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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-39871

SAB BIOTHERAPEUTICS, INC.
(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**85-3899721** **(I.R.S. 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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2022, was $114,540,000.

The number of shares of the registrant's common stock outstanding as of March 28, 2023 was 50,397,762.

Portions of the registrant's proxy statement for the 2023 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference in Part III of this Form 10-K.

Auditor Firm Id: 199 Auditor Name: Mayer Hoffman McCann P.C. Auditor Location: San Diego, California, United States

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are based on our management's current beliefs and assumptions and on information currently available to our management, and are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "best in class," "could," "seeks," "estimates," "expects," "first-in-class," "focused," "goal," "intends," "may," "objective," "opportunity," "pipeline," "plans," "potential," "predicts," "projects," "pursuing," "should," "target," "treatment option," "will," "would," "might," "can," "continue" or similar expressions and the negatives of those terms.

These forward-looking statements include, among other things, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding our plans for clinical development of our product candidates, the initiation and completion of clinical trials and related preparatory work and the expected timing of the availability of results of clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the potential indications, attributes and benefits of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete further development, approval and, if approved, commercialization of our product candidates;
- the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expense and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to identify, in-license or acquire additional product candidates;
- our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we are pursuing for our product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection;
- our ability to contract with and rely on third parties to assist in conducting our clinical trials and manufacturing our product candidates;
- our manufacturing capabilities, third-party contractor capabilities and strategy;
- our plans related to manufacturing, supply and other collaborative agreements;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- the impact of laws, regulations, accounting standards, regulatory requirements, judicial decisions and guidance issued by authoritative bodies;
- our ability to attract and retain key scientific, medical, commercial or management personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- our ability to maintain our listing on The Nasdaq Global Market;
- our ability to continue as a going concern; and
- the effect of COVID-19 on the foregoing.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of proprietary immunotherapeutic fully-human antibodies, or fully-human immunoglobulins (hIgGs), to treat and prevent immune and autoimmune disorders as well as infectious diseases that have significant mortality and health impacts on high-risk patients. These antibodies are target-specific and polyclonal, meaning they are made up of many different hIgGs that bind to multiple sites specific to an immunogen as opposed to a monoclonal antibody that binds to only a single site. Our development programs include autoimmune disorders, gastroenterological, and respiratory diseases. Using private resources and more than $200 million of funds awarded by the U.S. Government emerging infectious disease and medical countermeasures programs since September 2019, we have developed a novel drug development platform, which we refer to as our DiversitAb platform. This platform is based on the natural human immune system and has the unique capability to generate large quantities of specifically targeted, high-potency, hIgG that target multiple epitopes, antigens or binding sites without the need for producing these antibodies from convalescent plasma or human donors. We have refined, optimized, and advanced genetic engineering and antibody science to develop transchromosomic cattle (which we refer to as Tc Bovine) that produce hIgGs and the engineering of the platform drives IgG1 production primarily. These Tc Bovine form a key component of our versatile DiversitAb platform, a fully scalable production system for producing immunotherapies to multiple disease indications. Our platform represents the technology that can produce disease-targeted, fully human IgG without the need for human donors.

We are leveraging our DiversitAb platform to discover and develop product candidates with the potential to be first-in-class against novel targets or best-in-class against known, complex targets that treat diseases with significant unmet medical needs, including immune and autoimmune disorders, infectious gastroenterological and respiratory diseases, and oncology.

Key Product Differentiators Over Existing Technologies

The DiversitAb platform represents the first of its kind technology to produce large scale human high-titer, high-avidity antibodies across multiple modalities and a new source for novel treatments from a unique targeted human hIgG discovery and product development engine. (See Figure 1).

- *Polyclonal Antibody Development (hIgG)* represents the first time that fully human antibodies allow targeting to complex diseases with multiple dysregulated pathways through hyperimmunization to be fully explored as potent immunotherapies that can target multiple different targets and different modes of action all in the same regulated product. This is the first scalable technology that mimics the natural way humans fight disease through production of hIgG.
- *Human Immunoglobulin (hIgG)* is used to treat patients with primary and secondary immune deficiencies as well as other indications and SAB's antibodies have demonstrated comparability to approved subcutaneous delivered, human-derived products with the potential benefits that come from having a controlled source of human antibodies without the need for human donors.
- *Monoclonal Antibody (mAb) Discovery* is accomplished in two ways using the DiversitAb platform: 1) by sequencing antibodies produced from Tc Bovine B-cell clones; and 2) by direct sequencing of target-specific immunogen purified hIgG produced at high concentrations, each representing the potential to capture unique monoclonal antibody candidates.

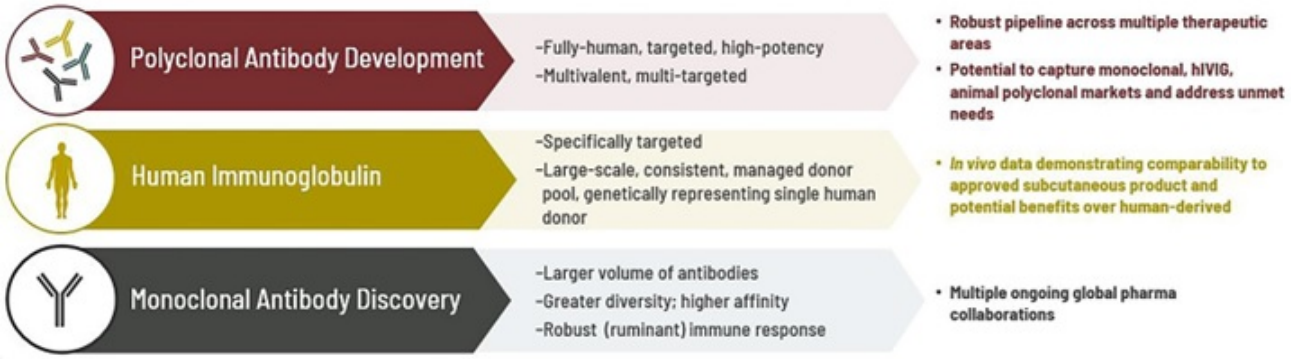


Figure 1: Versatile Antibody Platform with Ability to Capture Multiple Modalities

While we can rapidly generate specific, high-affinity monoclonal antibodies, the biggest potential in delivering new highly effective treatments lies within the multi-target approach. Complex diseases are conditions where multiple targets and multiple dysregulated pathways are involved. Except for diseases driven by a single genetic mutation, a vast majority of diseases that consistently cause human suffering with high unmet medical needs are complex. Examples of complex diseases include autoimmune disorders such as Type 1 diabetes or cancer. Historically we treat complex diseases by prescribing multiple single-target treatments to patients, that can have drug interactions and toxicities, and from the R&D perspective, inevitably results in operational, organizational, and financial challenges tied to requirements to conduct very large, long, and costly combination trials. Our DiversitAb platform develops treatments that address multiple dysregulated pathways, multiple targets, multiple epitopes in a single powerful fully human immunoglobulin treatment. Regulation of this approach primarily rests within the U.S. FDA Center for Biologics Evaluation and Research (CBER), which regulates the safety, activity and potency of the immunoglobulin mixture and not by characterization of individual antibody molecules.

In summary:

- hIgGs have natural multivalency that can be effective against highly mutating viruses and other diseases with epitope mutations or variants, due to the large number of different hIgGs and their ability to bind to or block multiple epitopes.
- hIgGs are the natural way the human body fights disease, as they work organically with the rest of the immune system to activate effector cell function, which are the cells that defend the body in an immune response.
- hIgGs can be rapidly and consistently produced to target many different diseases, and the regulatory pathway for plasma-derived hIgGs allows for broad potency to multiple disease targets within a single drug product vial. Our hIgGs can be used as both pre- and post-exposure prophylaxis and treatments.
- Our discovery and hIgG production process can occur simultaneously using our DiversitAb platform, which accelerates development of our hIgGs by leveraging the natural antibody selection that occurs in our Tc Bovine.
- We have a demonstrated regulatory pathway through the Center for Biologics Evaluation and Research (CBER) that understands our science and is familiar with the multivalent and multitarget properties of our single vial drug products. This further streamlines our ability to rapidly and efficiently develop new and novel drug products where mAbs simply can’t replicate or duplicate our drug product attributes.

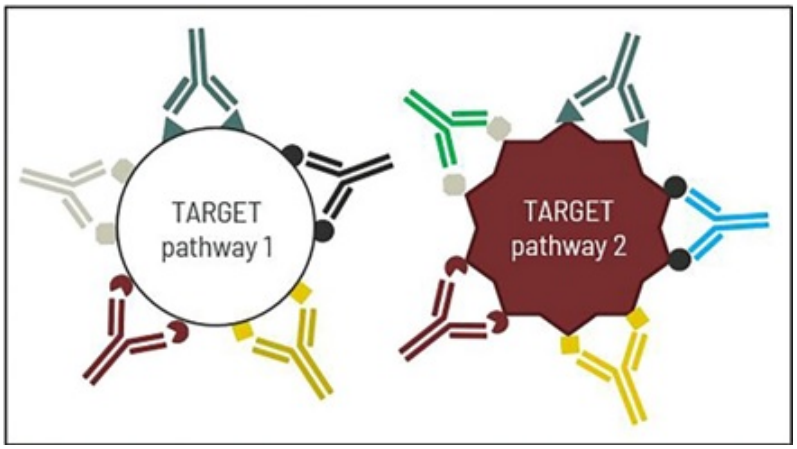


Figure 2: DiversitAb Platform Produces a Natural Mixture of Many Human hIgGs that bind to Multiple Epitopes but are Regulated as a Single Product

Recent Milestones

Since September 2019, we achieved multiple milestones, including:

- Established proof-of-concept for our DiversitAb platform and Chemistry, Manufacturing and Controls (CMC) for multiple disease indications.
- Performed multiple clinical trials establishing the safety profile of hpAbs produced in DiversitAb platform in hundreds of patients and have demonstrated proof of clinical concept for our DiversitAb platform across three SAB-sponsored INDs and one CTA (filed Ex-US) that encompass seven clinical trials from Phase 1 to Phase 3 across treatment of three indications (MERS, Influenza, and COVID-19) briefly summarized below (Figure 3)
    - Completed Phase 2a challenge study for SAB-176 in adults infected with influenza virus and Phase 2 study for SAB-185 in adults infected with SARS-CoV-2 virus.
    - Announced topline data demonstrating SAB-176 met its primary endpoint in our Phase 2a challenge study in adults infected with influenza virus.
    - Reported positive topline Phase 2 virology data demonstrating SAB-185 met criteria for advancement to Phase 3 and completed 50% enrollment in Phase 3. Phase 3 patient safety follow-up is ongoing.
- Announced that recent data demonstrated that SAB-185 retains neutralization activity against the Omicron SARS-CoV-2 in an *in vitro* pseudovirus model and in a human ACE2 receptor *in vivo* model study.
- Completed IND enabling in-vivo pilot and GLP tox safety and pharmacodynamic studies for SAB-142 for autoimmune disorders including Type 1 Diabetes.
- Established proof-of-concept for production of human anti-idiotype IgGs to human auto-antibodies using the DiversitAb platform.

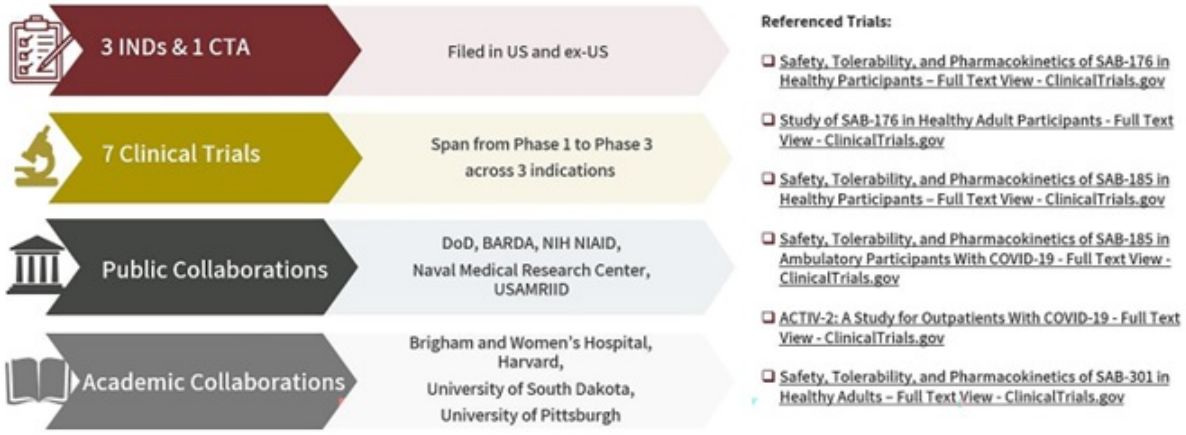


Figure 3: DiversitAb™ Platform Clinical Validations

Accomplishment Summary

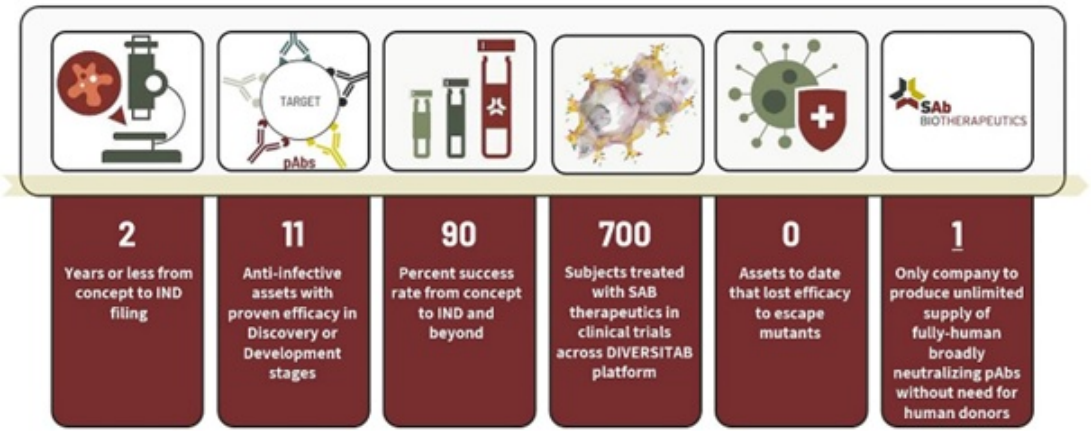


Figure 4: Fact Sheet of Accomplishments

Figure 4 shows a summary of our accomplishments in proof of principle and proof of concept for the use of the DiversitAb platform in development of multiple assets as well as the establishment of a clear regulatory framework. In short:

- Two (2) or less is the number of years it takes us to develop a new investigational product from concept to IND filing. Rapid response during the Covid-19 pandemic allowed for IND enablement and the start of Phase 1 clinical trials in 128 days.
- Eleven (11) is the number anti-infectives assets that have been developed in the DiversitAb platform through proof of concept and beyond in the preclinical or clinical setting.
- Ninety (90) is the percent of our biologic immunotherapeutics that successfully reached predefined milestones.
- Greater than seven hundred (>700) subjects have been treated with investigational therapeutics produced by the DiversitAb platform.
- Zero (0) assets to date lost total efficacy to viral escape mutants.
- One (1) SAB Biotherapeutics is the First and Only company able to produce an unlimited supply of fully human broadly neutralizing hIgGs without the need for human donors.

Pipeline Programs

We are leveraging our DiversitAb platform to advance a robust pipeline of differentiated hIgG-based therapies for the treatment of immune system disorders and infectious diseases. We are focused on developing, with partners or on our own, product candidates where we believe a differentiated human hIgG approach has the greatest potential to be either first-in-class against novel targets or best-in-class against complex targets to treat diseases with significant unmet medical needs, including diseases such as influenza, CDI, immune system disorders (including Type 1 diabetes or T1D), organ transplantation and early discovery oncology.

We believe route of administration is also an important component of the ability to access specific markets. While we are currently testing our lead programs using intravenous administration, we are pursuing the development of alternate routes of administration as an expansion of our market reach. These include subcutaneous and intramuscular routes of administration. Figure 5 summarizes the status of the therapeutic candidates in our current pipeline.

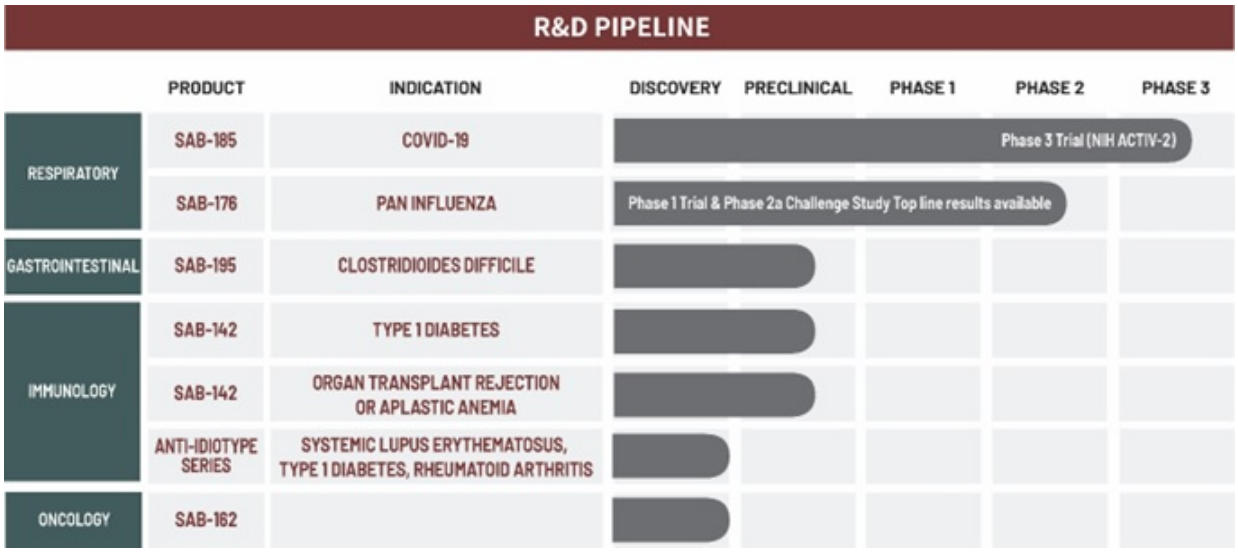


Figure 5: Summary of Therapeutic Candidates in Our Current Pipeline

Potential applications of multi-target multi-epitope approach are virtually limitless and our pipeline shows examples of targeted hIgG assets across several therapeutic areas. We continue building on our successful track record in respiratory diseases, including previous positive clinical trials in COVID-19 and Middle Eastern Respiratory Syndrome (MERS) indications, by focusing on SAB-176, a multitarget hIgG broadly neutralizing anti-influenza immunotherapy. This is one of the most advanced clinical assets and has progressed to mid-Phase 2 stage. Another asset is SAB-195, the first human hIgG for treatment of Clostridioides difficile Infection (also known as CDI or C. diff infection) and for prevention of recurrence of CDI. This asset is preclinical stage and anticipated to proceed to IND in the next 12 months. Finally, we are entering into the autoimmunity space with SAB-142, another preclinical stage asset, that is a disease-modifying fully human hIgG aimed to prevent onset or disease progression of Type 1 Diabetes and subsequently expand into other immunology indications. Additionally, we have a robust discovery and preclinical-stage pipeline in anti-idiotype disorders as well as emerging oncology programs.

Our top portfolio is balanced across early and late development assets with meaningful inflection points delivered every 12 months to assure rapid de-risking of individual assets and investments into these three programs as well as the entire DiversitAb platform. (See Figure 6).

