

**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): June 07, 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 June 7, 2022 at 12:40 EDT, SAB Biotherapeutics, Inc.'s Chief Operating Officer, Christoph Bausch, Ph.D., MBA, will give a presentation at the Large Animal Genetic Engineering Summit ("LAGE") as part of the summit's "Gene Editing to Improve Human Health" track.

The presentation, titled "Leveraging Genetically Engineered Ungulates to Produce Novel Human Biotherapeutics," will highlight SAB's novel immunotherapy platform of Transchromosomal (Tc) Bovine™ (genetically engineered cattle) that can consistently and reliably produce fully human antibodies without the need for convalescent plasma from human donors. Dr. Christoph Bausch will introduce a range of topics, including an overview of SAB's DiversitAb™ platform centered around Tc Bovine and an overview of SAB's pipeline programs that include SAB-185, the company's anti-SARS-CoV-2 therapeutic; SAB-176, the company's seasonal influenza therapeutic; and SAB-142, the company's Type 1 diabetes and organ transplantation therapeutic. Additionally, he will discuss the potential that SAB's novel immunotherapy platform has to expand into personalized medicine through the development of Transchromosomal (Tc) Goats™.

A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The foregoing (including Exhibits 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.

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 SAB-185, our influenza program and other discovery programs, our cash runway into 2023 and potential future government and third-party collaborations or funded programs.

These statements are based on the current expectations of SAB and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on, by any investor as a guarantee, an assurance, a prediction or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict, will differ from assumption and are beyond the control of SAB. A further description of risks and uncertainties can be found in the sections entitled "Risk Factors" in SAB's Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission and available at <https://www.sec.gov/>

Item 9.01 Financial Statements and Exhibits.

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

Exhibit Number	Description
99.1	Large Animal Genetic Engineering Summit Presentation by SAB Biotherapeutics, Inc. on June 7, 2022, furnished herewith.
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 thereunto duly authorized.

SAB Biotherapeutics, Inc.

Date: June 7, 2022

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



Leveraging Genetically Engineered Ungulates to Produce Novel Human Biotherapeutic

Large Animal Genetic Engineering Summit, June 2022

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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. 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.

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

Novel DiversitAb™ Platform for Developing Highly-Differentiated 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 US Government funded programs & partnerships totaling ~\$200MM

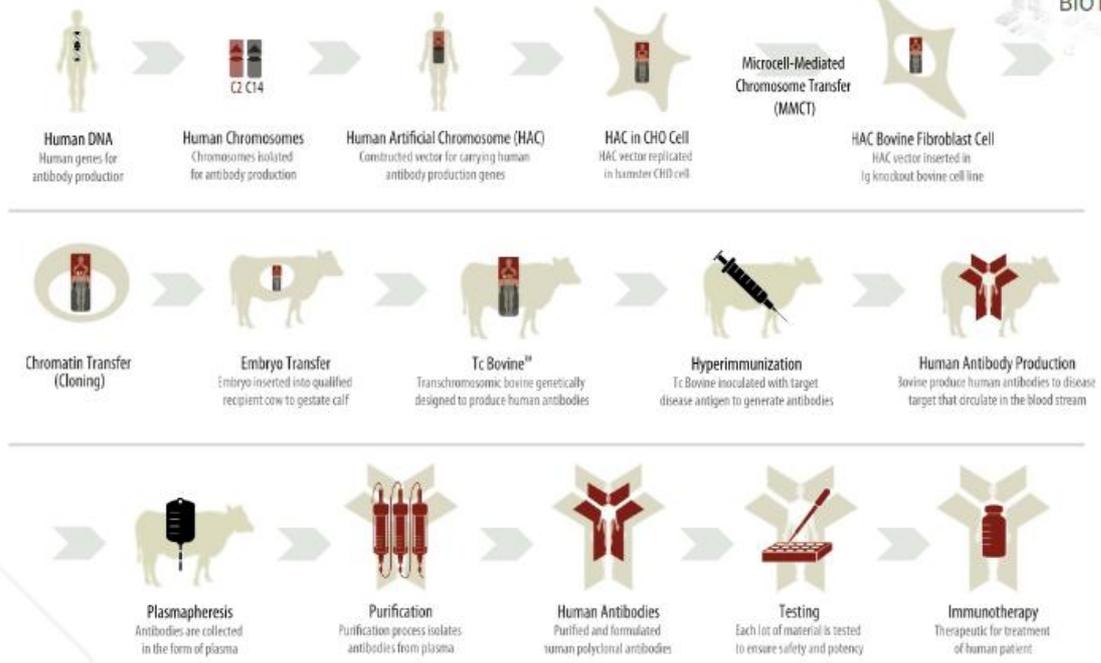


Strong corporate position with experienced leadership team and growing infrastructure



