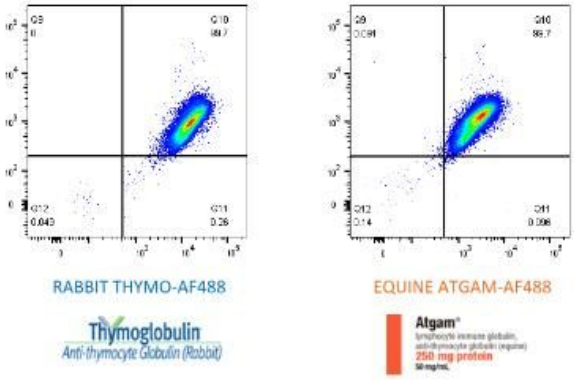
Changes in major subsets of peripheral blood lymphocytes (total lymphocytes. T and B cells, CD4+ and CD8+ T helpers and killers, respectively) following SAB-142 and ATG treatments. **Red: 5 mg/kg ATG; Blue: 1 mg/kg SAB-142; Grey: 5 mg/kg SAB-142**

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

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

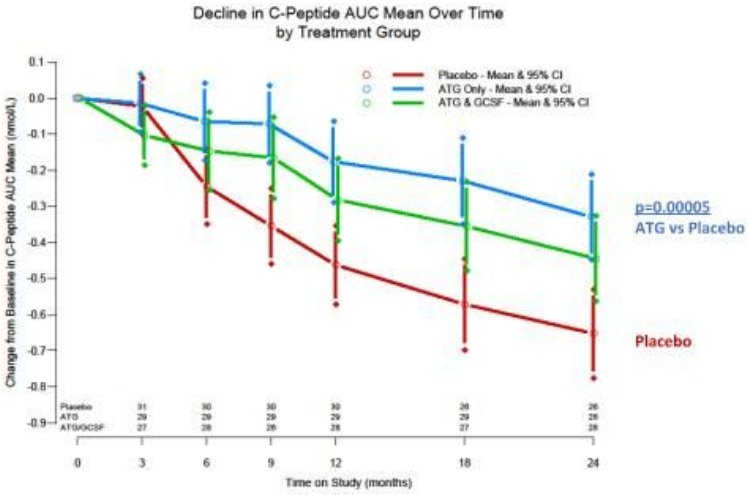
SAb BIOTHERAPEUTICS

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



RABBIT THYMO-AF488

EQUINE ATGAM-AF488



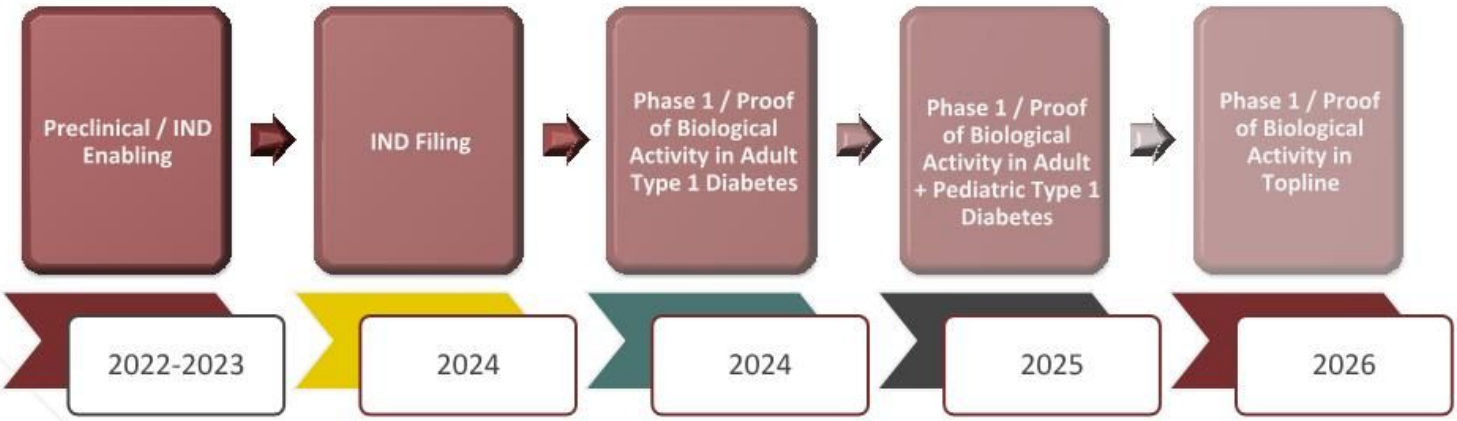
*RABBIT ATG FROM SANOFI – NOT SAB-142 (HUMAN TC-BOVINE DERIVED ATG)