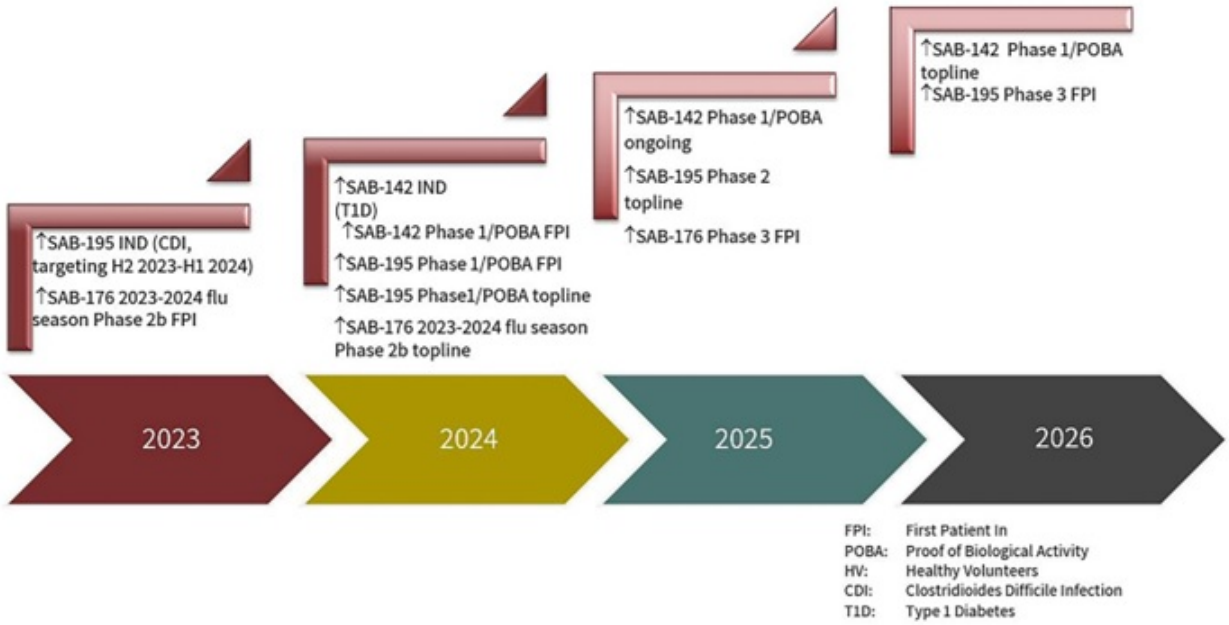


Figure 6: Clinical Development Programs and Expected Asset Progress

HIGH RISK COVID-19

SAB-185 (anti-SARS-CoV-2) Demonstrates Clinical Advancement to Phase 3 Clinical Trials

SAB-185 is a fully-human, specifically targeted, highly potent, and broadly neutralizing human IgG therapeutic candidate for COVID-19. SAB-185, generated from the full-length spike protein of the SARS-CoV-2 Wuhan strain, has shown neutralization of the Munich, Washington, South African, Delta, Lambda, and other variant strains in preclinical and nonclinical studies. In addition, recent data has demonstrated that SAB-185 retains neutralization activity against the Omicron variant of COVID-19 in an *in vitro* pseudovirus model. Preclinical data has shown SAB-185 to be significantly more potent than human-derived COVID-19 convalescent hIgG. We have completed multiple clinical and nonclinical studies to date, including a Phase 1 trial in healthy volunteers, and a Phase1b and Phase 2b clinical trial, both in COVID-19 patients. SAB-185 was being assessed in a Phase 3 clinical trial as part of the ACTIV-2 master protocol, sponsored, funded and conducted by the National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health (NIH) in collaboration with the AIDS Clinical Trials Group (ACTG). On February 28, 2022, the NIH decided to terminate the ACTIV-2 program, including ALL other COVID-19 products active at the time in the ACTIV-2 protocol, after determining that the decrease in hospitalizations resulted in operational futility and made it cost-prohibitive to demonstrate statistically significant clinical efficacy with the existing study design.

SAB-185 was advanced in collaboration with the U.S. Government, as part of the Countermeasures Acceleration Group, formerly Operation Warp Speed. We filed the IND application, produced the initial clinical doses, and entered the Phase 1 clinical trial in just 128 days from the program initiation. SAB-185 was designed and developed without the need for human convalescent plasma or human B-cell donations and has once again demonstrated DiversitAb platform advantage to neutralize multiple pathogen strains mutated overtime without significant loss of potency. Equally important, the data also confirmed that high-risk patient populations unable to generate a sufficient endogenous immune response may benefit the most from IgG treatments produced by the DiversitAb platform.

Due to COVID-19 market and commercialization uncertainties, we have chosen to pause development of SAB-185. This program has shown that we can rapidly develop and deliver a clinical trial-ready asset as well as the clear product development, manufacturing, control and regulatory pathway of assets developed from the DiversitAb platform. Further data and information on this program can be found in the Proprietary DiversitAb Platform Section.

HIGH RISK INFLUENZA

SAB-176 is a multivalent, broadly neutralizing fully-human polyclonal hIgG therapeutic candidate in development for the treatment or prevention of severe influenza. This novel, specifically targeted high-potency immunotherapy leverages the natural human immune response and is designed to bind and neutralize both Type A and Type B influenza, including emerging and mutating strains. It may also be modified to address annual strain changes when needed. Nonclinical and clinical data suggests that SAB-176 offers broad protection against diverse influenza strains, even those that were not specifically targeted, potentially because of its strong cross-reactive potencies to conserved epitopes. We have completed multiple clinical and nonclinical studies to date, including a Phase 1 trial in healthy volunteers, and most recently a Phase 2a challenge study that was initiated in June 2021. SAB-176 has the potential to complement seasonal vaccine programs to achieve better efficacy than small molecule anti-influenza antivirals in the general population, avoid development of resistant strains, and serve as a protective prophylactic in high-risk populations. We believe that this promising therapy is well-suited to address highly mutating viruses that have significant annual health impacts as well as pandemic potential.

Influenza Market

Seasonal influenza remains a meaningful burden for the healthcare system. While the influenza season differs each year, the CDC estimates there are on average 9 to 41 million cases of influenza each year, with 140,000-710,000 hospitalizations and 12,000-52,000 deaths per year (average 2010-2020). Oseltamivir phosphate (branded: Tamiflu®) is an effective therapy for treating the flu if used within two days of onset. However, some patients still develop severe disease and are resistant to treatment (estimates of resistance vary: 3-27%). As such, we see the potential for an additional treatment for flu, particularly in higher-risk patients.

While the severity of influenza is challenging to forecast year to year, for simplicity's sake, we assume a consistent incidence rate of 30 million cases in the U.S., within the average range of the last 10 years. In the 2020-2021 influenza season, cases and hospitalizations were down markedly (approximately 60% and 90%, respectively), as many of the vulnerable patients contracted COVID, rather than influenza, and COVID prevention measures stopped the spread of influenza. It is our expectation that influenza is globally persistent and case rates are expected to come back to historical levels in the coming years. We expect that at the time of launch, there will be approximately 30 million cases of influenza in the U.S. annually, about half of which will require a medical visit.

Competition and SAB-176 Value Proposition

First-in-class fully-human hIgG treatment aimed to provide superior long-lasting efficacy for prophylaxis and management of influenza in patients at high-risk

	Oseltamivir	Baloxavir marboxil	Broadly neutralizing human polyclonal SAB-176
Mechanism of Action (MoA):			
• Neuraminidase inhibitor	✓	☒	☒
• Polymerase acidic (PA) endonuclease inhibitor	☒	✓	☒
• Blocks virus from entering the host cell: neutralization of their infectivity	☒	☒	✓
• Opsonization, Complement activation, ADCC of the virus	☒	☒	✓
Single Dose	☒	✓	✓
• Extended protection against viral shedding, recrudescent infection, or new infection with another influenza strain	☒	☒	✓
Low risk of antiviral resistance/escape mutants while being treated	☒	☒	✓
Potential to treat patients infected with anti-viral resistant strains	☒	☒	✓

Figure 7: Only SAB-176 Provide Potential for "EVERGREEN" Influenza Biologic with Low Risk of Escape Mutants

To summarize, a few key differentiation aspects of this asset include a multi-pronged approach by neutralizing the virus directly and by inducing Antibody Dependent Cellular Cytotoxicity (ADCC), coupled with a long half-life aimed at providing an extended protection against viral shedding and recrudescent infection, low risk of antiviral resistance/escape mutants, and potential to treat patients infected with anti-viral resistant strains.

Phase 2a Challenge Trial

In December 2021, we announced topline data for a Phase 2a challenge trial that was initiated in June 2021. This was a randomized, double-blind, placebo-controlled study evaluating the safety and treatment efficacy of SAB-176 in 60 healthy adults challenged with a pandemic influenza virus strain (pH1N1). Participants were randomized to receive either SAB-176 (25 mg/kg dose) or placebo and were intranasally inoculated with pandemic H1N1 (2009/California) virus. Nasopharyngeal swabs were taken 8 days after inoculation.

The primary endpoint of the study was reduction of the nasopharyngeal viral load of subjects treated with SAB-176 (expressed as area under the curve, or AUC) compared to those receiving placebo over an 8-day timepoint as measured by qRT-PCR. SAB-176 met the primary endpoint of significantly reducing patient pH1N1 influenza viral load in the treated subjects ($p = 0.026$, one sided).

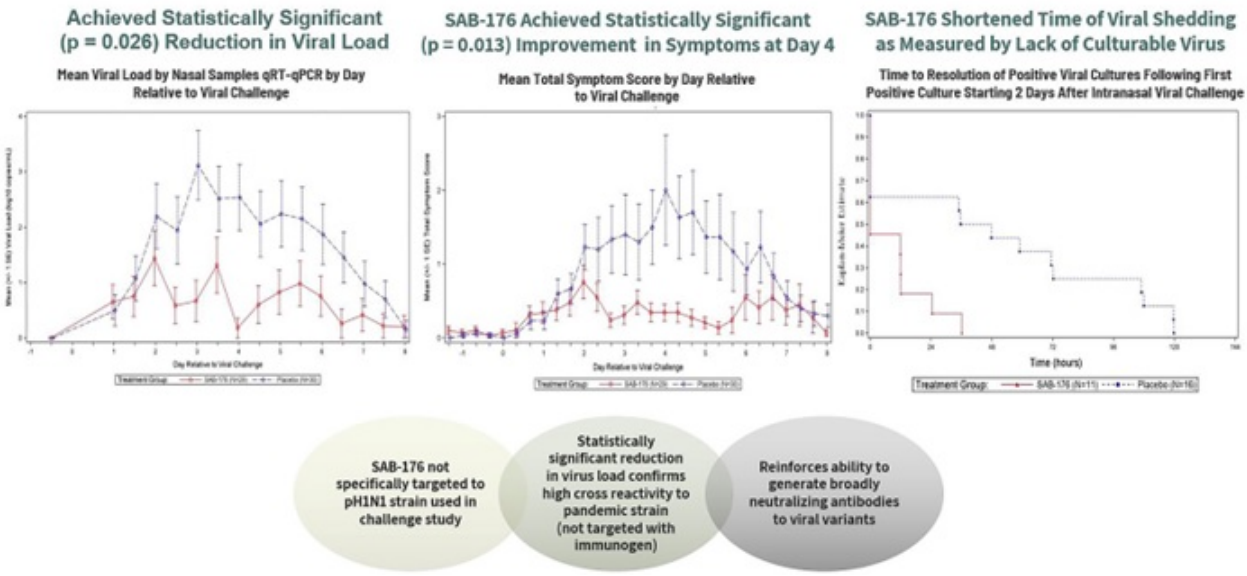


Figure 8: Phase 2a Double-Blind, Placebo-Controlled Study

Secondary end points produced similar results, showing separation of SAB-176 vs placebo. One of the secondary endpoints of the challenge study was reduction of clinical flu signs and symptoms in the subjects receiving active treatment (n=8) compared to placebo controls (n=12) for those who had signs and symptoms. SAB-176 achieved statistical significance in meeting the secondary endpoint at Day 4 (p = 0.013, one sided) in symptomatic patients. In this study, SAB-176 also appeared to be safe and well tolerated. No SAB-176-related serious adverse events (SAEs) were observed, and most adverse events were mild to moderate.

Phase 1 Trial

SAB-176 was evaluated in an ascending dose, double-blind, randomized, placebo-controlled Phase 1 safety trial in 27 healthy volunteers in 2020. The FDA allowed us to initiate a Phase 1 trial in healthy adults based on the safety profile in the preclinical data set. A Safety Review Committee (SRC) monitored adverse events after each cohort was infused and recommended that each later cohort could be infused with the next highest dose according to the study protocol. Although anticipated adverse events were noted among the SAB-176 and placebo participants, no drug related SAEs were identified by the SRC.

Preclinical Studies

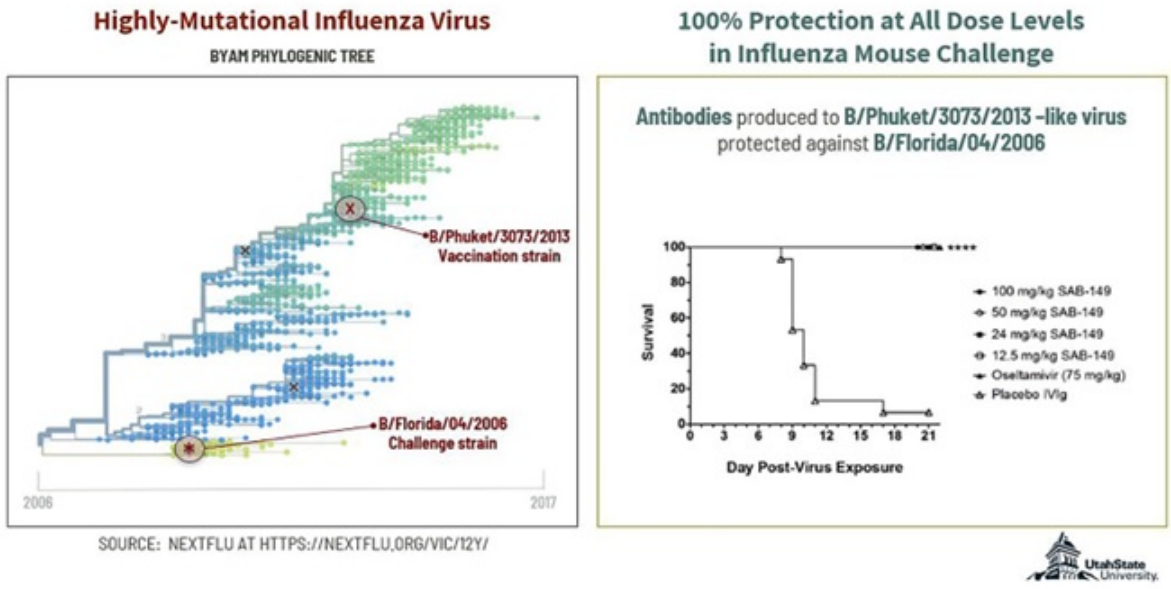


Figure 9: Preclinical Study Conducted at Utah State University

A pre-clinical study, conducted at Utah State University in 2017, demonstrated the ability of our anti-influenza human hIgGs (an earlier, non-optimized candidate designated SAB-149) to produce cross-reactive hIgGs to mutating influenza strains we did not initially target. The panel to the left above is a phylogenetic tree or ancestral map of the B Yamagata seasonal influenza strain. Specifically highlighted are the 2013 B/Phuket/ strain used to produce hIgGs from our platform and its distant relative from 2006, the B/Florida strain which we used as the challenge strain in a lethal mouse model in the left image of Figure 9. As shown in Figure 10, the hIgGs provided 100% protection down to 12.5 mg/kg demonstrating cross-protection to current and future emerging flu variants due to mutational drift. This is a potential advantage of hIgGs and our platform.

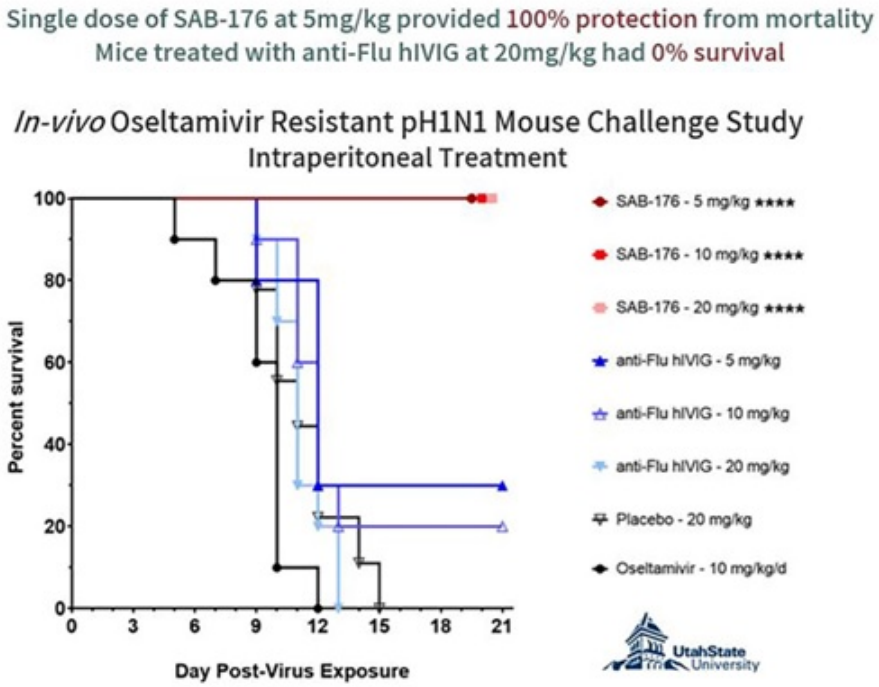


Figure 10: SAB-176 Study Conducted at Utah State University

One of the areas of growing concern with small molecule antivirals used to treat influenza is neuraminidase inhibitor resistance. For this reason, new treatments for influenza are needed. In this study conducted at Utah State University in 2019, the *in-vivo* efficacy of SAB-176 compared to a human-derived antibody product and the small molecule, Oseltamivir was assessed in a lethal mouse model after challenge with an Oseltamivir resistant pandemic H1N1 strain. Five mg/kg of SAB-176 provided 100% protection while 5, 10 and 20 mg/kg of the human-derived anti-influenza antibody or Oseltamivir did not. This suggests that SAB-176, at very low doses, could be effective in the treatment of humans infected with neuraminidase resistant or non-resistant H1N1 influenza.

SAB-176 Tissue Cross Reactivity

The objective of this study conducted in 2019 was to determine the potential cross reactivity of biotinylated SAB-176, a polyclonal human hIgG antibody directed against influenza virus, with cryosections of human and rabbit (New Zealand White) tissues. To detect binding, the biotinylated test article, designated SAB-176-Bio, was applied to cryosections of normal human tissues (at least three donors per tissue, where available) and rabbit tissues (at least two animals per tissue, where available) at two concentrations (20 and 2 µg/mL). In addition, the test article was substituted with a biotinylated human hIgG antibody, which has a different immunogenic specificity from that of the test article, designated HuIgG-Bio (control article). Other controls were produced by omission of the test or control articles from the assay (assay control).

SAB-176-Bio produced weak to strong staining of the positive control material (rHA1-H1N1 [A/Cal/07/09]-His [recombinant hemagglutinin protein] UV-resin spot slides [designated rHA1-H1N1]) at both concentrations. SAB-176-Bio did not specifically react with the negative control material (human hypercalcemia of malignancy peptide, amino acid residues 1-34, UV-resin spot slides [designated PTHrP 1-34]) at either staining concentration. The control article, HuIgG-Bio, did not specifically react with either the positive or negative control materials. There also was no staining of the assay control slides. The specific reactions of SAB-176-Bio in all staining runs with the positive control material and the lack of specific reactivity with the negative control material, as well as the lack of reactivity of the control article, indicated that the assay was sensitive, specific, and reproducible.

No staining was present with SAB-176-Bio in the human panel examined. As SAB-176-Bio binds to an influenza virus protein not expected to be expressed in normal human tissues, this result was anticipated. In the rabbit tissue panel, staining with SAB-176-Bio was restricted to the cytoplasm of rare epithelial cells in hair follicles in the skin. Binding to cytoplasmic sites in tissue cross-reactivity studies generally is considered of little to no toxicologic significance due to the limited ability of antibody drugs to access the cytoplasmic compartment in vivo. (Hall, et al., *Preclinical Safety Evaluation of Biopharmaceuticals: A Science-Based Approach to Facilitating Clinical Trials.* Wiley-Interscience; 2008. p. 208-40 and Leach et. al. *Toxicol Pathol* 2010 December;38(7):1138-66.)

SAB-176 Toxicology

The objectives of this study, conducted in 2019, were to determine the potential toxicity of SAB-176 for the treatment of Type A and Type B influenza illnesses, when given as a single intravenous infusion to rabbits and to evaluate the potential reversibility of any findings. In addition, the toxicokinetic characteristics of SAB-176 were determined.

The following parameters and end points were evaluated in this study: clinical signs, body weights, body weight gains, food consumption, ophthalmology, clinical pathology parameters (hematology, coagulation, clinical chemistry, and urinalysis), toxicokinetic parameters, immunogenicity analysis, gross necropsy findings, organ weights, and histopathologic examinations.

There were no test article-related effects noted on clinical signs, body weights, body weight gains, food consumption, ophthalmology, gross necropsy findings, organ weights, or histopathologic examinations.

There were no test article-related adverse effects on clinical pathology parameters. Decreased leukocytes (WBC) (down to 0.82X), lymphocytes (0.74X), monocytes (0.61X), eosinophils (0.50X), basophils (0.57X), and large unstained cells (0.73X), as well as increased neutrophils (1.2X) were noted in test article-treated females on Day 1 when compared to concurrent controls. These differences improved, but most were still present on Day 3 of the study. By Day 50, these values were similar to that of concurrent controls. Decreased activated partial thromboplastin time (0.76X and 0.80X) was noted in test article-treated females on Day 3 and Day 50 when compared to concurrent controls. Increased globulin (up to 1.59X) with associated decreased albumin to globulin ratio was noted in test article-treated males and females on Day 3 when compared to concurrent controls. These differences were not noted on Day 50.