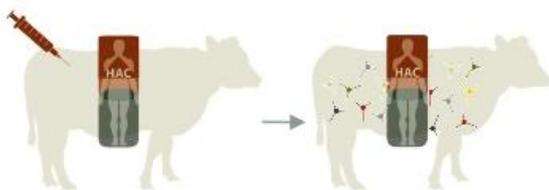
Innovative DiversitAb™ platform produces a new class of targeted fully-human, highly-potent polyclonal antibodies

DiversitAb™ Proprietary Platform Technology

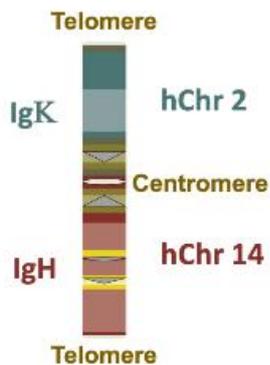


A Natural Way to Produce Human Polyclonal Antibodies

Tc Bovine™ contain all the human immunoglobulin genes



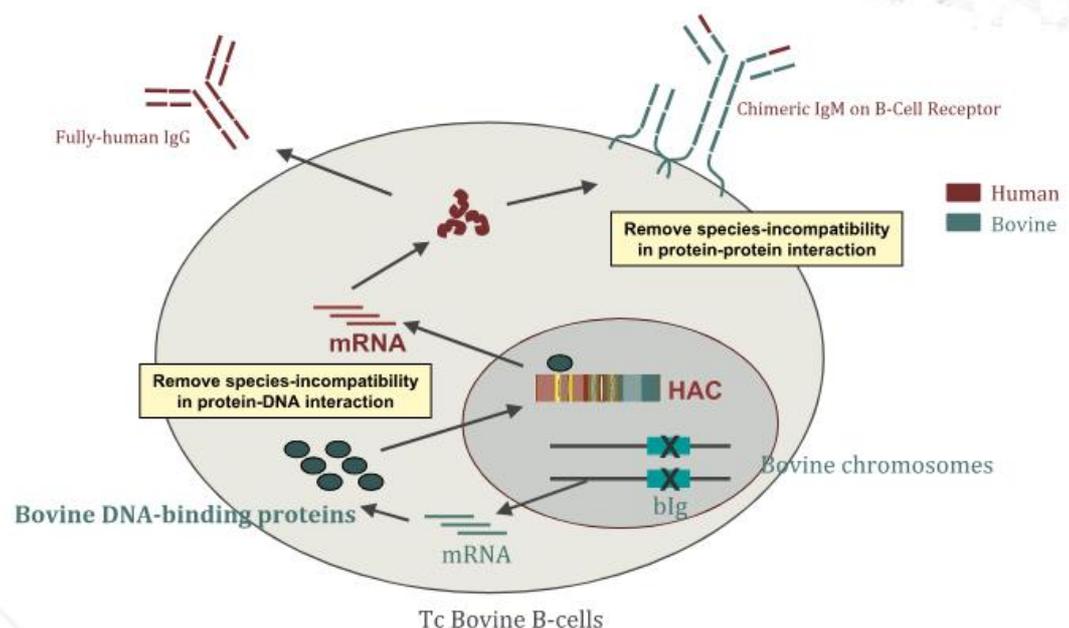
Human artificial chromosome (HAC) contains the entire human immunoglobulin loci (IgH + Igκ)



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 46 chromosomes.
- HAC present in the Tc Bovine allows for the highest production of human antibody repertoire most similar to humans.