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	• Open-label • Teplizumab or anti-thymocyte globulin more likely to be a control • XX participants • Ascending dose SAB-142 study • XXX mg/kg (preclinical NHP data will adjust) • Biomarker-driven escalation with adaptive randomization based on Safety + CD4, CD8+ cells and Tregs	• Randomized, blinded, placebo and teplizumab controlled • 90 (45:45), a control is either anti-thymocyte globulin or teplizumab • SAB-142 vs anti-thymocyte globulin / teplizumab
ENDPOINTS	• Primary: acute and long-term safety • Primary Proof of Biological Activity: C-peptide • Secondary: pharmacokinetics, pharmacodynamics, hypersensitivity (anti-drug antibody), C-protein, HbA1c, T regs, CD3, CD8/CD4 and other markers.	**New and Recent Onset T1D in Adults and Children (Study 1):** • Primary: improvement/control of TID disease • Secondary: safety, pharmacokinetics, pharmacodynamics, hypersensitivity and serum sickness (anti-drug antibody), C-protein, HbA1c, CD3, CD8/CD4 and other markers. **At Risk Adults and Children (study 2):** • Primary: time to onset of clinical stage (Stage 3) T1D • Secondary: safety, pharmacokinetics, pharmacodynamics, hypersensitivity and serum sickness (anti-drug antibody), C-protein, HbA1c, CD3, CD8/CD4 and other markers.

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-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-185:** First-in-class fully-human broadly neutralizing polyclonal antibody treatment designed to reduce risk of losing efficacy to escape mutants for high-risk COVID-19 patients.
- **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 submission expected in 2024.

SAb BIOTHERAPEUTICS

APPENDIX

Multi-Pronged Business Strategy Powered by Novel Proprietary Platform

*Opportunity **to** Create New Class of Immunotherapies*

DiversitAb Platform

- **RAPID PROOF-OF-CONCEPT** (90 days to cGMP)
- **NATURAL HUMAN ANTIBODIES** (without human donors or serum)
- **MULTI-VALENT CAPABILITIES** (by nature, & by design–multiple targets in one product)
- **TARGET AGNOSTIC** (virus, bacteria, toxin, allergen)
- **SCALABLE, REPLICABLE, CONSISTENT PRODUCTION**

Product Development of Pipeline Assets:
Best-in-Class, First-in-Class & Unmet Needs

- Demonstrated clinical safety and efficacy
- Proof-of-platform with highly-mutating infectious disease
- Robust pipeline with broad therapeutic reach
- Demonstrated *in vivo* efficacy to >12 targets

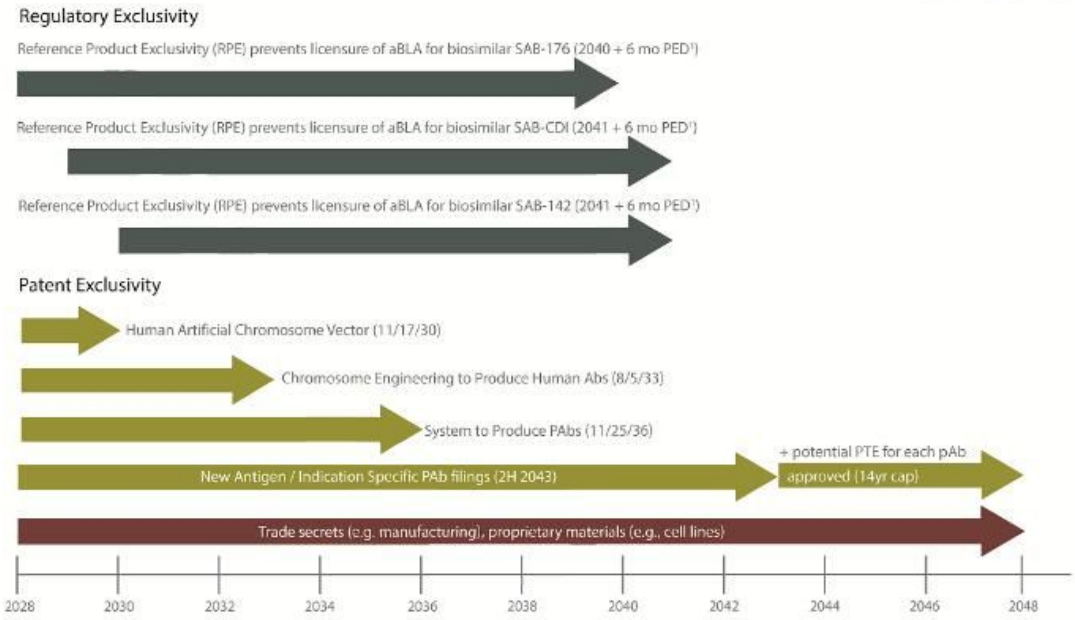
Industry Partnering & Research Collaborations:
Monoclonal Discovery & Polyclonal Development/Production

- Multiple ongoing collaborations with global pharma
- Opportunities in monoclonal discovery, human immune globulins and therapeutic innovation

Global Public Health Security:
Emerging Infectious Disease & Biothreats

- $200M awarded for rapid & pandemic response
- Advancement of programs from preclinical into Phase 3 clinical development in the respiratory therapeutic area

Intellectual Property



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

[1]Potential Pediatric Exclusivity + 6 months

Scaled Infrastructure & Capacity: Tc Bovine & Plasma Production Facility







Scaled Infrastructure & Capacity: Laboratory & Manufacturing


Manufacturing Facility (50L)


Manufacturing Facility (200L)


Fill Suite


Labeling Suite


Cell Culture Lab


50L Suite


CET Lab

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