In conclusion, administration of SAB-176 by single intravenous infusion was well tolerated in rabbits at levels of 362.65 and 725.30 mg/kg/day. No target organs were observed. Based on these results, the no-observed-adverse effect level (NOAEL) was considered to be 725.30 mg/kg/day.

SAB-176 was assessed in IND-enabling studies including Good Laboratory Practice (GLP) tissue cross reactivity and toxicology studies. The results were submitted to the FDA for review as part of the IND submission.

CLOSTRIDIOIDES DIFFICILE (C.DIFF) INFECTION (CDI)

SAB-195 is the first in class fully human hIgG treatment for treatment of CDI

We are currently advancing our top-priority preclinical therapeutic candidate, SAB-195, a high-unmet medical need asset for treatment of CDI-associated diarrhea and reduction in recurrence of CDI.

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

Epidemiology data support high unmet medical needs globally

CDI is one of the most prevalent healthcare–associated bacterial infections in the U.S. and developed world. CDC estimates that there are ~ 500,000 infections per year and >30,000 deaths from CDI in the U.S. alone. CDI is associated with significant costs: Up to $4.8 billion each year in excess health care costs for acute care facilities alone. Patients with the first CDI recurrence have a risk of subsequent recurrence from 25% to 40% and higher. CDI-attributable median length of stay and costs (in US$) 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. The risk of death for patients with recurrent CDI is 33% higher compared to those patients without recurrence.

While treatments exist, they are associated with high rates of recurrent CDI that are even more difficult to treat than primary infection. It is also well known that antibiotics, the current standard of care treatment for CDI, are associated with emergence of bacterial resistance. Finally, fecal transplants, last-line treatment of CDI, may be associated with a risk of transmitting infectious agents as they are manufactured from human fecal matter, and many are contraindicated in immuno-compromised patients. That triple mechanism of action – C. diff spores, vegetative cells, and multiple types of toxins – not only comprehensively target the entire complex life-cycle of this pathogen, but also aim to provide superior efficacy in reducing infection recurrence, hospitalizations, and hospitalization duration of hospital stay.

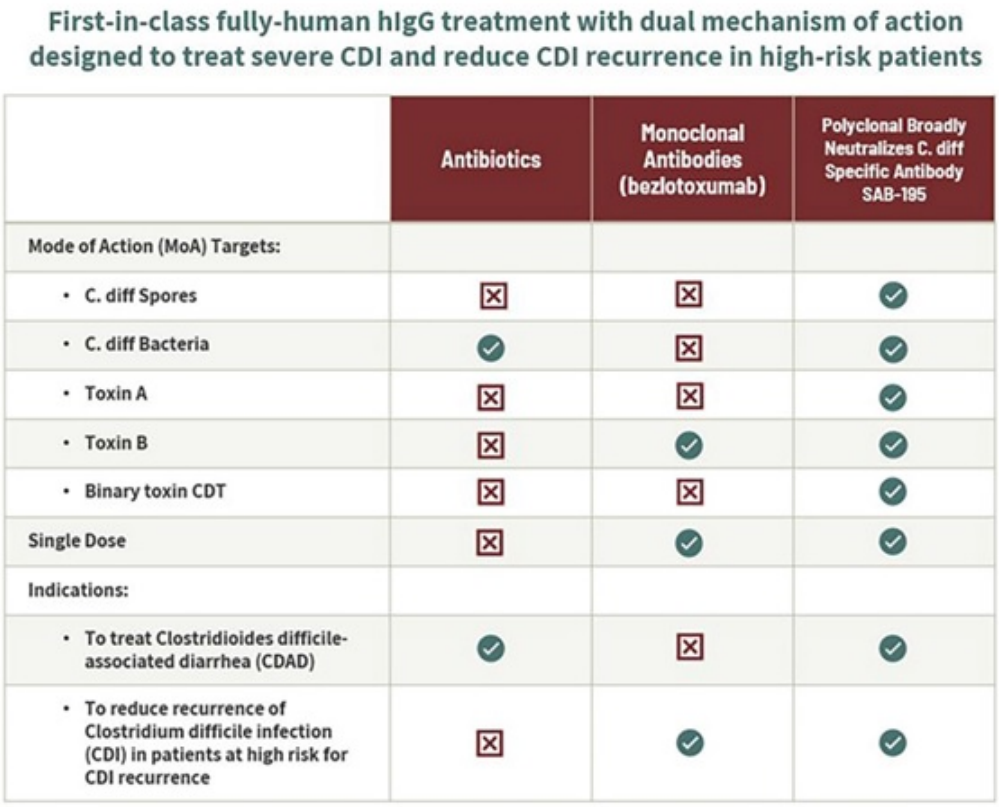


Figure 11: Only SAB-195 Can Target Multiple CDI Bacterial Antigens and Toxins in One Therapeutic

Preclinical proof of principle data of DiversitAb platform in CDI

Available preclinical data indicates that SAB-195 will deliver on its product value proposition to target multiple antigens including vegetative state of bacteria and toxins from multiple strains. The data was published in the peer-reviewed journal "Vaccine." Fully human polyclonal antitoxin hIgGs were produced in the DiversitAb platform by immunizing transgenic bovine with 4 fusion proteins representing several types of toxins from different C. diff strains. In a hamster CDI model presented on this slide, hamsters treated with human antitoxin hIgG were protected when challenged with historical (left image of Figure 12) or epidemic strains of C.diff as presented in the right image of Figure 12. All animals in the control group died within 24 to 48 hours following challenge, while 40% treated with 10 mg hIgG and 90–100% treated with 60 mg hIgGs survived the 8-day observation period.

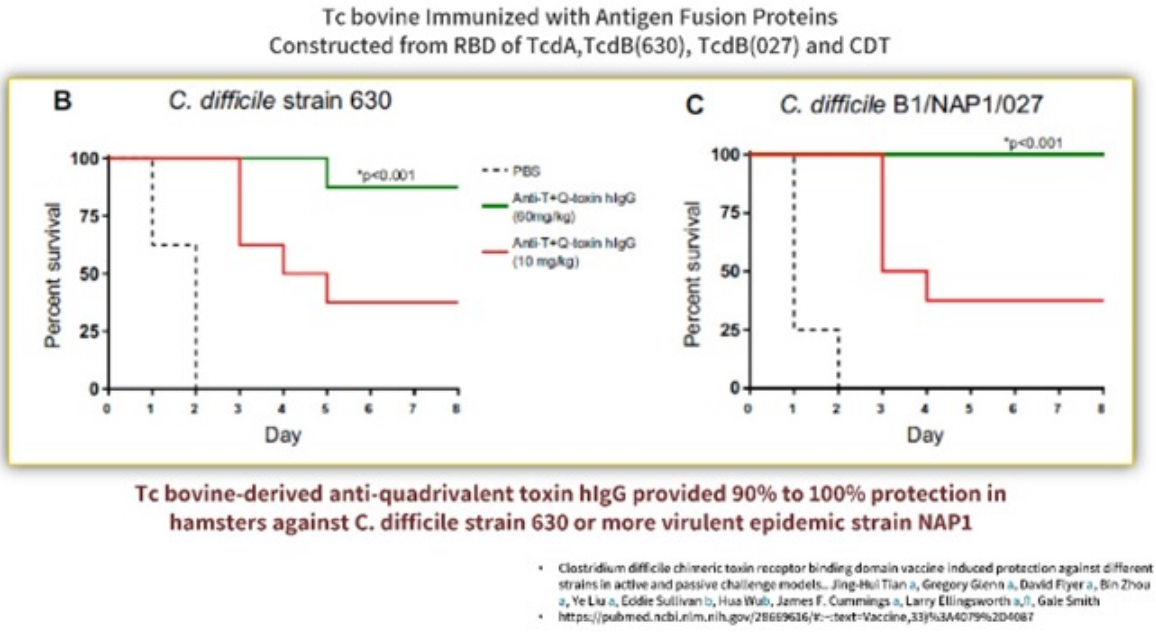


Figure 12: SAB-195 Preclinical Data

Clinical Development Path

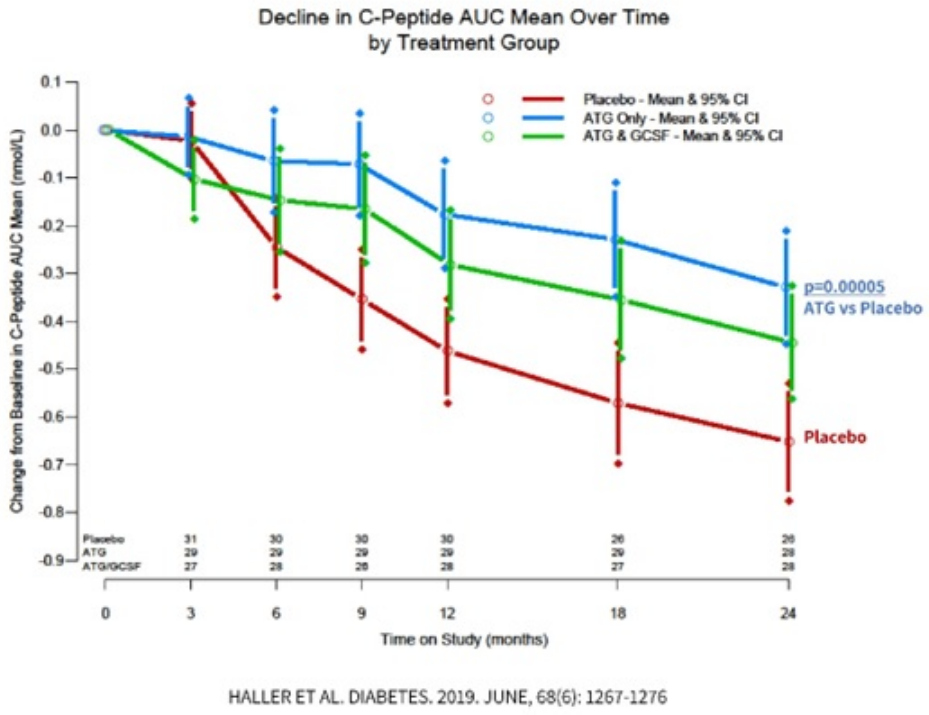
We plan to file an IND in first quarter 2024 and subsequently have topline results from Phase 1 and Proof of Biological activity available in 2024. Confirmation of SAB-195 antibacterial effects and good microbiome-sparing effects are highly critical for prevention of CDI recurrence. Following such confirmations and the subsequent initiation of the dose-range finding Phase 2b trial in 2024, we would expect top line results to be available by the end of 2025.

TYPE 1 DIABETES

We are currently advancing therapeutic candidates through its SAB-142 program aimed at delaying the onset and progression of T1D. SAB-142 is a multi-indication potential asset also being developed for organ transplant induction and organ transplant rejection among other immunological indications.

Therapeutic Potential in New-Onset Type 1 Diabetes

A potentially significant application for SAB-142 is for the delay or prevention of the onset of T1D, a serious lifelong autoimmune disease. T1D affects 1.6 million people and there are 60,000+ new diagnoses each year in the U.S. alone. The full potential of agents such as Thymoglobulin to delay or prevent T1D is limited by the unsuitability of animal products for repeat dosing. SAB-142 represents an opportunity to offer a novel fully-human alternative to rabbit- or equine-derived ATG IgGs, which has the potential for re-dosing and avoids current risk factors such as serum sickness, anaphylaxis, and loss of efficacy of currently available therapies. Based on results of a Phase 2 clinical trial conducted by Dr. Michael Haller at the University of Florida, a single dose of rabbit ATG (Thymoglobulin) showed sustained benefit in T1D over two years by maintaining significantly higher C-peptide levels (a marker of pancreatic beta cell function) than placebo controls. However, more than 65% of treated patients in this study acquired serum sickness due to infusion of an animal antibody (rather than human) that included rash, 3-4 days of malaise, fever, and joint swelling. The symptoms often required treatment with steroids that impair diabetes management and reduces capacity to give the rabbit ATG again as C-peptide levels begin to drop as shown in Figure 13 below. In addition to potentially preserving beta cell function in early T1D patients, a human ATG like SAB-142 could open the possibility of re-dosing when clinically meaningful indicators such as C-peptide levels and glycosylated hemoglobin blood tests indicate worsening disease, without the potential risk of inducing the major immune reactions that can occur with fully-animal IgGs (See Figure 14).



HALLER ET AL. DIABETES. 2019. JUNE, 68(6): 1267-1276

Figure 13: Rabbit ATG Study for Type 1 Diabetes

Competition and SAB-142 Value Proposition

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

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

Figure 14: SAB-142 is the Only Fully-Human IgG Anti-Thymocyte Globulin showing the Same *In-Vitro* Mode of Action as Low Dose Rabbit ATG

Preclinical Studies for SAB-142

We have completed the GLP toxicology results that enable filing an IND submission. Figure 14 shows lymphocyte cell population comparing SAB-142 to one of the approved and commercially available animal ATG products. Following administration of 5mg/kg animal ATG and 1mg, 5mg/kg, and 10mg/kg SAB-142 to treatment-naive non-human primates, immuno-profiling analysis of two top SAB-142 dose-levels shows significant reduction of lymphocytes vs baseline. While both SAB-142 and animal ATG induced substantial lymphocyte reduction, the dynamics of such depletion show more prolonged effects with SAB-142 treatment. These *in vivo* results strongly suggest that SAB-142 may have efficacy attributes desired for numerous auto-immune indications including but not limited to T1D, organ transplant induction and maintenance therapy, aplastic anemia among others while having the impactful product advantage of an improved safety profile. IND filing is anticipated on or before the first quarter of 2024.

Objectives:

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

Results:

- GLP-tox study demonstrated SAB-142 is well tolerated at escalating doses tested
- Both SAB-142 and its active control, an FDA-approved rabbit-derived ATG, induced transient and prolonged lymphodepletion for the duration of the study. The dynamics of such depletion appears to be more prolonged with SAB-142 treatment in a dose-dependent manner

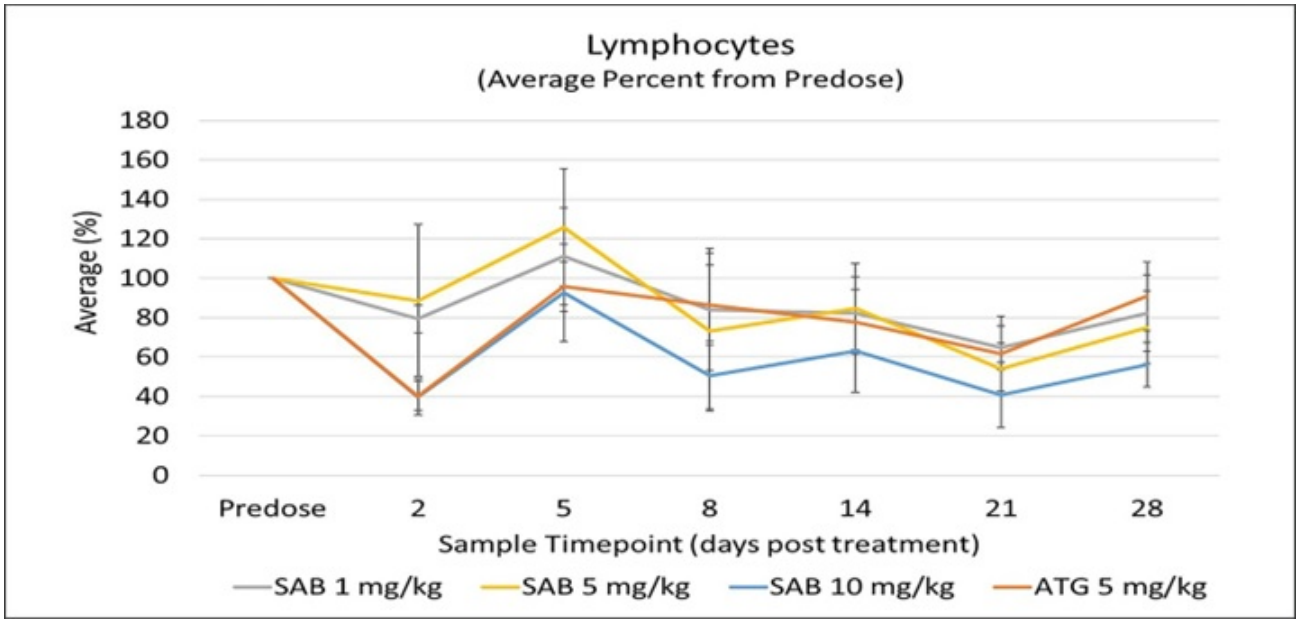


Figure 15: SAB-142 GLP Toxicology Study Results Enable IND Submission

Potentially Significant Opportunity in Transplant and Other Immunological Diseases

SAB-142 is a fully-human anti-thymocyte globulin (ATG) candidate for preventing organ transplant rejection. Current approved ATG products are sourced from animals, including transplant market leader rabbit-derived Thymoglobulin, and equine-derived ATGAM. A human ATG alternative has the potential for higher potency without toxicity, presenting an opportunity to redefine the standard of care. Dosing advantages of a human ATG may include a longer half-life and potential for repeat dosing, without significant potential to generate serum sickness or anaphylaxis, which can be caused by the presence of animal proteins in the current therapies.

Despite broad use, there are several limitations of approved ATG products. Risks of serum sickness and anti-drug antibody (ADA) formation have limited use of animal ATG products, with rates of serum sickness >30% and repeat dosing not recommended. Therefore, physicians typically reserve its use for immune induction or acute rejection – but not both. A human alternative such as SAB-142 is expected to have several advantages over ATG animal antibody products. In the established transplant market, a human ATG that has a reduced risk of adverse events such as serum sickness has the potential to penetrate the current market and expand existing clinical use.

SAB-142, has demonstrated a comparable profile *in vitro* to approved animal ATG products–equine-derived ATGAM and rabbit-derived Thymoglobulin. The Tc Bovine-derived human ATG has also demonstrated higher potency compared to Thymoglobulin *in vitro*. We expect to show improved safety, dosing, and efficacy profiles for our human ATG program in future human studies.

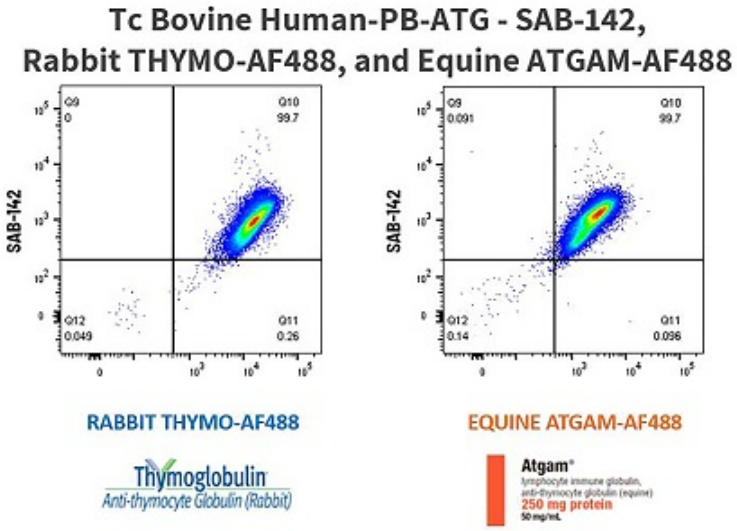


Figure 16: SAB-142 Flow Cytometry Analysis

Figure 16 provides a flow cytometry analysis of a gated lymphocyte cell population comparing SAB-142 to the two FDA approved and commercially available rabbit and horse ATG products on the market. As you can see, SAB-142 binds to the same T-cell population as both rabbit and horse ATG IgGs, suggesting comparable mode of action.