Human Antibody Production in Bovine B-Cell



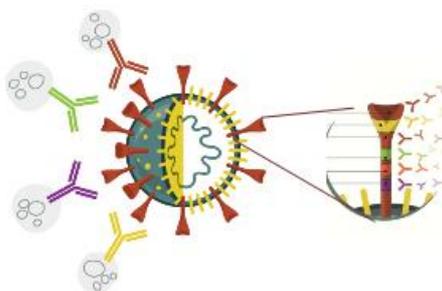
B-Cells Produce Anti-Target Fully-Human Polyclonal Antibodies



Antigen



Transferred full germline repertoire of human antibody response



Rich diversity of IgG antibodies to Spike protein epitopes
Fc binding to FcR ligands allows effector cell recruitment & activates complement



Hyperimmunization

Multiple immunizations drive titers to extremely high levels with exceptional avidity maturation and potency

B-Cells Produce Human Antibodies

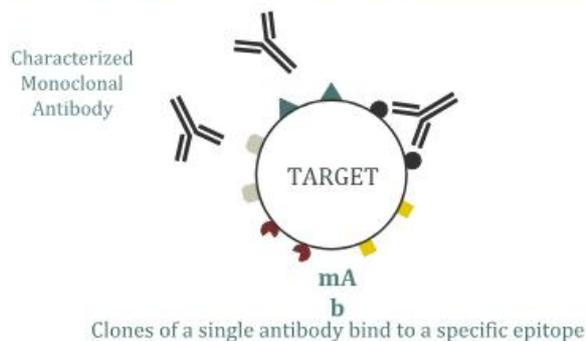
Natural and somatic mutation drives very high-level B-cell clone avidity maturation in Tc Bovine

Therapeutic

Diverse mixture of anti-Target human polyclonal antibodies allowing production of a fully-human immunoglobulin (hIgG)

Polyclonals: Broader Spectrum Efficacy Valuable in Range of Indications

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

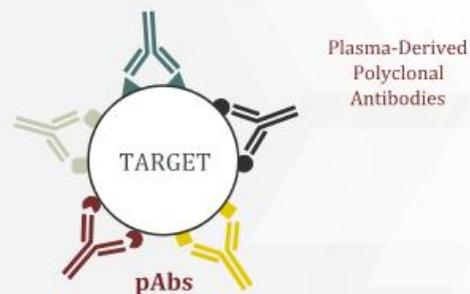


Monoclonal Approach

- 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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FDA: CENTER FOR **BIOLOGIC** EVALUATION & RESEARCH (CBER)



Polyclonal Approach

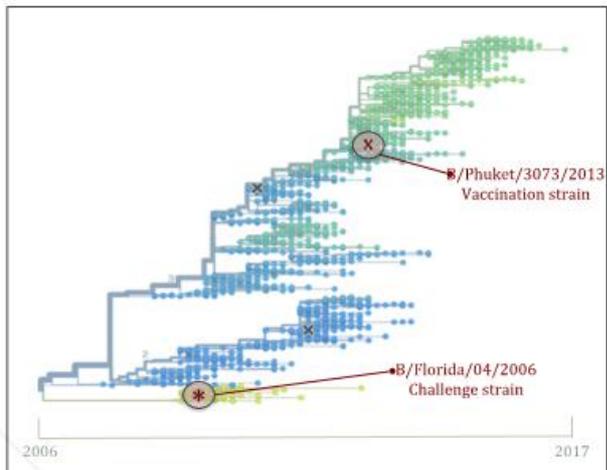
- Diversity of antibodies with multiple modalities
- Naturally selected and produced *in vivo*
- Effective against escape mutants
- Reduced possibility of resistance
- Activates cellular immunity
- Synergistic properties not duplicated by mono- or oligoclonals