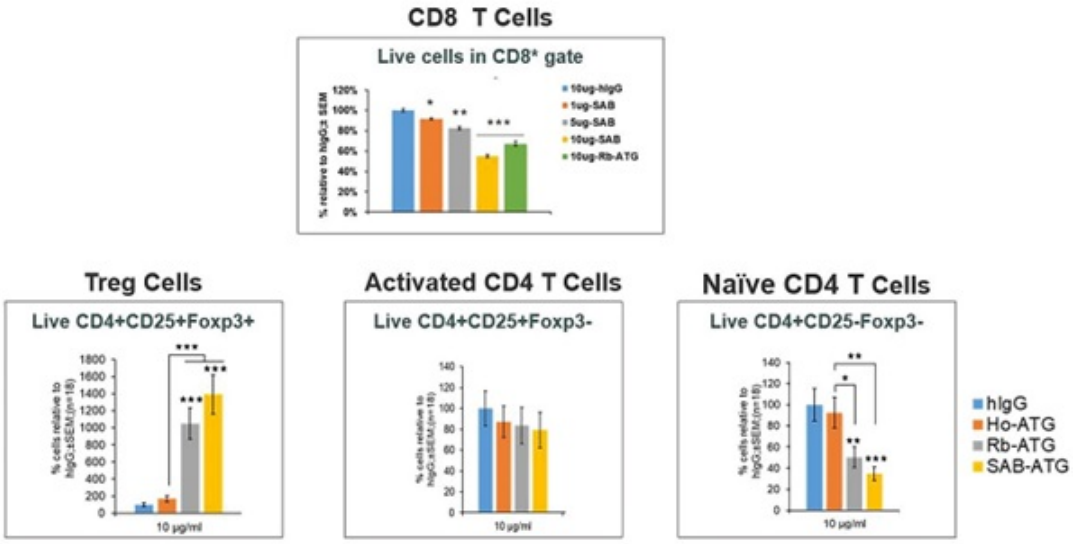


Figure 17: SAB 142 Study – Mode of Action Against T-Cell Subsets

We further explored the mode of action of SAB-142 against T-cell subsets. SAB-142 had higher CD8 killing activity compared to the rabbit antibody and had similar performance in survival of T-regulatory cells, induction of activated CD4 T Cells, and reduction of naïve CD4 cells. These *in vitro* results strongly suggest that SAB-142 may have the potency attributes needed for transplant induction and rejection therapy while having the impactful product advantage of an improved safety profile. The product attributes of SAB-142 are potentially also well aligned to address the desired safety profile of ATG treatments that have been shown to be beneficial in treating T1D.

AUTOANTIBODY IMMUNE DISORDERS

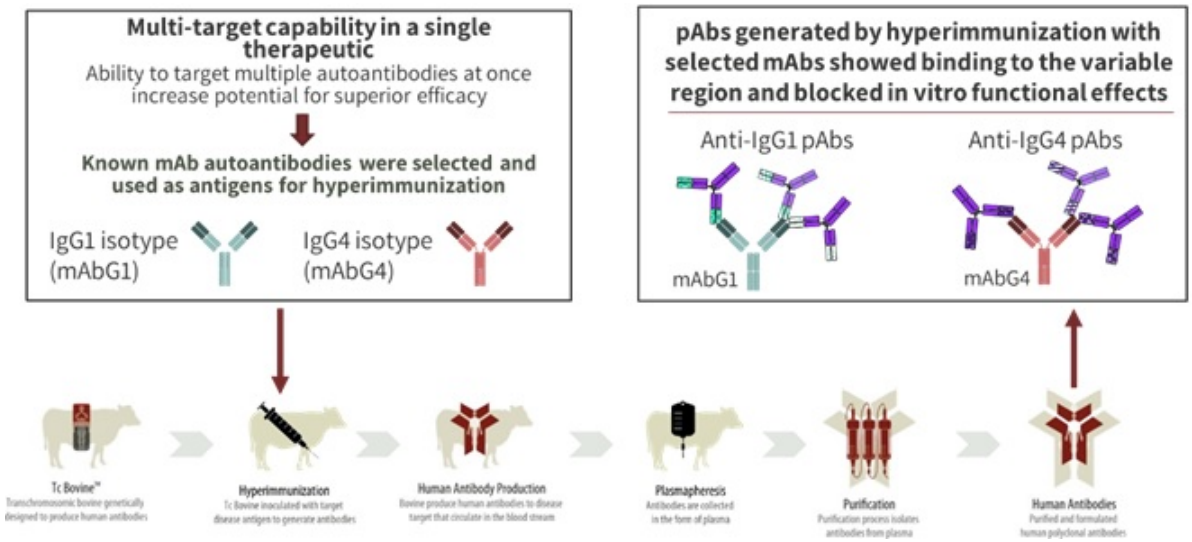


Figure 18. DiversitAb Platform Anti-Idiotype Proof of Principle in Autoimmune Disease

Figure 18 shows recent data on using the DiversitAb platform to produce Anti-idiotype hIgGs to treat auto-antibody mediated immune disease such as System Lupus Erythematosus (SLE) or Scleroderma. Known mAb autoantibodies were selected and used as antigens for hyperimmunization in Tc bovine. One was an IgG1 isotype and the other an IgG4 isotype. Tc bovine derived hIgGs against these autoantibodies were produced and purified.

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

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

Figure 19. Anti-Variable/Anti-Idiotype hIgGs are Specific to the Variable Region

This in-vitro data for Tc bovine hIgGs produced to both autoantibodies in a single Tc bovine shows the percent of inhibition of binding to the variable regions of both the IgG1 and IgG4 auto-antibodies. Controls showed the specificity of binding to the variable regions indicated by the lack of inhibition of binding to the Fc fragments of each antibody as well as the mAb framework of each of the autoantibodies.

As an example, this polyclonal mechanism of action of these Tc bovine derived hIgGs is differentiated from current treatments of autoantibody mediated disease like Systemic Lupus Erythematosus by presumably NOT causing general immune suppression nor suppression of all B-cells but by actively suppressing or eliminating specific autoreactive antibodies and B cell clones, and through polyclonality and somatic hypermutation, have activity against mutated antibodies and their B-cell clones. This approach has the potential further benefit of extending remission without immune suppression.

We are very excited to continue to explore this novel approach using the DiversitAb Platform with proven ability to produce antibodies to multiple human antigen targets including autoreactive antibodies.

ONCOLOGY (Undisclosed Targets)

We have the potential to develop IgG therapeutic candidates that address multiple aspects of cancer. We are pursuing undisclosed target opportunities for which we expect to release early developmental data in the fourth quarter of 2023.

We believe that the DiversitAb platform may lead to oncology applications for our IgGs because of our potential to address mutations, polymorphisms, and resistance pathways. Our human IgGs may offer advantages as cancer therapies, including:

- *Multi-targeting* – Ability to simultaneously target multiple modalities of cancer in a single product.
- *Multivalency* – Leverages native immune response – IgGs – with binding to multiple epitopes to address mutations.
- *Metastasis Prevention* – Literature suggests human polyclonal IVIG may help prevent tumor metastases.
- *Effector Function* – Enhanced effector functions such as antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity.
- *Replicability* – Developed IgGs against a variety of oncology targets using our DiversitAb platform.

We have recruited and deployed an oncology-focused team with the goal of pioneering human IgGs for use in treating cancer. We have filed several patent applications and expect to demonstrate initial proof-of-principle in oncology in the fourth quarter of 2023.

Proprietary DiversitAb Platform Overview

Our proprietary DiversitAb platform gives us the unique ability to generate targeted, fully-human hIgGs without the need for human donors or plasma. These diverse and high-potency IgGs can be targeted to viruses, bacteria, toxins, and human immunogen targets. The current platform relies on advanced genetic engineering that functionally replaces bovine IgGs with human hIgGs (resulting in our Tc Bovine) produced from the full germ-line repertoire of human antibody heavy chain and kappa light chain genes on an engineered human artificial chromosome (HAC). The human antibody genes have been further engineered to efficiently produce a diverse repertoire of human immunoglobulin G (which is referred to as hIgG) in bovine B-cells in response to specifically targeted immunogens as a result of the hyperimmunization of the Tc Bovine. Bovine were selected because they are large animals that produce large amounts of plasma, and as ruminants, have high concentrations of circulating hIgGs with a robust response to immunogen challenge that produces high potency, high avidity human immunoglobulins (hIgGs).

The novel capability of the DiversitAb platform uses the natural human biological immune response that makes our platform well-suited to address multiple therapeutic categories, presenting potential opportunities for new therapies to address unmet medical needs.

Figure 20 below depicts the main elements of product development and manufacturing using our DiversitAb platform.

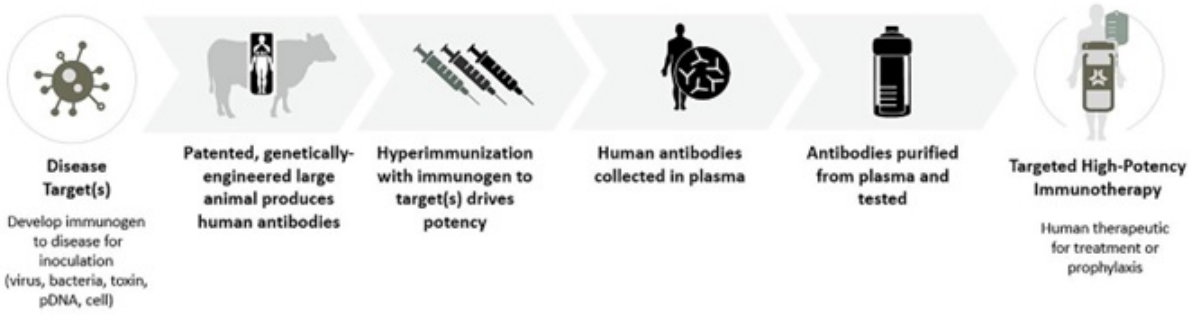


Figure 20: Development and Manufacturing Using DiversitAb™ Platform

Through our DiversitAb platform, we have engineered a targeted human immunoglobulin production system that emulates the way that the natural human immune system synergistically targets the complexity of human disease. The discovery, development and production process represent a "plug-and-play" approach:

- *Develop Immunogen for Disease Target*. An immunogen is developed for a specific target in much the same that human vaccines are developed. The platform is designed to address virtually any target including bacteria (whole killed), viruses, toxins, nucleic acids (i.e., RNA and DNA vaccines), whole cells, and human tissues.
- *Hyperimmunize Tc Bovine*. Tc Bovine are genetically engineered to produce fully-human IgGs, and then hyperimmunized with the immunogen, driving the immune response beyond protective levels that have been shown in some cases to be 40-60 times more potent than hIgGs produced in convalescent patients.
- *Collect Plasma*. The target specific human IgGs are collected from the Tc Bovine by plasma donations.
- *Isolate Human IgGs*. Human IgGs are then isolated from the plasma through a well-established plasma fractionation process and Quality Control tested. These IgGs are then ready for use as a human immunotherapy treatment or prophylactic.

Our DiversitAb platform is replicable and scalable since the Tc Bovine are all clones. If more plasma is needed, more animals can be produced through cloning technology and plasma fractionation is a well-established and scalable GMP process. We believe that targeted human IgGs can be produced against the same immunogen or multiple immunogens, depending on the disease target and indication, in as many Tc Bovine as necessary to generate sufficient doses to fully supply the target market. Human IgG consistency of product is achieved by testing the potency of IgGs contained in each plasma collection and then combining plasma collections in a manufacturing pool that generates specified potencies within a specified antibody protein concentration.

We believe that the speed with which we can deploy our DiversitAb platform to develop countermeasures for emerging diseases and pandemics represents a significant advantage relative to other antibody manufacturers. We have successfully utilized our DiversitAb platform technology to generate early proof –of concept and initial clinical lots that address specified immunotherapy targets in as little as 128 days, including completion of IND-enabling studies, in response to the COVID-19 pandemic.

We have vertically integrated the platform technology across a significant series of value inflection points. Our capabilities include advanced animal reproduction methods (cloning) to produce Tc Bovine, animal husbandry, immunogen or antigen development, plasma collection, plasma purification, drug substance manufacturing and product fill/finish, nonclinical and clinical study management, quality assurance, quality control, regulatory compliance, and program collaboration. We have built a broad-based network of third-party collaborators, service providers, vendors, consultants, and government partners that can help support each of these vertically integrated activities. This work has generated a technology which allows collaborating companies that may be unfamiliar with animal production systems or plasma fractionation processes to partner with us in the development and commercialization of products derived from the DiversitAb platform with confidence in the CMC and regulatory pathways that have been established.

Figure 21: Scaled Infrastructure & Capacity: Tc Bovine & Plasma Production Facility

Figure 22: Scaled Infrastructure & Capacity: Laboratory & Manufacturing

Fully Human Target Specific High Potency IgGs

Our novel multivalent IgG approach, including hyperimmunization of the Tc Bovine results in specifically targeted, highly potent, high-avidity, broadly diverse, fully human IgGs, overcoming the challenges and exceeding the capabilities of traditional animal and human-derived IgGs. Animal-derived IgGs, such as from horses or rabbits, have the disadvantage of being immunogenic in humans, and they often cause severe hypersensitivity reactions, limiting their clinical use for repeat dose administration. Human-derived IgGs are limited by the difficulty of collecting IgGs from humans and the inability of humans to produce IgGs to endogenous proteins under normal circumstances.

In addition, only our proprietary process of hyperimmunization of the Tc Bovine can yield high target potency as demonstrated in Figure 23 below where SAB-185 potency was superior to the highest titer convalescent plasma.

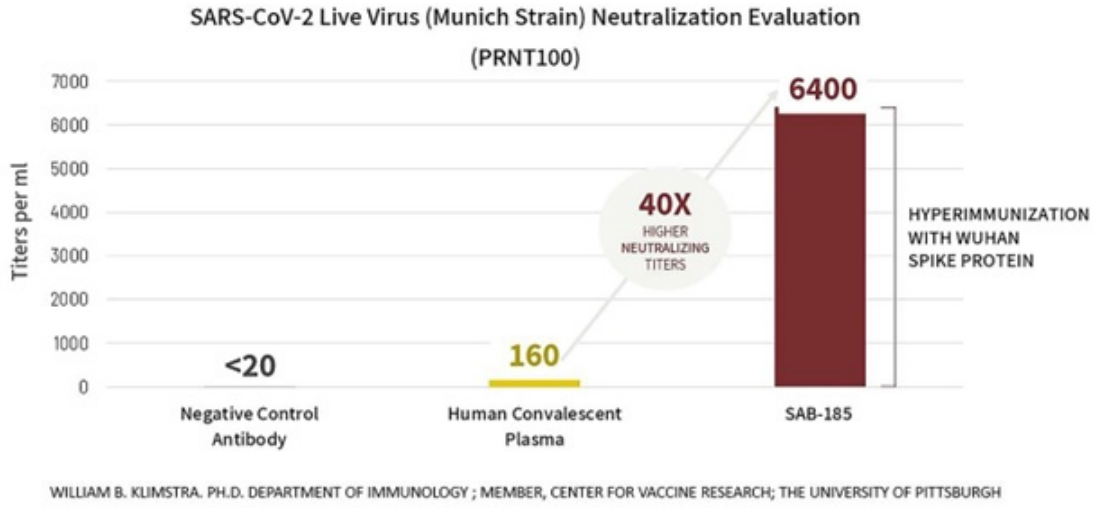


Figure 23: SAB 185 Study - Neutralization Evaluation Conducted at The University of Pittsburgh

In this study conducted at the University of Pittsburgh in 2020, SAB-185 was compared to the highest titer convalescent plasma available using the plaque reduction neutralization titer needed to neutralize 100% of the SARS- CoV-2 virus. These results suggest that SAB-185 is 40 times more potent than high titer convalescent plasma. This high titer, target-specific human IgG is achieved through our hyperimmunization strategy. These high-titer human IgGs cannot be achieved with convalescent plasma from human donors.

Natural Multivalent and Effector Function Properties of IgGs

Nature has spent millions of years evolving the sophisticated mammalian innate and adaptive immune system to protect humans and all other mammals against disease. We have harnessed that nature by design through our DiversitAb platform to produce our fully-human IgG therapeutics and by doing so have intentionally harnessed the competitive advantage of the natural properties of a polyclonal immunoglobulin to protect against highly mutating or evolving pathogens or disease targets like a cancer that fully activates our body's own immune system in a target-specific way. Our IgGs are engineered to primarily produce the IgG1 isotype, and to a lesser extent the IgG2 isotype, and have fully functional unmodified antibody variable regions (or Fab domains) that specifically bind to target antigens that provide natural multivalent properties. This multiepitope targeting neutralizes highly mutating targets and prevents mutation escape. The broad diversity of the Fab domains also contain the natural mixture of high and low affinity binding IgGs referred to as avidity and have fully functional IgG Fc domains that further activate the native human immune system by activating effector cells.

We believe there is a demonstrable and significant potential advantage of Tc Bovine-produced human IgGs in their ability to bind to both foreign exogenous or human endogenous protein targets, activate human effector cells, and not cause hypersensitivity reactions.

Multivalent properties of our Tc Bovine Derived hIgGs

Figure 24 shows preclinical data demonstrating the multivalent properties of our hIgGs for SAB-185, an anti-SARS-CoV-2 hIgG therapeutic that has shown broad neutralization potency to recent SARS-CoV-2 variants that have emerged over the COVID-19 pandemic, which including the Delta and Omicron variants.

VARIANT	WT IC50 (µg/ml)	Mutation IC50 (µg/ml)	Average IC50 ratio (Variant/WT[D614G])
Alpha	0.0643	0.0735	**1.2**
Delta	0.0497	0.1389	**2.8**
Lambda	0.0782	0.0744	**1.0**
Omicron	0.0871	1.129	**13**

<5 NO SIGNIFICANT IMPACT 5-10 MILD IMPACT 10-50 MODERATE IMPACT 50 COMPLETE LOSS

UNITED STATES FOOD AND DRUG ADMINISTRATION , CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER), WEISS LABORATORY, DECEMBER 2021.

Figure 24: In vitro Neutralization Against VSV-SARS-CoV-2 Mutants

Multiple SARS-CoV-2 variants with spike protein mutations have arisen and are infecting humans globally, and their impact on the effectiveness of both vaccines and immunotherapies is a growing concern. We collaborated with the U.S. Government COVID response team throughout 2020 and 2021 to evaluate the ability of SAB-185 to neutralize these mutant strains using a pseudovirus assay developed and conducted by scientists at the US Food and Drug Administration ("FDA") Center for Biologics Evaluation and Research (CBER). In this study, FDA researchers evaluated the inhibitory concentration at 50% of SAB-185 against lentiviral-based pseudovirions containing mutations in the spike protein representative of the Alpha, Delta, Lambda, and Omicron (B.1.1.529) SARS-CoV-2 variants. This assay incorporates a stable 293T cell line expressing human angiotensin converting enzyme 2 (ACE2) and transmembrane serine protease 2 (TMPRSS2). The results in Figure 24 above demonstrate that SAB-185 effectively neutralizes all tested recombinant S protein lentiviral pseudoviruses that mimics the SARS-CoV-2 variants. Although SAB-185 retained potent neutralization of the Omicron variant, it did show a mild-to-moderate reduction in potency compared to the Alpha wild type.

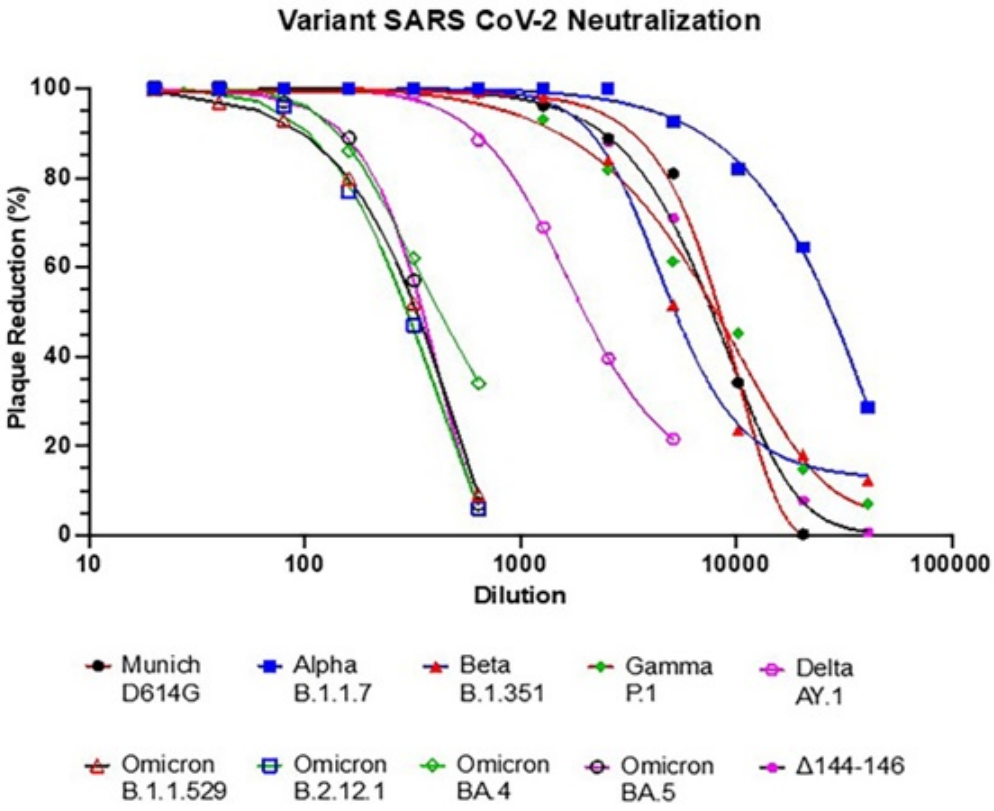


Figure 25: In vitro Neutralization Against Clinical SARS-CoV-2 Isolates

In Figure 25 we further expanded our analysis to a broader panel of pandemic SARS-CoV-2 variants, specifically the Omicron lineage that emerged in 2022 which contained novel mutations that rendered many of the existing monoclonal antibody therapeutics ineffective. In this study, we collaborated with the Center for Vaccine Research and Department of Immunology at the University of Pittsburgh (UPITT) to evaluate the ability of SAB-185 to neutralize clinically isolated SARS-CoV-2 variants using a Vero hAce2/TMPRSS2 cell plaque reduction neutralization assay. SAB-185 retained potent neutralization to all variants despite a reduction of activity against the Omicron lineage.

Due to the nature of SAB-185 fully human IgGs, it is important to note that neutralization of viral entry into the cell as measured in Figure 24 and Figure 25 is only one component of the overall efficacy measurement for a polyclonal antibody therapeutic. SABs hIgGs contain a fully human antibody Fc domain that activates the immune system through effector functions that kill the virus, so SAB-185 efficacy is not just measured by effective blocking of the RBD used for viral entry but activating immune effector functions that target and kill the virus. This in combination with the fact that SAB-185 targets multiple epitopes spanning the entire surface of the spike protein including the RBD means that changes observed in neutralization activity due to specific mutations in the RBD should not significantly impact the overall efficacy of SAB-185 as a therapeutic. This is not the case for mAbs that targeted a single epitope on the spike protein as viral mutations spanning the single binding site could result in complete loss of blocking virus entry (neutralization) and/or complete loss of efficacy as effector functions are no longer possible which is exactly what transpired for many of the mAb therapeutics during the pandemic.

To demonstrate the competitive advantage of our hIgGs and measure the full therapeutic potential of SAB-185 against clinical isolates of the SARS-CoV-2 variants, we collaborated with UPITT and Utah State University (USU) to perform an *in-vivo* efficacy study using a human ACE2 (hACE2) transgenic Syrian hamster model (Figure 26). This hamster model exhibits rapid lethality after intratracheal SARS-CoV-2 challenge with the Munich, Alpha, Beta, Delta, and D144-146 variants; the Omicron B.1.1529 variant resulted in a delayed, less severe and non-lethal disease similar to what is observed in the clinic with the Omicron variants. As can be seen detailed in Figure 26 and Figure 27 below, prophylactic treatment with SAB-185 provided 100% protection from death and minimized clinical signs of infection when challenged with six clinical isolates of the SARS-CoV-2 variant viruses including the Omicron variant. Although reduced *in vitro* neutralization activity was observed with Delta and Omicron variants, SAB-185 was still highly protective at human-relevant doses *in vivo*. Therefore, reduced *in vitro* neutralization titers of SAB-185 against SARS CoV-2 variants were not associated with any reduction of *in vivo* efficacy.

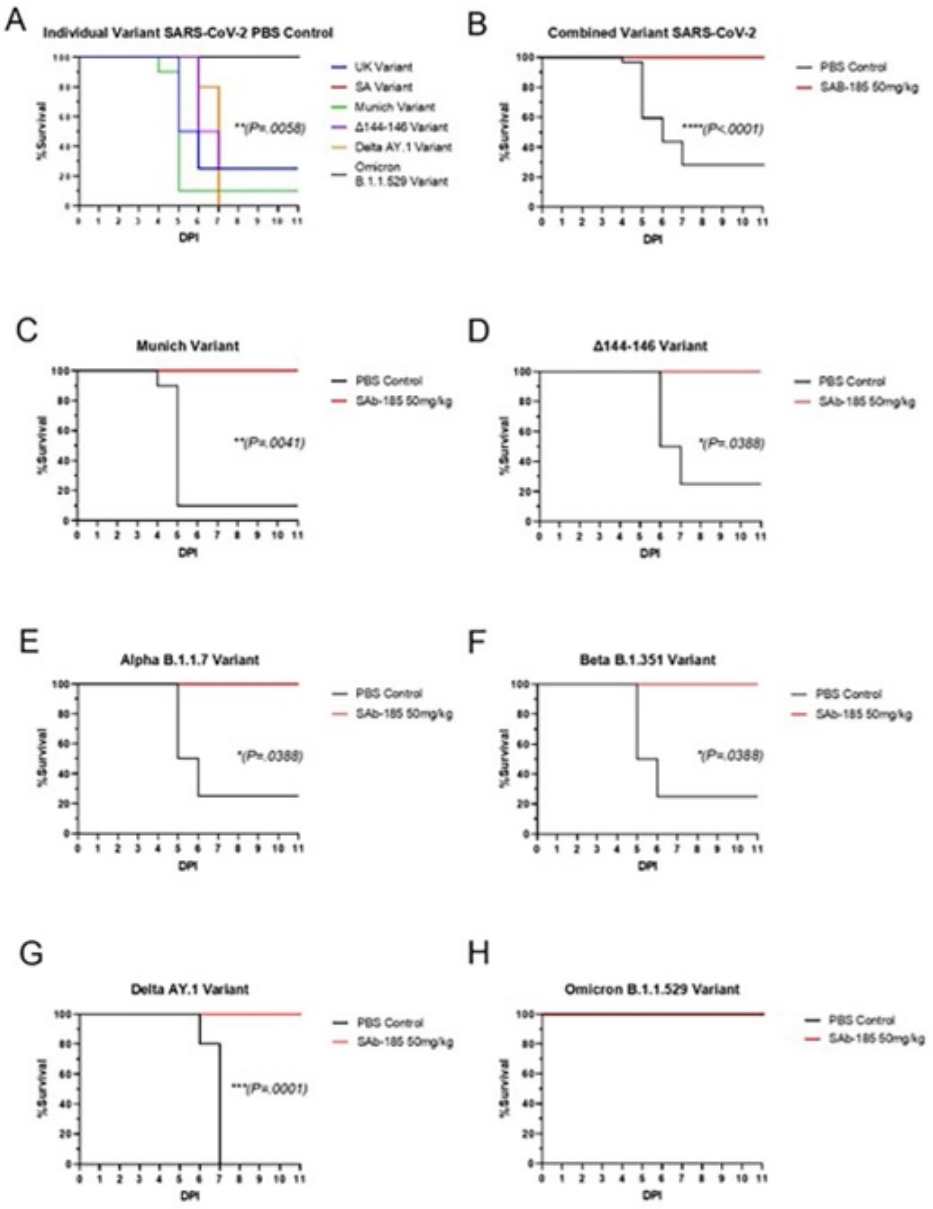


Figure 26: SAB-185 protection from mortality in hACE2 hamsters challenged with six variant SARSCoV-2 isolates

Figure 26 shows data on hamsters that were administered SAB-185 (50mg/kg) or PBS intramuscularly and then challenged intratracheally 24 hours later with 1000 plaque forming units of variant viruses. Mortality for individual variant PBS controls (A) and for combined (all SARS-CoV-2 variants tested) PBS control versus SAB-185 treated groups (B). Individual mortality data for Munich (C), D144-146 (D) Alpha (E), Beta (F), Delta (G), and Omicron (H) viruses. Mantel-Cox log-rank significance is indicated within each panel. *p<0.05, **p<0.01, ***p<0.005.

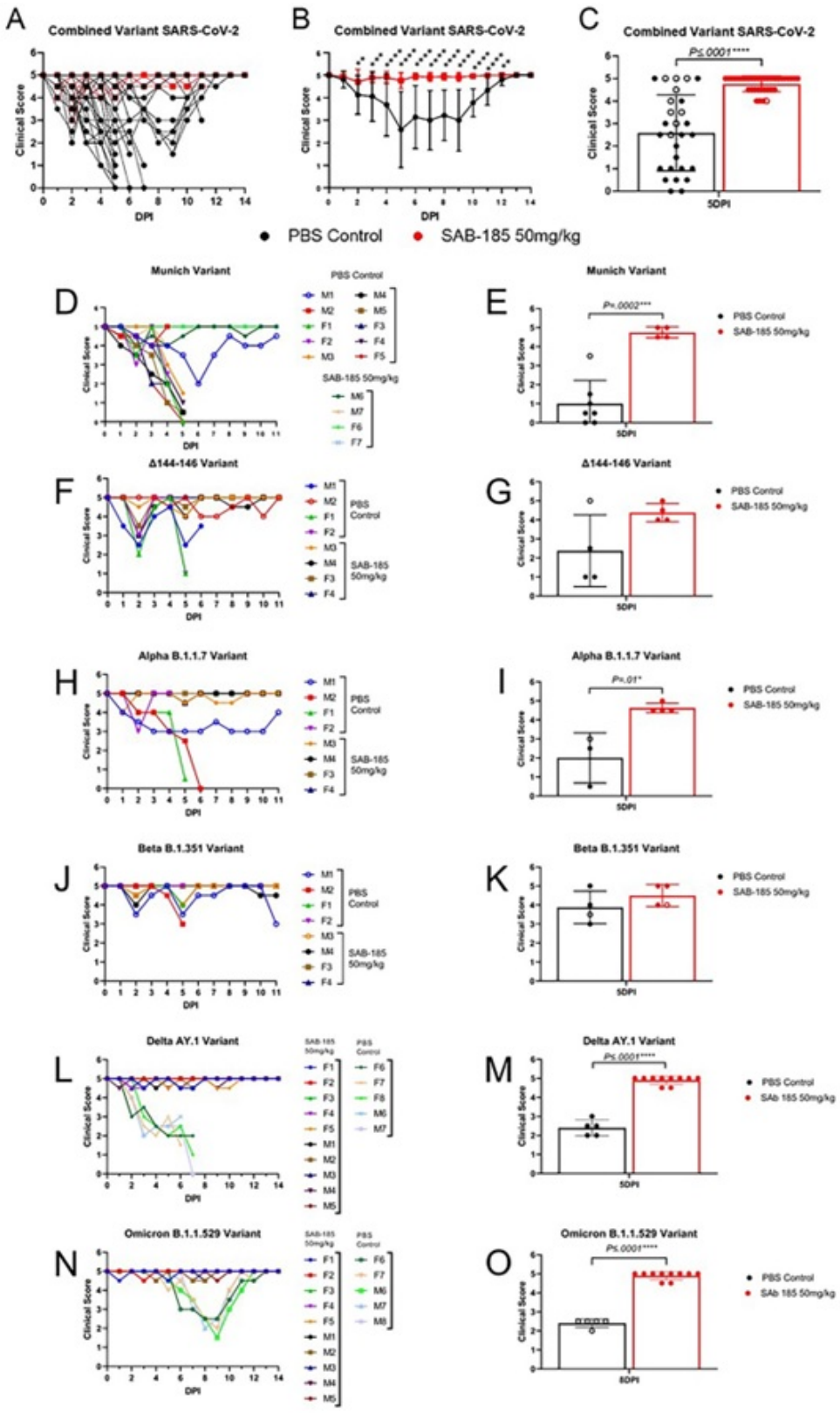


Figure 27: SAB-185 protection from clinical signs in hamsters challenged with six variant SARSCoV-2 isolates

Figure 27 shows data presented as the inverse of the clinical score sum values. Each data point represents an average of morning and afternoon observations. A) Clinical sign scoring for individual hamsters in all groups. B) Combined clinical sign scoring data for SAB-185-treated and control hamsters. (C) Combined clinical sign scoring data for SAB-185-treated and control hamsters on D5 (last day all animals were alive) post challenge or D8 post challenge for Omicron-infected animals (peak clinical signs). Individual clinical sign scoring data for Munich (D), D144-146 (F) Alpha (H), Beta (J), Delta (L) and Omicron (N) viruses. Individual clinical sign scoring data for Munich (E), D144-146 (G) UK (I), SA (K), Delta (M) and Omicron (O) variants on D5 (last day all animals were alive) post challenge or D8 post challenge for Omicron (peak clinical signs).

* $p<0.05$, ** $p<0.01$, *** $p<0.005$. Open circles are surviving (controls and Omicron) and the SAB-185 treated animal that exhibited delayed replication (data not shown).

The multivalent competitive advantages of our hIgGs have the potential to prevent escape mutations that could arise from natural selective pressures of a highly mutating communicable disease like COVID-19 or therapeutic selective pressure where mutations arise from an inferior monovalent targeted treatment regimen like a single monoclonal antibody or small molecule. To further support this point the preclinical data in Figure 28 and Figure 29 below demonstrates the ability of our hIgG therapeutics to potentially prevent mutation escape and protect against new mutations that may arise due to natural or monovalent drug induced selective pressure. This unfortunately played out with the COVID-19 pandemic, where monovalent monoclonal antibody treatments as single or in combination were reported to have lost significant neutralization activity against the highly mutating SARS-CoV-2 variants like Omicron.

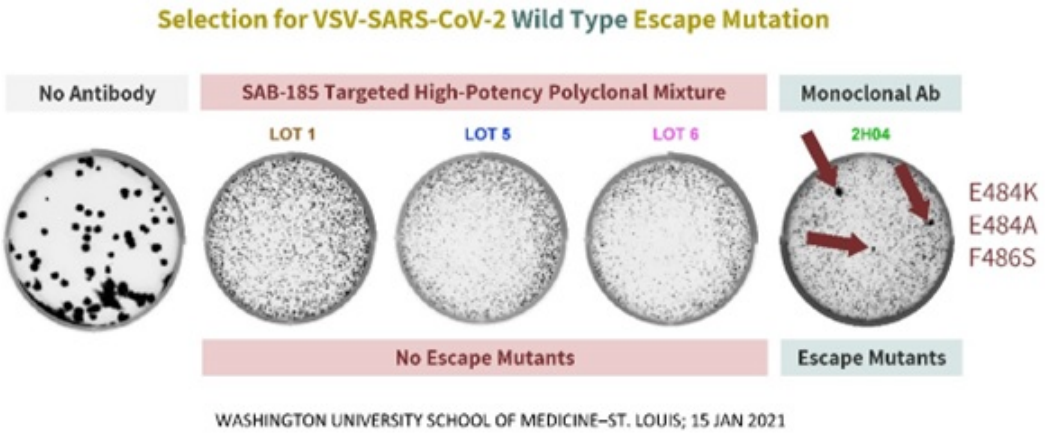


Figure 28: SAB-185 Study Conducted at Washington University School of Medicine

The study represented in Figure 28 was conducted at Washington University School of Medicine in 2020, we evaluated the ability of three different lots of SAB-185 and an anti-SARS-CoV-2 monoclonal antibody (2H04) to prevent SARS-CoV-2 escape mutants. The three different lots of SAB-185 and the monoclonal antibody were serially passaged in the presence of SARS-CoV-2 virus. As shown, no SAB-185 lots allowed the development of escape mutants. However, several SARS-CoV-2 escape mutants developed in the presence of the monoclonal antibody indicated by the three red arrows in Figure 28 above, one of which included a E484K mutant. This specific mutation that was lab generated was also a naturally circulating mutation found in multiple SARS-CoV-2 variants of concern and variants of interest that were infecting humans globally.

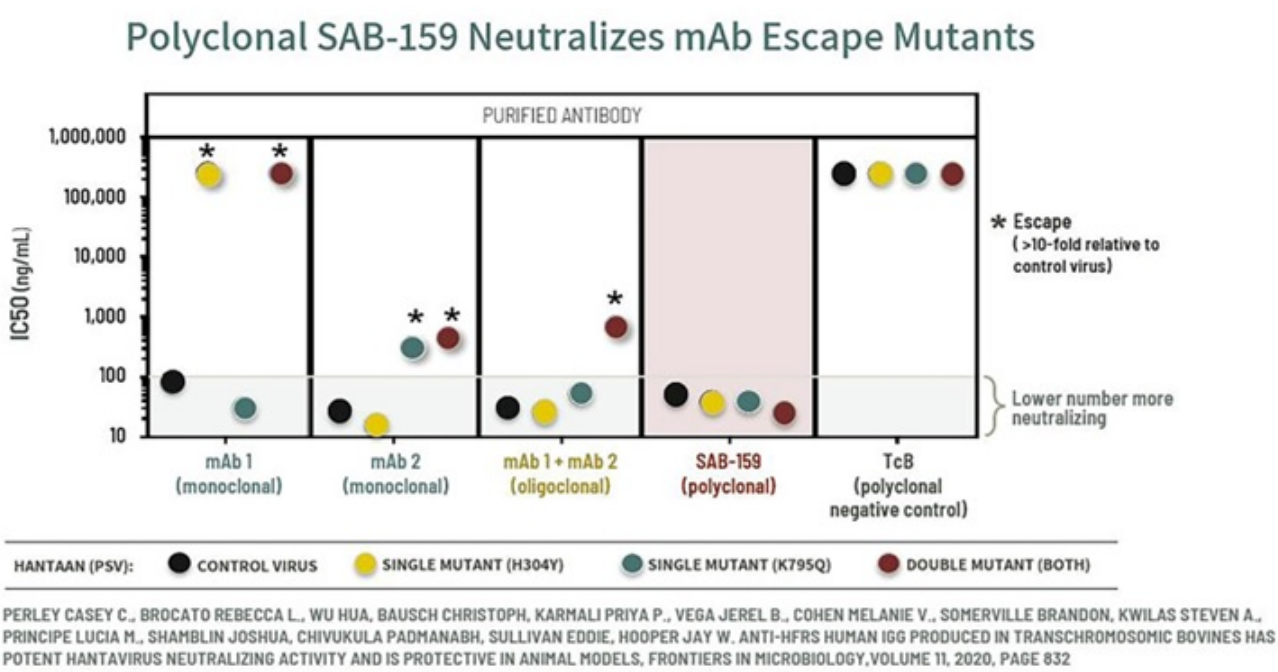


Figure 29: SAB-159 Study

Figure 29 above demonstrates the potential therapeutic advantage of our IgGs to effectively neutralize highly mutating pathogens such as Hantaan viruses. A study conducted in 2019 demonstrated SAB-159, an anti-Hantaan hIgG, completely neutralized the original wild-type virus, as well as both single mutants, and a double mutant of Hantaan virus. Effective neutralizing potency is indicated by the low *in vitro* IC50 threshold concentration below 100ng/mL indicated by the small grey area at the bottom of Figure 29. In contrast, two neutralizing mAbs alone or in combination could not completely neutralize the two different mutations individually or in combination.

Effector Functions of our hIgGs

hIgGs specifically bind to antigens through their variable regions, but also, depending on their specific hIgG isotype, activate effector functions via their Fc domains. Native humoral immune responses against pathogens or target antigens do not consist of a single antibody, but of complex hIgGs composed of multiple affinity matured hIgGs binding to numerous epitopes. The binding of polyclonal hIgG's to multiple epitopes aids in eliciting the activation of innate host effector mechanisms, such as antibody dependent-cellular cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC) and antibody-dependent cellular phagocytosis (ADCP). As mentioned previously our DiversitAb produced hIgG therapeutics also contain a fully functional antibody Fc domain that is unmodified and naturally diverse as well. This fully functional Fc domain allows for effector cell engagement and activation as demonstrated in the data presented below.