Efficacy Against Mutational Drift

Adaptive & Cross Reactive to Mutating Strains

Highly-Mutational Influenza Virus

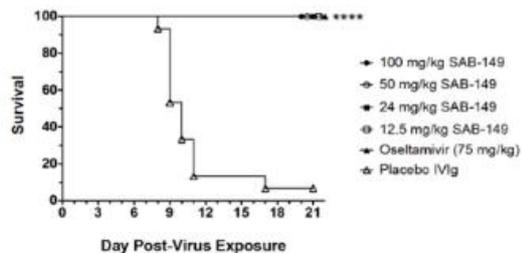
BYAM PHYLOGENIC TREE



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



Consistent, Replicable Platform

In Vivo Efficacy Demonstrated Across a Broad Range Targets

TARGET	EFFICACY	MODEL(S)	COLLABORATORS
Anthrax	100%	mouse (lethal)	Food and Drug Administration
Alphaviruses	100% 100%	mouse (lethal aerosol) non-human primate (viral clearance)	Naval Medical Research Center, University of Pittsburgh, NIH: National Institute of Allergy and Infectious Diseases
Clostridium Difficile	100% 87%	hamster (lethal) mouse (lethal)	Novavax
Dengue	100%	non-human primate (viral clearance)	Naval Medical Research Center
Ebola	90% 100%	mouse (lethal) non-human primate (lethal)	Naval Medical Research Center, NIH: National Institute of Allergy and Infectious Diseases, Novavax
Hantavirus	80-100% 100%	hamster (lethal) non-human primate (viral clearance)	United States Army Medical Research Institute of Infectious Diseases
Influenza	100% 100%	mouse (lethal) mouse (lethal aerosol)	National Institutes of Health, University of South Dakota, Utah State University, Naval Medical Research Center
Plague*	100%	Mouse (lethal aerosolized)	United States Army Medical Research Institute of Infectious Diseases
MERS-CoV	100%	mouse (viral clearance)	Biomedical Advanced Research and Development Authority, Naval Medical Research Center, NIH: National Institute of Allergy and Infectious Diseases, Novavax
Zika	100% 100% 100%	mouse (lethal) hamster (lethal) non-human primate (viral clearance)	Public Health Agency of Canada, Utah State University Harvard University

*Current DoD interest

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Human Clinical Trial Experience

Clinical Trial Proof of Concept

CLINICAL TRIAL	INDICATION	COLLABORATORS
Phase 1b	Mycoplasma hominis	Brigham and Women's Hospital, Harvard
Phase 1	MERS-CoV	Naval Medical Research Center; NIH NIAID
Phase 1	Type A and B Influenza	Naval Medical Research Center; University of South Dakota
Phase 2a	Type A and B Influenza	Naval Medical Research Center; University of South Dakota
Phase 1	SARS-CoV2	DoD; BARDA; University of Pittsburgh
Phase 1b	SARS-CoV2	DoD; BARDA; University of Pittsburgh
Phase 2	SARS-CoV2	DoD; BARDA; DAIDS NIH NIAID; University of Pittsburgh
Phase 3	SARS-CoV2	DoD; BARDA; DAIDS NIH NIAID; University of Pittsburgh

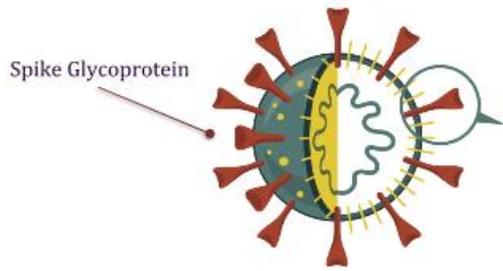


SAB-185 Anti-SARS-CoV2



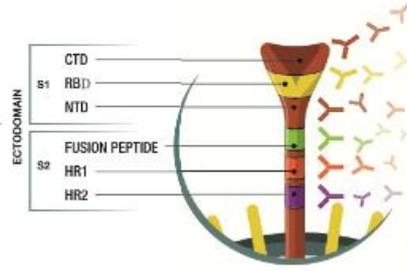
SAB-185: Specifically Targeted Human Immune Response

MOA of Novel Polyclonal Antibody Raised Against SARS-CoV-2 Spike Protein



Spike Glycoprotein

Receptor binding domain in S1 spike protein binds to ACE-2 receptor on human cells; then undergoes a conformational change to allow the S2 spike protein domain to fuse with the cellular membrane leading to infection of the cell



Multiple blocking and neutralizing antibody species bind to single epitope

Multiple blocking and neutralizing antibodies with uniquely determined and multifactorial paratopes bind to single multi-conformational antigen epitope

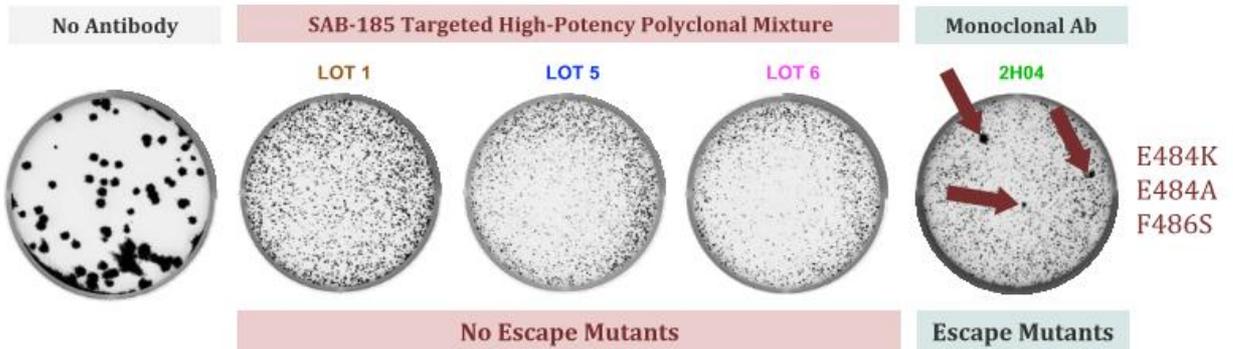
Diversity of antibodies and uniquely combinatorial paratopes drives effector functions including antibody and complement dependent cellular cytotoxicity