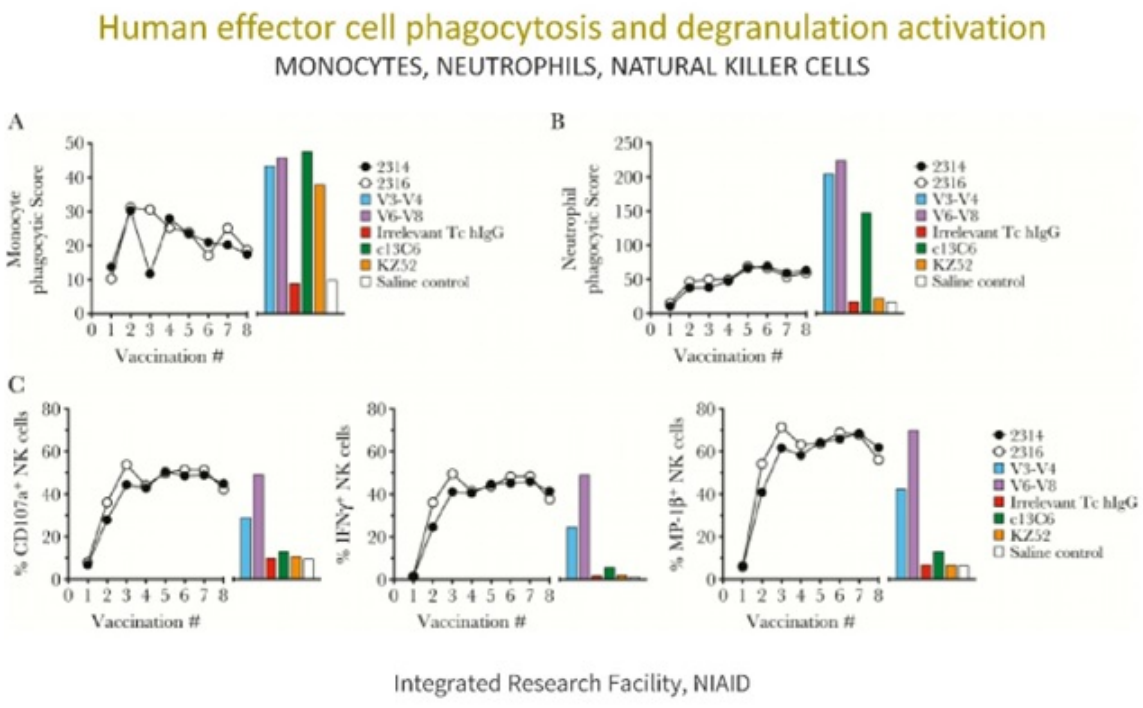


Figure 30: Activation of Human Effector Cell Function

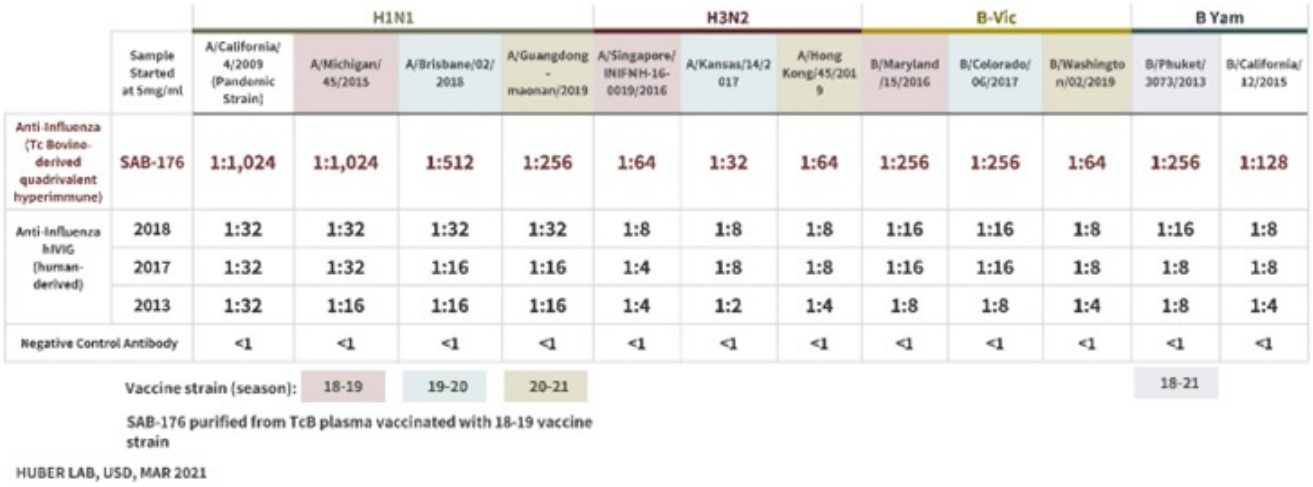
In Figure 30 above, the lines with solid black and white circles represent monocyte and neutrophil phagocytosis in Figure A and Figure B and Natural Killer cell degranulation in Figure C from the serum of two Tc Bovines hyperimmunized with Ebola glycoprotein on eight occasions. The blue and purple bars represent two Tc Bovine human IgG lots produced from their plasma after the third and fourth immunizations and from the sixth, seventh and eighth immunizations respectively. The red and white bars represent a naïve Tc Bovine human IgG and normal saline respectively. The green and orange bars represent two anti-Ebola glycoprotein monoclonals. As can be seen, both lots of anti-Ebola Tc Bovine human IgGs demonstrated the ability to induce monocyte and neutrophil cell phagocytosis and Natural Killer cell degranulation. The lot produced from plasma after the sixth to the eighth immunization had better activity and is consistent with avidity maturation of the IgGs. In contrast, while the monoclonals induced monocyte phagocytosis, only one was able to induce neutrophil phagocytosis. And critically, neither monoclonal antibody had the ability to induce Natural Killer cell degranulation. This demonstrates that Tc Bovine-produced human IgGs induce human effector cells which are critically important to the control of viruses, bacteria, and other pathogens.

Multitarget Immunoglobulin Diversity in a Single Vial Designed to Effectively Treat Complex Disease

Another key product differentiator of our hIgGs is the ability to produce a multitarget product that addresses the complexity of disease in a single drug product vial. This is a particularly powerful multivalent combination when multiple antigen targets are combined with the natural muti-epitope targeting of a single antigen (described above), as the therapeutic advantage is expanded to address multiple disease modalities all within a single vial. We believe single or combinatorial monoclonal antibody therapies are significantly challenged to reproduce this competitive product advantage. Replicating this hIgG product attribute is costly and challenging for mAbs due to constraints adhering to the full factorial clinical trial design requirements by CDER where dosing two mAbs targeting separate epitopes for a combinatorial product is challenging enough let alone potentially hundreds of epitopes to multiple antigen targets covered by a hIgG therapeutic. In addition, mAbs are specifically at risk regarding the treatment of highly mutating disease targets such as upper respiratory viral infections like Influenza or COVID-19, complex bacterial infections (like *C. diff.*), or anti-microbial resistant bacteria, highly complex immune diseases like Type 1 diabetes, or highly mutating cancers. This risk was realized for monoclonal antibody therapy during the COVID-19 pandemic where single and combinatorial mAb therapies were reported to have lost significant neutralizing activity against highly mutating SARS-CoV-2 viruses.

A multi-target approach was used to produce SAB-176 developed to target both Type A and Type B seasonal influenza strains, and data demonstrating the multi-target neutralization from cross protective IgGs to non-targeted influenza strains like pandemic H1N1 (pH1N1) is shown in the Figure 31 below. The competitive advantage of this multi-target product approach for SAB-176 was further supported with our Phase 2a challenge trial where the primary endpoint was met by significantly reducing the viral load of patients challenged with pH1N1 influenza. The versatility of this multitarget approach can be further expanded with a strain add approach, where new seasonal strains are included in the production of SAB-176. This will maintain or expand the broad neutralization capability to both current and future seasonal influenza variants, and potentially extend to pandemic outbreaks. This strain add approach was implemented in producing SAB-176 for our Phase 2a challenge trial, where two influenza seasonal vaccines were used. This seasonal strain add approach simply requires strain add supplements to our regulatory filings.

We have additionally implemented this similar multi-target approach to produce our current preclinical pipeline products SAB-195 and SAB-142.



		H1N1				H3N2			B-Vic			B Yam	
	Sample Started at 5mg/ml	A/California/4/2009 (Pandemic Strain)	A/Michigan/45/2015	A/Brisbane/02/2018	A/Guangdong-maonan/2019	A/Singapore/INIFNH-16-0019/2016	A/Kansas/14/2017	A/Hong Kong/45/2019	B/Maryland/15/2016	B/Colorado/06/2017	B/Washington/02/2019	B/Phuket/3073/2013	B/California/12/2015
Anti-Influenza (Tc Bovine-derived quadrivalent hyperimmune)	SAB-176	1:1,024	1:1,024	1:512	1:256	1:64	1:32	1:64	1:256	1:256	1:64	1:256	1:128
Anti-Influenza hIVIG (human-derived)	2018	1:32	1:32	1:32	1:32	1:8	1:8	1:8	1:16	1:16	1:8	1:16	1:8
	2017	1:32	1:32	1:16	1:16	1:4	1:8	1:8	1:16	1:16	1:8	1:8	1:8
	2013	1:32	1:16	1:16	1:16	1:4	1:2	1:4	1:8	1:8	1:4	1:8	1:4
Negative Control Antibody		<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1

Figure 31: SAB-176 Study

Hemagglutination Inhibition (HAI) titers of SAB-176 and anti-Flu human IVIG (hIVIG) are reported against the individual viruses indicated in the heading with color coded for specific annual flu season vaccines. Three lots of anti-Flu human IVIG were cGMP manufactured from the pooled human plasma selected with high anti-Flu HAI titers in 2013, 2017 and 2018, respectively. SAB-176 was purified from Tc Bovine plasma vaccinated with the 2018-19 flu season vaccine strains. As shown in Figure 31 above, SAB-176 had higher HAI titers than anti-Flu hIVIG against seasonal flu vaccine strains and demonstrates the broad neutralization capability to past & future non-vaccine or non-targeted strains including the pandemic H1N1 strain.

Rapid Product Development Capability with Proven Regulatory Pathway

A final key differentiator is embedded in our polyclonal development approach that leverages our DiversitAb platform to capture discovery and production efficiencies not available to mAb product development. Through the utilization of our Tc Bovine, we are able to simultaneously perform discovery and production functions of our polyclonal development, significantly improving the time of antibody discovery and production. This efficiency was demonstrated during the COVID-19 pandemic where SAB-185 cGMP product was produced in 90 days from initial product concept. Our discovery process simply involves antigen design and production as the vaccinated Tc Bovine does the rest including antibody design, down selection, and scaled production all in one system.

Our regulatory pathway has also been established with the FDA. The FDA regulates polyclonal hIgGs and mAbs completely differently as mAbs are regulated through CDER and pAbs through CBER. CBER has approved over 40 IgG products from human- and animal-derived plasma and is very familiar with our DiversitAb platform and pAb product. We have navigated three SAB drug products through seven clinical trials with one product advanced to Phase 3. In combination with our rapid product development and vertically integrated process we have demonstrated our ability to file and IND in 128 days from product concept and rapidly advance through the clinic.

Proven DiversitAb Platform Product Development Versatility

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
Clostridioides 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

Figure 32: Overview of Our *In-Vivo* Animal Data From 2008 to 2018

Figure 32 provides an overview of our *in vivo* animal data from 2008 to 2018 that has enabled several pre-clinical studies with efficacy data demonstrating the broad potential of the DiversitAb platform to address diverse human diseases, globally. As shown in Figure 32, infectious disease has been a strategic proving ground for the validation of our platform. Listed above are several significant human diseases for which adequate countermeasures may not exist. These include Ebola, Middle East respiratory syndrome coronavirus (MERS-CoV), and Zika, among others. We have completed preclinical development for multiple potential infectious disease products to address these global emerging human biothreats, and we have repeatedly demonstrated 100% preclinical efficacy in several animal models for most targets. This consistent *in vivo* efficacy demonstrates the broad potential of the platform and has ultimately led to the clinical advancement of multiple Phase 1 clinical trials including MERS-CoV, and our advanced infectious disease pipeline products, SAB-176 and SAB-185.

Clinically Validated Across Several Targets Spanning Ph1 to Ph3 Clinical Trials

Initial Demonstration of Human Efficacy and Multi-Dosing Capability

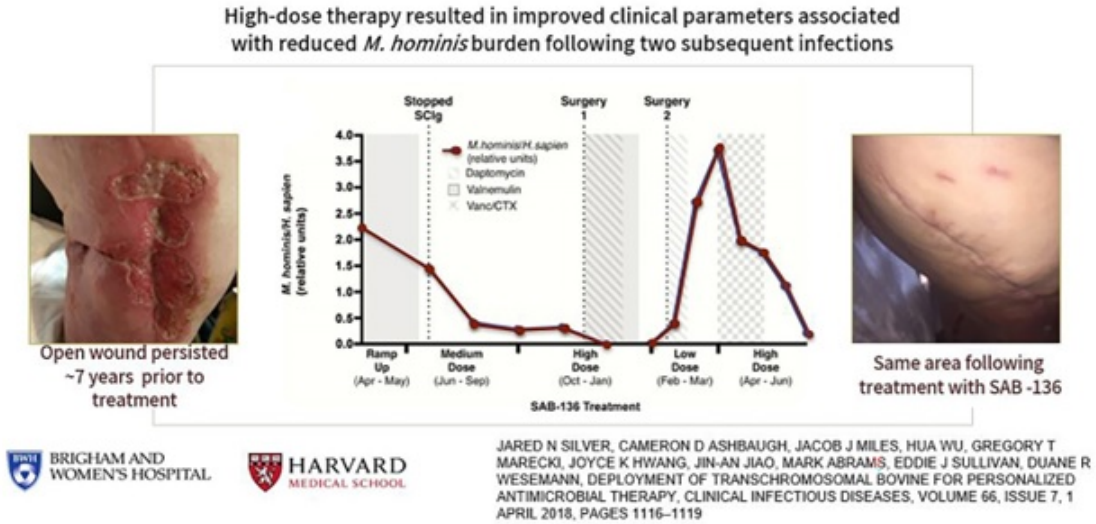


Figure 33: Demonstration of Human Efficacy and Multi-Dosing Capability

Figure 33 depicts a small efficacy trial in a single patient who had an antibiotic-resistant *mycoplasma hominus* infection. Conducted in 2017 at Brigham and Women's Hospital, this study showed an initial indication of efficacy in Tc Bovine-derived anti-Mycoplasma human hIgGs in an immunosuppressed 68-year- old man diagnosed with a *M. hominis* septic polyarthritis who developed a chronically draining right hip fistula following a failed hip replacement surgery. The fistula is shown on the far-left image in Figure 33. He was treated with human-derived intravenous immunoglobulin and antibiotics for seven years during which time the mycoplasma became multi-antibiotic resistant. At the request of the patient and his physician, we produced the anti-mycoplasma human IgG therapeutic, which was intravenously administered to the subject at doses up to 100 mg/kg as shown in the center image of Figure 32. This was done under an FDA allowed Phase 1b study. The human hIgG product was well tolerated, and the subject's mycoplasma load fell to undetectable levels with rapid healing and closure of the fistula as shown on the far-right image in Figure 33.

The patient then elected to undergo a repeat hip replacement surgery and he developed a Staphylococcus Aureus and other bacteria wound infection including mycoplasma. The patient was then re-treated with the Tc Bovine- derived human IgGs which resulted in marked reductions in mycoplasma load as shown in the center table. This remarkable case study demonstrates the potential utility of Tc Bovine-derived human hIgGs to treat serious antibiotic resistant infections in general, but also the potential opportunity to produce specific human IgG therapeutics to treat individuals with intractable infections using a personalized medicine approach.

We have performed multiple clinical trials demonstrating safety in hundreds of patients and have demonstrated proof of concept for our DiversitAb platform in the clinic that includes three SAB-sponsored INDs and one CTA (filed Ex-US) that encompass seven clinical trials from Phase 1 to Phase 3 across treatment of three indications (MERS, Influenza, and COVID-19) briefly summarized below.

First-in-Man Clinical Safety and Efficacy

The first-in-human clinical trial of SAB-301for MERS-CoV, conducted in 2017 and sponsored by the NIH, evaluated safety of this Tc Bovine-derived human IgGs. The study was a blinded, placebo controlled, ascending dose study in healthy adults that investigated doses of 1.5 mg/kg to 50 mg/kg of intravenously administered product in 38 participants that were followed for 90 days post-infusion. The conclusion was that SAB-301 was safe and well tolerated. Pharmacokinetic analysis demonstrated a half-life of the anti-MERS-CoV human IgGs of 28 1/2 days, which is the reported half-life of human-derived hIgGs in humans.

Importantly, anti-drug antibodies, or antibodies to ligands used in our DiversitAb purification process, or anti-bovine plasma protein antibodies were not detected.

SAB-176 (anti-Influenza) Advanced through a Phase 2a Challenge Trial

Our SAB-176 program is a multitarget anti-influenza product that specifically targets both Type A and Type B seasonal influenza strains. In December 2021, we announced topline data for a Phase 2a challenge trial that was initiated in June 2021. This was a randomized, double-blind study in 60 healthy adults that were challenged with a pandemic influenza virus strain (pH1N1). The primary endpoint of the study was achieved despite the fact that SAB-176 was not produced specifically targeting the pH1N1 strain. This was not only a successful Phase 2a for our influenza program but demonstrated in a human study the multivalent competitive advantage of our DiversitAb produced hIgGs as cross protective IgGs generated from our multitarget seasonal Type A and Type B influenza product, SAB-176 met the primary end point criteria of significantly reducing patient pH1N1 influenza viral load. Our SAB-176 program is further detailed in the Pipeline section above.

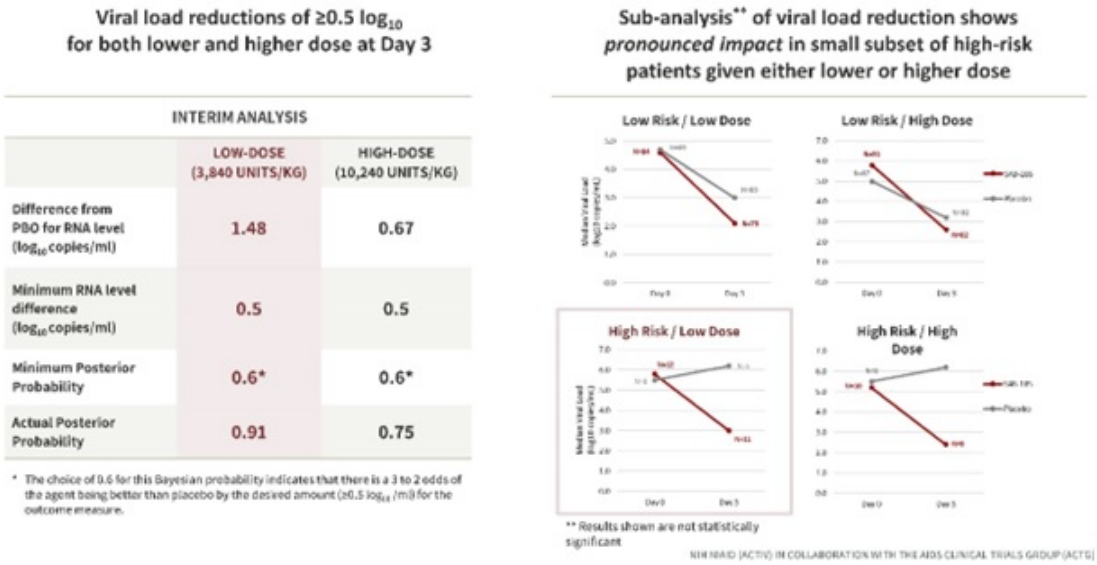


Figure 34: SAB-185 Study - Double-Blind Study in Ambulatory Adults

Figure 34 above presents a randomized double-blind study in ambulatory adults with confirmed SARS-CoV-2 infection with symptoms less than 7 days. 110 were randomized to low dose, 110 randomized to high dose, and 110 to placebo. The graduation criteria to the Phase 3 portion of this adaptive phase 2/3 study included a minimum posterior probability of reducing nasopharyngeal qRT-PCR of > 0.5 log compared to placebo by at least 0.6. Both doses exceeded this criterion at day 3. A post hoc sub-analysis showed that pronounced reductions in NP viral load was only observed in high-risk patients (obesity, chronic illness, etc.). This suggests that similar reductions in lung viral load could also occur and possibly provide protection against progression to pneumonia and/or severe disease.

Government Contracts and Collaborations

We have collaborated extensively with U.S. Government agencies within both the U.S. Department of Defense ("DoD") and the U.S. Department of Health & Human Services (HHS). We executed an award from Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO - CBRND) Joint Project Lead for Enabling Biotechnologies (JPL-EB) (hereafter JPEO-EB) within the DoD that includes co-funding from the Defense Health Authority and from BARDA (within HHS). The award totaled approximately $200 million. The scope of the award included proof-of-concept, scaling and live-fire of a Rapid Response Antibody Program leveraging our response capabilities and was expanded to include our COVID-19 therapeutic, SAB-185, as part of the Countermeasures Acceleration Group (formerly Operation Warp Speed). That expansion included significant capacity growth, addition of capabilities, and expansion of infrastructure including human resources and facilities. On August 3, 2022, we received notice from the DoD terminating the JPEO Rapid Response contract. No termination penalties were incurred by SAB in connection with the termination. SAB received two final payments from the U.S. Government for work performed and winddown activities on this award in November 2022 and January 2023 which totaled approximately $16.8M.

Manufacturing Strategy

In support of our operations, we currently operate two plasma fractionation purification facilities in Sioux Falls, South Dakota: a 50L small batch scale cGMP suite that has produced clinical grade drug product to accommodate Pre-Clinical and Phase 1 studies, and a 200L scale larger batch cGMP suite that was completed in 2021 which can be used to produce clinical grade drug substance and drug product to accommodate larger sized advanced Phase 2 clinical studies or Emergency Use.

In addition, we maintain supportive laboratory facilities and operations in Sioux Falls, South Dakota, for drug discovery, product and process development, and clinical manufacturing. We have fully compliant quality control testing facilities and we have further developed our own internal antigen (immunogen) discovery and production capabilities to accommodate the Tc Bovine immunizations that improve our overall plasma production speed and efficiency further enhancing our drug discovery and clinical manufacturing timeline.