SAB-185 Polyclonal Spike Protein MOA

Antibodies bind multiple conformations of SARS-CoV-2 extracellular spike protein epitope and appears to prevent most all conformations of the infectious determinant spike protein from interacting with ACE-2 receptors on host cells, allowing effector cells to phagocytize virus and eliminate/lyse infected cells via complement

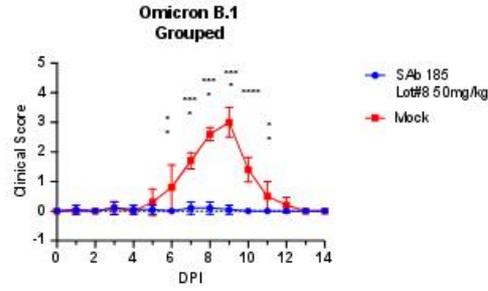
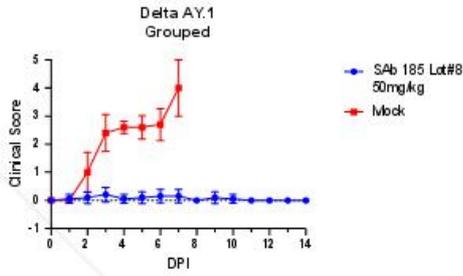
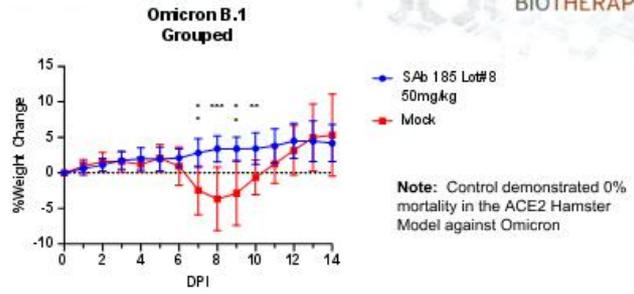
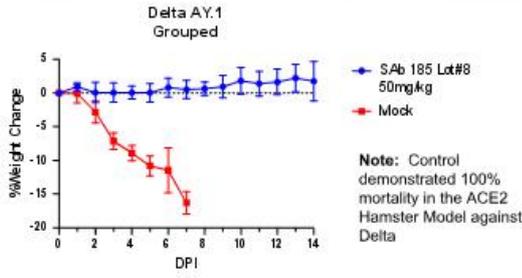
Addresses Escape Mutants: SAB-185 Superior to Monoclonal Antibody

Selection for VSV-SARS-CoV-2 Wild Type Escape Mutation



WASHINGTON UNIVERSITY SCHOOL OF MEDICINE-ST. LOUIS; 15 JAN 2021

SAB-185 Provides 100% protection against Delta and Omicron in an in-vivo hACE2 Hamster model



PERFORMED BY WILLIAM KLIMSTRA'S LAB AT UNIVERSITY OF PITTSBURGH; hACE2 HAMSTER MODEL DEVELOPED BY WANG LAB AT USU



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

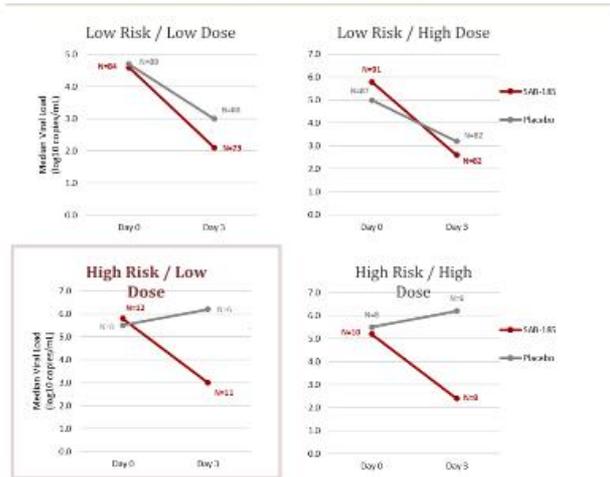
Viral load reductions of $\geq 0.5 \log_{10}$ for both lower and higher dose at Day 3

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 ($\geq 0.5 \log_{10}$ /ml) for the outcome measure.