Our Tc Bovine are housed at dedicated specialty facilities that cater to the production, health, safety, and welfare of the animals, and provide plasma production. We recently completed an expansion of our research and development laboratory facilities to accommodate our discovery programs, support for our pre-clinical pipeline programs, and process development research for our product candidates. The upstream process is easily scalable. Animals donate plasma three times per month (2.1% of bodyweight each time). To produce more product, more animals are added to the program and immunized to the target.

Competition

The biopharmaceutical industry is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We believe our scientific knowledge, technology, and development capabilities provide us with substantial competitive advantages, but we face potential competition from multiple sources, major pharmaceutical, specialty pharmaceutical and existing or emerging biotechnology companies, academic research institutions, governmental agencies, and public and private research institutions worldwide.

Our competitors may have significantly greater financial resources, robust drug pipelines, established presence in the market and expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing, and management personnel, in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

If any future product candidates identified through our current lead programs are eventually approved for sale, they will likely compete with a range of treatments that are either in development or currently marketed for use in those same disease indications. Our success will partially depend on our ability to obtain, maintain, enforce, and defend patents and other intellectual property rights with respect to our IgGs that are proven to be safer or more effective or are less expensive than competing products. We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, better tolerated, more effective, more convenient to administer, less expensive, more resistant to viral escape, or receive a more favorable label than our product candidates.

Intellectual Property

We actively seek to protect the intellectual property and proprietary technology platform that we believe is important to our business, which includes seeking and maintaining patents covering our technology platform and products, and any other inventions that are commercially or strategically important to the development of our business. We also seek to protect the confidentiality of trade secrets that may be important to the development of our business. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. For more information, please see “Risk Factors – Risks Related to Our Intellectual Property.”

The portfolio of intellectual property and trade secrets that we have developed includes patents related to the activity of our human artificial chromosome and methods that we expect to generate fully human IgGs at commercial scale. The patent portfolio includes composition and method patents. Our goal is to continue expansion of the breadth of claims and length of claim protections. Our technologies may be difficult to replicate, creating potential barriers to entry, as our genetic engineering know-how and suite of proprietary platform IP and trade secrets have been developed and optimized over nearly two decades.

We expect our global patent protection to extend to 2041 and beyond with respect to producing commercial-scale human IgGs using our chromosome engineering that generates high concentrations of human IgGs in ungulates. However, we recognize that patents and other intellectual property rights in biotechnology are constantly evolving with many risks and uncertainties, which may affect those rights.

As of December 2022, our patent portfolio includes over 40 issued patents or pending applications. We have made strategic filings in jurisdictions including the United States, Australia, Canada, China, Europe, Japan, Korea, and Mexico.

These patent families cover:

- Granted U.S. patent relating to methods of cloning a non-human mammal using transgenic ungulate embryos of one or more cells that have a human chromosome fragment and transgenic ungulate embryos of one or more cells that have a human chromosome fragment, and methods for making them (expiring in 2023 and 2025).
- Granted patents in the U.S., Europe, Japan, and other major markets relating to a human artificial chromosome vector comprising a gene encoding the human antibody heavy chain, a gene encoding the human antibody light chain, and a gene encoding IgM heavy chain constant region derived (at least in part) from a nonhuman animal (expiring in 2033).
- Granted patents U.S., Europe, Japan, and other major markets relating to large-scale production of human IgGs by transgenic animals with high production of fully human hIgG of at least 1 g/L in sera (expiring in 2030 and in the U.S., 2031).
- A granted U.S. patent relating to reprogramming a call to express a T-cell receptor reactive with an antigen of interest (expiring in 2025).
- A granted U.S. patent and a pending U.S. application relating to methods for producing human IgGs against a pathogen comprising injecting a non-human animal with a viral pathogen-derived DNA vaccine in at least two locations of the animal (expiring in 2036).
- Granted U.S. patents covering cloned transgenic ungulates (e.g., bovines) in which prion protein activity is reduced by one or more genetically engineered mutations (expiring in 2023 and 2025).
- Related to anti-thymocyte globulin (ATG) products, pending patent applications in the U.S., Europe, Japan, and other major markets covering ungulate-derived polyclonal immunoglobulin compositions comprising fully human or substantially human immunoglobulins that specifically bind human thymocytes, T cells, B cells, and/or monocytes, and methods of making and using the same in treating or preventing organ transplant rejection or type 1 diabetes (if issued, naturally expiring in 2041).
- Pending international and U.S. patent applications covering ungulate-derived human immunoglobulins that specifically bind coronavirus S protein, and methods of making and using the same in treating or preventing coronavirus disease (if issued, naturally expiring in 2041).
- Pending U.S. provisional application covering ungulate-derived human immunoglobulins that specifically bind influenza antigen, and methods of making and using the same in treating or preventing influenza (if issued, naturally expiring in 2042).

Our proprietary know-how and trade secrets include the following:

- Complex chromosome engineering trade secrets.
- Immunogen dose levels used for nucleotides, peptides, proteins, closely autologous proteins, virus particles, whole inactivated viruses, cell membranes, whole cells, bacteria, glycol-proteins, human cell immunogens, tissue preparation.
- Our adjuvants formulations for immunogen hyperimmunization.
- Bovine plasma fractionation procedures and trade secrets contained within our proprietary Standard Operating Procedures.
- Animal husbandry procedures for human antibody-producing ungulates.
- Transgenic neo-natal ungulate IVIG administration for failure of passive immunity.
- Certain cell culture and cloning practices.
- Plasma collection procedures.

U.S. Patent System

In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may potentially be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. PTO in examining and granting a patent considering delays on the part of the patentee or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the patent term of a patent that covers an FDA-licensed biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product licensure, only one patent applicable to a licensed biologic may be extended and only those claims covering the licensed biologic, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers a licensed biologic. In the future, if and when our product candidates. Receive FDA approval or licensure, we expect to apply for patent term extensions on patents covering those products. We expect to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors – Risks Related to Our Intellectual Property."

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of useful applications of our proprietary technologies and products, as well as new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We may periodically reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that coverage and value are obtained for our processes, and compositions, given existing patent law and court decisions. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on several factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy subject matter, written description, and enablement requirements of the various patent jurisdictions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will be issued as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented, or invalidated by third parties.

In addition to patent protection, we also rely on trade secrets, know-how, other proprietary information and/or continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors, or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors – Risks Related to Our Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific, and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the U.S. PTO to determine priority of invention. For more information, see the section titled "Risk Factors – Risks Related to Our Intellectual Property."

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of FDA approval of product candidates, some of a sponsor's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the product development and FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval or licensure date. The patent term restoration period generally is- once the patent issues- one-half the time between the effective date of an IND and the submission date of a biologics license application ("BLA") less any time the sponsor did not act with due diligence during the period, plus the time between the submission date of a BLA and the approval of that application less any time the sponsor did not act with due diligence during the period. Only one patent applicable to an approved biological product is eligible for the extension, only those claims covering the licensed biologic, a method for using it or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent. Moreover, a given patent may only be extended once based on a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Government Regulation

In the United States, we expect our hIgG product candidates to be regulated by the FDA as biological products. Additionally, in manufacturing our product candidates, we alter the genomic DNA in animals, and FDA considers such altered genomic DNA in an animal to be a new animal drug, which require submission and approval of a New Animal Drug Application (NADA) prior to being marketed in the United States.

Regulation of Transgenic Animals and New Animal Drugs

The U.S. Department of Agriculture (USDA) regulates the company's Tc Bovine husbandry activities, including housing, healthcare, and general management of these specialized animals. This includes regulations and periodic facility inspections and reporting. We also are voluntarily accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). The AAALAC International accreditation program evaluates organizations that use animals in research, teaching or testing. Those that meet or exceed AAALAC standards are awarded accreditation. The accreditation process includes an extensive internal review conducted by the institution applying for accreditation.

The FDA considers, with limited exclusions, the altered genomic DNA in an animal to be a drug because such altered DNA is an article intended to affect the structure or function of the body of the animal, and, in some cases, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the animal. In the United States, new animal drugs are subject to regulation under the Federal Food, Drug, and Cosmetic (FD&C) Act, and under the FD&C Act, in general, a new animal drug is "deemed unsafe" and adulterated unless the FDA has approved a new animal drug application (NADA) for its intended use or unless the drug is only for investigational use and conforms to specified exemptions for such use under an investigational new animal drug (INAD) exemption. Further, early in the development process, FDA has allowed the submission of information to FDA's Center for Veterinary Medicine (CVM), without the establishment of an INAD file, such as through creation of a veterinary master file (VMF), subject to certain conditions such as restrictions on introducing any food derived from such investigational animals into the food supply.

The requirements governing development and approval of a new animal drug are analogous to those for new human drugs. A NADA must generally be accompanied by payment of a substantial user fee and must contain substantial evidence of the safety and effectiveness of the new animal drug as well as detailed descriptions of the methods used in and the facilities and controls used for the manufacturing, processing and packaging of the new animal drug to enable FDA to reach a determination that such methods, facilities and controls are adequate to preserve the identify, strength, quality and purity of the new animal drug. Further, when FDA reviews and approves a NADA, FDA generally conducts a review of environmental risks pursuant to the requirements of the National Environmental Policy Act (NEPA), if any and where required.

The steps involved in completing the INAD/NADA process are cumulative and risk based with each component of the assessment forming the basis on which the next step is evaluated.

Step 1: Product Identification

Product identification (21 CFR 514.1(b)(1)), which many molecular biologists would refer to as product definition, forms the foundation for the evaluation process and drives subsequent data generation and review. It encompasses the specific GE animal (that is, the article as well as the GE animal containing it) and the purpose (i.e., intended use) of the article that is the subject of the NADA.

Step 2: Molecular Characterization of the Construct

This step of the process serves to describe the components and composition of the article. (21 CFR 514.1(b)(4).

Step 3: Molecular Characterization of the GE Animal Lineage

This step continues the analysis of the rDNA construct in the resulting GE animal, as well as the production of the GE animal(s) intended to be used in commerce and any potential hazards that may be introduced into those animals as part of their production.

Step 4: Phenotypic Characterization of GE Animal

The previous steps of the review process have concentrated on establishing and characterizing the rDNA construct and its integration into the resulting GE animals. Information in this and the following steps helps establish whether the GE animal poses any risks to humans, risks to health of the GE animal, or risks to the environment.

Step 5: Genotypic and Phenotypic Durability Assessment

As in Step 3, this step also addresses some additional components of the manufacturing requirements codified in 21 CFR 514.1(b)(5). It is intended to provide information to ensure that the rDNA construct in the GE animal resulting from the specific transformation event and defining (identifying) the GE animal being evaluated is durable – that there is a reasonable expectation that the rDNA construct is stably inherited, and the phenotype is consistent and predictable.

Step 6: The Food/Feed Safety and Environmental Safety Assessments

Food/Feed Safety

This portion of step 6 addresses the food and feed safety requirements in 21 CFR 514.1(b)(8). It focuses on the issue of whether food or feed derived from a GE animal is safe for humans or animals consuming edible products from the animals.

Environmental Safety

This portion of Step 6 addresses the environmental component of an NADA. 21 CFR 514.1(b)(14). GE animal applications have to be evaluated to determine whether such an application individually or cumulatively affects the environment (i.e., whether an extraordinary circumstance exists). 21 CFR 25.21. An Environmental Assessment that demonstrates the GE animal will not significantly affect the quality of the human environment leads to a finding of no significant impact (FONSI).

Step 7: Effectiveness/Claim Validation

The previous steps of the review process primarily address identity and safety issues. This last step of pre-market review addresses effectiveness, i.e., whether the claims have been validated for the characteristics that the GE animal is intended to exhibit. 21 CFR 514.1(b)(8).

CVM manages the regulation of our Tc Bovine technology, and we engage in scientific and regulatory communications with CVM focused on SAB's animal plasma as the source of drug substance and product. CVM has regulatory oversight of animals with intentional genomic alterations (IGA) to produce drugs and biological products intended for human use.

This is a one-time approval process for a platform technology that may produce multiple targeted products in the future that would be regulated by another Center at FDA (i.e., CBER).

CVM has regulatory responsibility for veterinary and food safety issues associated with final products and the use of IGA animals. CVM and other FDA Centers work interactively to regulate IGA animals and their products. Regulations 21 CFR, Parts 58, 210, 211, 600, 680 and 9 CFR, Parts 1, 2, 3 are applicable to aspects of production or disposition of these IGA animals. CVM has Guidance 187 for Regulation of Intentionally Altered Genomic DNA in Animals for the regulatory oversight and approval process for IGA animals intended for production of biological products for human use, as well as CBER's Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals (CBER 1995).

We have a longstanding relationship with CVM and have an Investigational New Animal Drug (INAD-011204) on file. Data and information on the safety and effectiveness of the genetic modifications of Tc Bovine are currently in the process of being submitted in a series of seven steps in accordance with Guidance 187 and under review by CVM. Once all steps are completed and reviewed by CVM, an administrative New Animal Drug Application (NADA) will be submitted for final review and approval. The current expectation is to have the NADA completed by the fourth quarter of 2024. We are also currently filing a new animal drug application (NADA) assessing the safety and effectiveness of genetic modifications to the Tc Bovine animals with the CVM. This is a one-time process that includes future post approval responsibilities related to the durability of animal health and antibody response.

U.S. Biological Products Development Process

In the United States, biologic products are licensed by the FDA for marketing under the Public Health Service Act, (PHS Act), and regulated under the Federal Food, Drug, and Cosmetic Act (FDCA). Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, record keeping, storage, distribution, marketing, sales, import, export, reporting, advertising, and other promotional practices involving biologic products. FDA authorization is required prior to clinical testing of biologic products. FDA licensure also must be obtained prior to marketing of biologic products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial financial resources and time.

Multiple immunoglobulin and monoclonal antibody products have been approved by the FDA to prevent or treat human diseases. Though the FDA regulates both monoclonal antibodies and immunoglobulin products, Monoclonal antibodies are regulated by the Center for Drug Evaluation and Research (CDER). A monoclonal antibody is characterized by its molecular structure. This approach is similar to the process that CDER uses to regulate small molecule drugs. Because mAbs are designed to bind to a single epitope, mutation is a significant concern due to selective pressure. IgGs derived from animals or humans are regulated by the Center for Biologics Evaluation and Research (CBER). CBER has currently approved thirty-nine unique immunoglobulin products for commercial sale. Human and animal-derived IgGs are characterized by their in vitro potency and not by the molecular structure of each antibody in the product. U.S. Development Process.

Hybrid Process for a Biological Product Is Developed from Animals with Intentionally Altered Genomic DNA

The process required by the FDA before a biologic product may be marketed in the United States is generally well documented. In the case of a product that is developed from animals with intentionally altered genomic DNA as the donor material source, the process is more complex and involves both CVM, to oversee the intentionally altered genomic DNA in animals and the Office of Tissues and Advanced Therapies (OTAT) at FDA's Center for Biologics Evaluation and Research (CBER) to oversee the immunoglobulin products.

Key aspects of the process include the following:

- completion of nonclinical laboratory tests and animal studies according to Good Laboratory Practices (GLPs), and the Animal Welfare Act administered and enforced by the U.S. Department of Agriculture;
- submission to CVM of an application for an INAD, which must become effective before human clinical trials may begin; completion of nonclinical laboratory tests and animal studies according to Good Laboratory Practices (GLPs), and the Animal Welfare Act administered and enforced by the U.S. Department of Agriculture;
- preparation of clinical trial material in accordance with Good Manufacturing Practices (GMPs);
- submission to the FDA of an application for an Investigational New Drug Application (IND), which must become effective prior to beginning any human clinical trials;
- approval of the protocol and related documentation by an institutional review board (IRB) or ethics committee at each clinical site prior to initiation of each clinical trial;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices (GCPs), and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity, potency, and efficacy of the proposed biologic product for its intended use;
- preparation of and submission to CVM of a NADA for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed altered genome in animals for its intended indication, including from results of nonclinical testing and clinical trials;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, potency, and efficacy from results of nonclinical testing and clinical trials;
- payment of user fees for FDA review of the NADA and BLA, unless a fee waiver applies;
- satisfactory completion of an FDA inspection prior to a BLA approval of the manufacturing facility or facilities where the biologic product is produced to assess compliance with GMPs to assure that the facilities, methods, and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- potential FDA Advisory Committee meeting to elicit expert input on critical issues, including a vote by external committee members;
- FDA review and approval of the NADA and BLA, which may be performed in parallel, but the NADA must be granted before a final decision can be made on the BLA, resulting in the licensure of the biological product for commercial marketing; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

Before testing any biologic product candidate in humans, the product candidate enters the preclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, pharmacology, toxicity, and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements, including GLPs.

Prior to beginning the first clinical trial with a product candidate developed from an animal with altered genomic DNA in the United States, an INAD must be submitted to CVM and an IND must be submitted to CBER, and the FDA must allow the INAD and IND to proceed. INAD submission is a one-time process and doesn't have to be repeated with our investigational products for each IND submission for products produced by Tc Bovine with the same HAC. An INAD and IND are exemptions from the FD&C Act that allow an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an INAD, applicants must submit to the FDA the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things. In support of a request for an IND, applicants must submit to the FDA a protocol for each clinical trial and any subsequent protocol amendments. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted as part of an IND. An INAD and IND must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial.

Additionally, under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee (IBC), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials may involve the administration of the biologic product candidate to healthy volunteers or subjects under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials involving some products for certain diseases may begin with testing in patients with the disease. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects or his or her legal representative provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. IRBs are charged with protecting the welfare and rights of study participants and consider such items as whether the risks to individuals participating in clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The biologic product is initially introduced into healthy human subjects and tested for safety. In the case of some biologic products for rare diseases, the initial human testing is often conducted in patients.

- *Phase 2*. The biologic product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the biologic product for specific targeted diseases and to determine dosage tolerance, optimal dosage, and dosing schedule.

- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the biologic product and provide an adequate basis for product labeling. In biologics for rare diseases where patient populations are small and there is an urgent need for treatment, Phase 3 trials might not be required if an adequate risk/benefit can be demonstrated from the Phase 2 trial.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written INAD and IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biologics, the PHS Act emphasizes the importance of manufacturing control for biologic products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its clinicaltrials.gov website. Disclosure of the results of such trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit trial results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on clinicaltrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have recently begun enforcing those requirements against non-compliant clinical trial sponsors. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a NADA requesting approval of the altered genomic DNA in donor animals and a BLA requesting approval to market the product for one or more indications. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort, and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended, or the PDUFA, each BLA may be accompanied by a significant user fee. Under federal law, the submission of most applications for approval of drug and biologic products is subject to an application user fee. The sponsor of an approved application is also subject to an annual program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of a BLA or within 30 days following submission of a NADA, the FDA reviews the submitted application to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the application must be resubmitted with additional information. The resubmitted application also is subject to review to determine if it is substantially complete before the FDA accepts it for filing. In most cases, the submission of an application to FDA is subject to a substantial application user fee, although the fee may be waived under certain circumstances.

Under the performance goals and policies implemented by the FDA under the Animal Drug User Fee Act (ADUFA) for original NADAs, the FDA targets 180 days from the submission date in which to complete its initial review and act on a standard application. A NADA is considered incomplete if it requires additional data or information to enable the FDA to complete and reach a decision on issues presented in the NADA. Once the sponsor reactivates the NADA by addressing identified deficiencies, the FDA targets 135 to 180 days, depending in part on whether the deficiencies are identified as not substantial or substantial, respectively, to complete its review and respond to the applicant.

The sponsor of a new animal drug may voluntarily decide to utilize FDA's "phased review" process to complete all technical sections required for approval of a new animal drug before submitting a NADA by submitting such information during the investigational phase of the animal drug development process. Utilizing this process, the sponsor may submit an administrative NADA, which is a NADA submitted after all technical sections necessary to fulfill the requirements for the approval of a new animal drug have been reviewed by the CVM and the CVM has issued a technical section complete letter for each of the required technical sections. The FDA targets 60 days from the filing date to complete its review and act on an administrative NADA.

Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act (PDUFA) for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NADA and BLA. The FDA reviews the applications to determine, among other things, whether the proposed product is safe, pure, and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity, and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a NADA or BLA, the FDA may inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical trial sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To ensure GMP and GCP compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production and quality control.