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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)

Robust Pipeline with Broad Therapeutic Reach



	Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Infectious Disease	SAB-185	COVID-19 (USG FUNDED)	Phase 3 Trial (NIH ACTIV-2)			
	SAB-176	SEASONAL INFLUENZA	Phase 1 Trial & Phase 2a Challenge Study Enrollment Complete			
Autoimmune Disease	SAB-142	TRANSPLANT (INDUCTION/REJECTION)				
	SAB-142	TYPE 1 DIABETES				

Ongoing discovery programs in oncology, autoimmune, infectious and idiopathic diseases

Government-funded clinical-stage program in Middle East Respiratory Syndrome (MERS) coronavirus



Tc Goats™ - Expanding The Human Immunotherapeutic Platform for Personalized Medicine

Genetic Engineering Science Applied Across



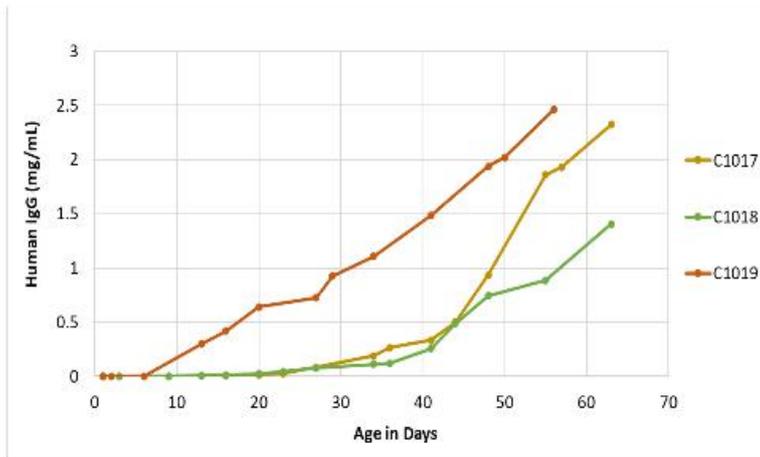
- SAB Capra, LLC. is a wholly-owned subsidiary of SAB Biotherapeutics, Inc.
- Advancing novel antibody production platform leveraging transgenic goats
- Functionality of the HAC proven in a second species (ruminant ungulate)
- Generated H7N9-specific human polyclonal antibodies from Tc Goat (caprine) platform. Scientific Reports, 2019
- SAB Capra Phase 2 STTR Grant (NIH/NIAID): in collaboration with Utah State University
- Total funding \$1,501,157 (\$926,194 to SABC, \$574,963 to USU)
- Two years: 18 Apr 2019 – 31 Mar 2021
- Two times of 12-month no cost extension granted—new end date 31 Mar 2023
- Genetic optimization in our Tc Bovine was done in 10 years while the goat optimization was done in 2 years.

Demonstrated Fully Human IgG in Tc Goat



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Human IgG in Tc Capra Kids



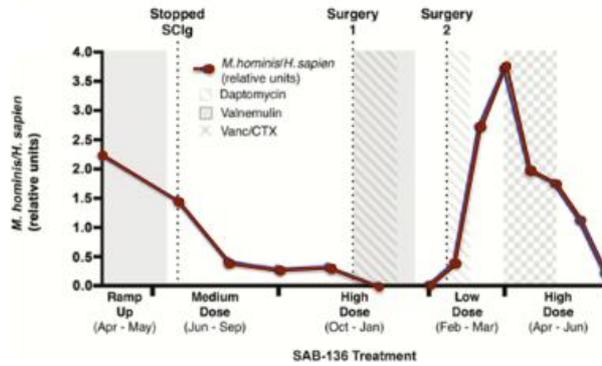
Positioned for Personalized Medicine

Confirms Feasibility of Multi-dosing

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.

Advancing the Tc Platform for Continued Advancement of Human Health



- Developing targeted human polyclonal antibodies for use in personalized medicine
- Tc Goat platform production ready for producing diagnostics and testing reagent applications.
- Accommodating smaller volume markets, lower cost of development and maintenance, and accelerated scaling (shorter gestation, multiple births)