After the FDA evaluates a NADA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or for an NADA and BLA respectively, an Incomplete Letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. An Incomplete Letter or a Complete Response Letter will describe all of the deficiencies that the FDA has identified in the NADA or BLA. Where the FDA determines that the data supporting a BLA are inadequate to support approval, the FDA may issue a Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing an Incomplete Letter or Complete Response Letter, the FDA may recommend actions that the applicant might take to place the NADA or BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a NADA or a BLA if applicable regulatory criteria are not satisfied or require additional testing or information.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings precautions or interactions be included in the product labeling. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Further, for biological products, the FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the biological product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We will rely, and expect to continue to rely, on third parties to produce clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Following approval, the manufacturing facilities are subject to periodic inspections by the FDA, and such inspections may result in an issuance of FDA Form 483 deficiency observations, an untitled letter, or a warning letter, which can lead to plant shutdown and other more serious penalties and fines. Prior to the institution of any manufacturing changes, a determination needs to be made whether FDA approval is required in advance. If not done in accordance with FDA expectations, the FDA may restrict supply and may take further enforcement action. Annual product reports are required to be submitted annually. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse events, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA may conduct laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. Manufacturers of biological products must establish systems to record and evaluate adverse events reported by healthcare providers and patients and to assess product complaints. An increase in severity or new adverse events can result in labeling changes or product recalls. Defects in manufacturing of commercial products can result in product recalls.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions. Failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Additionally, rigorous and extensive FDA regulation of new animal drugs continues after approval. Owners of approved NADAs continue to have ongoing responsibilities under the FD&C Act, including registration and listing, recordkeeping, filing supplements, and periodic reporting.

Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, priority review, accelerated approval and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new biological products to patients earlier than under standard FDA review procedures. To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a biological product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a fast-track BLA before the application is complete, a process known as rolling review.

The FDA may give a priority review designation, such as a rare pediatric disease designation, to biological products that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA's review of an application is six months, rather than the standard goal of ten months under current PDUFA guidelines. Most products that are eligible for fast- track designation may also be considered appropriate to receive a priority review. In addition, biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a biological product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints, and the biological product may be subject to accelerated withdrawal procedures. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Moreover, under the FDA Safety and Innovation Act enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all the benefits of fast-track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. Drug and biological products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification and the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval and may not ultimately expedite the development or approval process.

Emergency Use Authorizations

While, in most cases, a biologic must be approved by the FDA pursuant to a BLA before the product may be sold, when there is a public health emergency involving chemical, biological, radiological, or nuclear agents, including infectious diseases like COVID-19, new therapeutics may be distributed pursuant to an Emergency Use Authorization (EUA). Under an EUA, the FDA may authorize the emergency use of an unapproved medical product or an unapproved use of an approved product for certain emergency circumstances to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, and after the Secretary of the Department of Health and Human Services has issued a declaration of emergency or threat justifying emergency use. EUAs are intended to address serious or life-threatening diseases or conditions caused by a chemical, biological, radiological, or nuclear agent, including emerging infectious disease threats, such as the COVID-19 pandemic. To receive an EUA, the product sponsor must demonstrate that the product "may be effective" in the prevention, diagnosis, or treatment of an applicable disease or condition. Additionally, the FDA must determine that the product's known and potential benefits outweigh the known and potential risks. Further there must be no adequate, approved, and available alternative product for the indication. Potential alternative products may be unavailable if there are insufficient supplies to meet the emergency need. The FDA may establish additional conditions on an EUA that are necessary to protect public health, including conditions related to information that must be disseminated to health care providers and patients, the monitoring and reporting of adverse events, and record keeping. Conditions may also relate to how a product is distributed and administered and how a product is advertised. Importantly, EUAs are not full marketing approvals. Rather, EUAs are only effective for the duration of the applicable EUA declaration. Full approval of the product under applicable standards established under the FDCA would be necessary to continue to distribute the product absent an EUA. EUAs may also be revised or revoked by FDA at any time.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Pediatric Trials

Under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug or biologic product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product via an approved BLA. Biosimilarity to an approved reference product requires that there be no differences in conditions of use, route of administration, dosage form and strength and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity is demonstrated in steps beginning with rigorous analytical studies or "fingerprinting," in vitro studies, in vivo animal studies and generally at least one clinical study, absent a waiver from the Secretary of the HHS. The biosimilarity exercise tests the hypothesis that the investigational product and the reference product are the same. If at any point in the stepwise biosimilarity process a significant difference is observed, then the products are not biosimilar, and the development of a stand-alone BLA is necessary. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA. Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

In addition to exclusivity under the BPCIA, a biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Regulation Outside of the United States

In addition to regulations in the United States, we are and will continue to be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies.

In the European Union, for example, a clinical trial application (CTA), must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with the applicable requirements, clinical study development may proceed. The requirements and process governing the conduct of clinical studies are to a significant extent harmonized at the European Union level but could vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. On January 31, 2022, the European Union's (EU's) Clinical Trial Regulation (Regulation (EU) No 536/2014) became effective. The Regulation harmonizes the assessment and supervision processes for clinical trials throughout the European Union via a Clinical Trials Information System, which contains a centralized European Union portal and database. We expect the Regulation to have significant material changes to clinical trials conducted or proposed to be conducted in the European Union.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, except for, among other things, country-specific document requirements. Innovative products that target an unmet medical need may be eligible for several expedited development and review programs in the European Union, such as The Priority Medicines (PRIME), scheme, which provides incentives similar to the breakthrough therapy designation in the United States. Such products are generally eligible for accelerated assessment and may also benefit from different types of fast-track approvals, such as a conditional marketing authorization or a marketing authorization under exceptional circumstances granted on the basis of less comprehensive clinical data than normally required (respectively in the likelihood that the sponsor will provide such data within an agreed timeframe or when comprehensive data cannot be obtained even after authorization).

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. A Pediatric Investigation Plan (PIP), in the European Union is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All applications for marketing authorization for new medicines must include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorization holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the European Union. Medicines authorized with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate by six months, even when the results of the studies are negative. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use marketing authorization, which if granted, provides 10 years of market protection.

Beginning on January 1, 2021, the Medicines and Healthcare products Regulatory Agency (MHRA), became the U.K.'s standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules apply in Northern Ireland than in England, Wales, and Scotland (together Great Britain). Northern Ireland continues to follow the European Union regulatory regime, but its national competent authority remains the MHRA. The MHRA has published a draft guidance on how various aspects of the U.K. regulatory regime for medicines operate in Great Britain and in Northern Ireland following the expiry of the Brexit transition period on December 31, 2020. The guidance includes clinical trials, marketing authorizations, importing, exporting and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the U.K. The new guidance has been given effect via the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019, or the Exit Regulations. The U.K. regulatory regime largely mirrors that of the European Union.

European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

- *Centralized Procedure*. Under the Centralized Procedure a so-called Community Marketing Authorization is issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA. The Community Marketing Authorization is valid throughout the entire territory of the European Economic Area (EEA) (which includes the 28 Member States of the European Union plus Norway, Liechtenstein, and Iceland). The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the European Union.

- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific, or technical innovation, or if its authorization would be in the interest of public health.

- *National Authorization Procedures*. There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

- Decentralized Procedure. Using the Decentralized Procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure. Under the Decentralized Procedure the applicant chooses one country as Reference Member State. The regulatory authority of the Reference Member State will then be in charge of leading the assessment of the marketing authorization application.

- Mutual Recognition Procedure. In the Mutual Recognition Procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Pharmaceutical coverage, pricing, and reimbursement

Significant uncertainty exits as to obtaining and maintaining coverage and adequate reimbursement for our product candidates, including SAB-185 and SAB-176, and the extent to which patients will be willing to pay out-of-pocket for such products in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage or adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided, and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that a procedure is safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. There may be pricing pressures from third-party payors in connection with the potential sale of any of our product candidates. Decreases in third- party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and coverage and adequate reimbursement may not be available with respect to the treatments in which our product candidates, if approved, are used under any foreign reimbursement system.

Other Healthcare Laws and Regulations

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti- kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. The term "remuneration" has been broadly interpreted to include anything of value;

- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- The Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage to obtain or retain business.

Many states have similar laws and regulations, such as anti-kickback and false claims laws, that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines and state laws that require drug and biologics manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Additionally, to the extent that any of our product candidates if approved, are sold in a foreign country, we may be subject to similar foreign laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and biologics. In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs and biologics administered by physicians. CMS also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. The ACA was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the ACA expanded manufacturers' rebate liability under the Medicaid Drug Rebate

Program by increasing the minimum Medicaid rebate for both branded and generic drugs and biologics, expanded the 340B program, and revised the definition of average manufacturer price (AMP), which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug

Rebate program under the ACA. These regulations became effective on April 1, 2016. Since that time, there have been significant efforts to modify or eliminate the ACA. For example, the Tax Cuts and Jobs Act ("Tax Act"), enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended ("Code"), commonly referred to as the individual mandate.

Other legislative changes have been proposed and adopted since passage of the ACA. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional congressional action is taken. However, pursuant to COVID-19 relief legislation, the 2% Medicare sequester reductions have been suspended from May 1, 2020, through December 31, 2021. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or have been effectively repealed through Executive Orders and/or executive agency actions. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. It is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing, or other legislation in individual states, could have a material adverse effect on the health care industry in the U.S.

The ACA requires pharmaceutical manufacturers of branded prescription drugs and biologics to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." The Bipartisan Budget Act of 2018 (BBA), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

The ACA also expanded the Public Health Service's 340B drug pricing program. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The ACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the ACA. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the way manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for pharmaceutical products.

Healthcare reform proposals recently culminated in the enactment of the Inflation Reduction Act (the "IRA"), in August 2022, which, among other things, will allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least seven years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also, beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates certain provisions under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. Thus, it is unclear how the IRA will be implemented but will likely have a significant impact on the pharmaceutical industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Our Corporate History

SAB Sciences, Inc. (formerly SAB Biotherapeutics, Inc.) was incorporated in April 2014 as a Delaware corporation ("Legacy SAB"). We acquired all the intellectual property rights to Tc Bovine and the DiversitAb platform from Sanford Applied Biosciences, a wholly owned subsidiary of Sanford Health, to develop targeted human IgGs to specific targets and advance clinical development and commercialization. The technology was originally contemplated in 1998 by professors at the University of Massachusetts Amherst and Amherst College who recognized a significant gap in immunotherapy applications, namely, using the natural way our bodies fight disease through a human immunoglobulin response. The technology founders established a biotech company called Hematech to develop the technology. This founding company was purchased and became a wholly owned subsidiary of Kirin in Tokyo, Japan in 2005. In 2007, the pharmaceutical division of Kirin became Kirin Pharma and in 2008 merged with Kyowa Hakko Kogyo to become Kyowa Hakko Kirin (KHK). The technology was developed through 2012 by Hematech as a wholly owned subsidiary of KHK. On December 31, 2012, KHK divested the technology and transferred ownership of all property, assets, and intellectual property of Hematech to Sanford Health and the technology was further developed by Sanford Applied Biosciences until we acquired it in its entirety in June 2014.

Since acquiring the technology in 2014, we have continued to develop intellectual property and specifically targeted human IgGs to multiple disease indications, and we have conducted or collaborated in eight clinical trials (six of which are in review), where we have demonstrated safety and efficacy in multiple Tc Bovine-derived human IgG product candidates. We have developed our rapid response capabilities and completed proof of concept using private resources as well as over $200 million of funds awarded from the U.S. Government emerging disease and medical countermeasures programs. In October 2021 we completed our business combination with Big Cypress Acquisition Corp. ("BCYP"), pursuant to which we debuted as a publicly traded company (the "Business Combination").

BCYP was incorporated as a special purpose acquisition company in the State of Delaware on November 12, 2020. On January 14, 2021, BCYP completed its initial public offering. On October 22, 2021, BCYP consummated the Business Combination with Legacy SAB, which changed its name from SAB Biotherapeutics, Inc. to Legacy SAB. In connection with the closing of the Business Combination, BCYP changed its name to SAB Biotherapeutics, Inc. and Legacy SAB became a wholly-owned subsidiary of SAB Biotherapeutics, Inc.

Corporate Information

Our principal executive offices are located at 2100 East 54th Street North Sioux Falls, South Dakota 57104, and our telephone number is (605)-679-6980. Our corporate website address is www.sab.bio. Our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements, and all amendments thereto, are available free of charge on our website. These reports are posted on our website as soon as reasonably practicable after they are electronically filed with the SEC. The public may read and copy any materials that we file with the SEC electronically through the SEC website (www.sec.gov). The information contained on the SEC's website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be part thereof.

Human Capital

As of December 31, 2022, we had 56 full-time employees, including 8 who hold advanced degrees. Of these employees, 35 were engaged in research and development activities, 7 were engaged in clinical activities and 14 were engaged in general and administrative activities. As of December 31, 2022, none of our employees were represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. We emphasize several measures and objectives in managing its human capital assets, including, among others, (i) employee safety and wellness, (ii) talent acquisition and retention, (iii) employee engagement, development, and training, (iv) diversity and inclusion and (v) compensation. These targeted ideals may include annual bonuses, stock-based compensation awards, a 401(k) plan with employee matching opportunities, healthcare, and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, family care resources, and/or employee assistance programs. We also provide our employees with access to various innovative, flexible, and convenient health and wellness programs. We designed these programs to support employees' physical and mental health by providing tools and resources to improve or maintain their health status and encourage engagement in healthy behaviors.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Special Note Regarding Forward-Looking Statements," you should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report, including our financial statements and related notes included at the end of this Annual Report and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our securities could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risk Factors Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. You should carefully consider the full risk factor disclosure outlined in this Annual Report, in addition to the other information herein, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes.

- We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We may incur losses for the foreseeable future and may not be able to generate sufficient revenue to maintain profitability.
- The successful development of pharmaceutical products is highly uncertain.
- All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.
- Regulatory approval for the genetic modification of animals, including those from which antibodies are isolated for injection into human patients, requires the approval of a New Animal Drug Application, which can be a lengthy and expensive process with uncertain outcomes, delays to which could substantially harm our business.
- If we encounter difficulties enrolling patients in clinical trials, clinical trials of our product candidates may be delayed or otherwise adversely affected.
- Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We may never obtain FDA approval for any product candidates in the United States, and even if we do, we may never obtain approval for or commercialize any product candidates in any other jurisdiction, which would limit our ability to realize their full market potential.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.
- Our current and future relationships with customers and third party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.
- Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.
- Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.
- We depend upon our senior management and senior scientific staff, and their loss or unavailability could put us at a competitive disadvantage.
- We rely on third parties to perform some of our research and preclinical studies and we plan to rely on third parties to conduct our clinical trials. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- We intend to rely on third parties to produce commercial supplies of our product candidates.
- If we fail to successfully operate our animal production facility, it may adversely affect our clinical trials and the commercial viability of our product candidates.
- We have not entered into long term manufacturing and supply agreements with any producers.
- Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.
- Collaborations with third parties may be important to our business. If these collaborations are not successful, our business could be adversely affected.
- We have historically relied on awards from, and contracts with, the U.S. Government to fund our business and operations, and will need to find new and alternative sources of funding following the discontinuance of certain such arrangements.
- We are subject to stringent environmental regulation and potentially subject to environmental litigation, proceedings, and investigations.
- If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.
- We may, now or in the future, be required to reimburse our counterparties in connection with costs incurred during performance of our contractual

arrangements.

- Our success depends on our ability to maintain the proprietary nature of our technology.

- We have third party collaborators that might claim rights in or to our technology and/or assets.
- We incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, financial condition, and results of operations.
- If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.
- We have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of December 31, 2022. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations, and adversely affect the trading price of our common stock.
- Our warrants are accounted for as liabilities and changes in value of the warrants could have a material effect on our financial results.
- The market price of our securities may be volatile, which could cause the value of any investment in our securities to decline.
- An investment in our common stock is extremely speculative and there can be no assurance of any return on any such investment.
- There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.
- Our failure to meet the continuing listing requirements of Nasdaq could result in a de-listing of our securities.
- Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.
- We have a significant number of warrants which are currently exercisable for shares of our common stock, and the exercise thereof would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- We may be subject to securities litigation, which is expensive and could divert management attention.
- Our ability to continue to operate as a going concern depends on our ability to obtain adequate financing in the future.
- Changes in tax laws and regulations or exposure to additional tax liabilities could adversely affect our financial results.

Risks Related to Our Business and Operations

We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We realized net losses in the fiscal years ended December 31, 2022 and 2021, we expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We are a clinical-stage biopharmaceutical company. We expect to experience variability in revenue and expenses which makes it difficult to evaluate our business and prospects. As such, we have incurred and anticipate that we will continue to incur significant operating losses in the foreseeable future. Our historical losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of product candidates as well as costs incurred for research programs and from general and administrative costs associated with these operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for the next several years. We expect that our operating expenses will continue to increase significantly, including as we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery stage programs, including further pre-clinical and clinical development of SAB-176, SAB-195 and SAB-142;
- advance our preclinical-stage product candidates into clinical development;
- invest in our technology and platform;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- market and sell our solutions to existing and new partners;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our operations;
- maintain, expand, enforce, protect, and defend our intellectual property portfolio;
- create additional infrastructure to support operations;
- add operational, financial, and management information systems and personnel to support operations as a public company;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties; and
- experience any delays or encounter issues with any of the above.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Our expenses could increase beyond expectations for a variety of reasons, including as a result of our growth strategy and the increase in the scope and complexity of our operations. In executing our strategy and plans to invest in enhancing and scaling our business, we will need to generate significant additional revenue to achieve and maintain future profitability. We may not be able to generate sufficient revenue to achieve profitability and our recent and historical growth should not be considered indicative of future performance

Our limited operating history makes future forecasting difficult.

We commenced operations in April 2014 and became a public company in October 2021. As a result of our limited operating history, it is difficult to accurately forecast revenues or to predict operating expenses. Our current and future expense estimates are based, in large part, on our estimates of future revenue and on our research, development and commercialization plans. In particular, we plan to increase operating expenses significantly in order to expand our research, development and sales and marketing operations. To the extent that these expenses precede increased revenue, our business, results of operations and financial condition would be materially adversely affected. We may be unable to, or may elect not to, adjust spending quickly enough to offset any unexpected revenue shortfall. Therefore, any significant shortfall in revenue in relation to our expectations would also have a material adverse effect on our business, results of operations and financial condition.

The successful development of pharmaceutical products is highly uncertain.

We currently have no products approved for sale and are investing substantially all of our efforts and financial resources in the development of our DiversitAb platform and clinical development of our current lead programs. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of therapeutic biological product candidates. We will need to raise sufficient funds for, and successfully complete, our preclinical development programs and future clinical trials of product candidates for our lead programs.

There is no guarantee that any product candidate we develop will proceed into and through clinical development or achieve regulatory approval to allow such products to be commercialized. Successful development of therapeutic biological products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- clinical trial results may show the product candidate to be less effective than expected (e.g., a clinical trial could fail to meet its primary or key secondary endpoint(s) or have an unacceptable safety or tolerability profile);
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals; and
- post-marketing approval requirements.

In addition, the length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly among product candidates, and any delay in receipt of marketing approval for a product candidate could negatively impact market acceptance of any resulting product. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (ensure that our third-party providers comply) with current Good Manufacturing Practices (cGMPs), and good clinical practices (GCPs), for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities, which regulations differ from country to country. Our product candidates are in various stages of development and are subject to the risks of failure typical of drug development. The development and approval process is expensive and can take many years to complete, and its outcome is inherently uncertain. We have not submitted an application for or received marketing approval for any of our product candidates. We have limited experience in conducting and managing the later-stage clinical trials necessary to obtain regulatory approvals, including approval by the FDA. To receive regulatory approval, we must, among other things, demonstrate with substantial evidence from clinical trials that the product candidate is safe and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development.

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number and types of preclinical studies and clinical trials that the FDA will require to establish substantial evidence of safety and effectiveness for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among countries and regulatory authorities, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, either of which may cause delays or limitations in the approval or the decision not to approve an application. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the clinical trial results may not confirm the positive results from earlier preclinical studies or clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; and
- regulatory agencies may change their approval policies, clinical development guidelines and recommendations, or adopt new regulations in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or which we may lead us to decide to abandon the development program.

In addition, even if we were to obtain marketing approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may require a REMS that restricts prescribing or distribution of our therapeutic biological product candidates, may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Regulatory approval for the genetic modification of animals, including those from which antibodies are isolated for injection into human patients, requires the approval of a New Animal Drug Application (NADA), which can be a lengthy and expensive process with uncertain outcomes, delays to which could substantially harm our business.

We cannot commercialize our therapeutic biological product candidates in the United States without first obtaining a regulatory approval for our animal drug candidates, i.e., the genomic modifications to our Tc Bovine, in the form of a NADA. The requirements governing development and approval of a new animal drug are largely analogous to those for new human drugs, requiring a demonstration of the safety and efficacy of the drug for the target indication, a demonstration that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency, and a review of potential environmental impacts from the altered genomic DNA and the transgenic animals pursuant to the requirements of the National Environmental Policy Act (NEPA).

The time required to obtain approval for a NADA by the FDA and comparable foreign regulatory authorities is unpredictable. Approval policies, regulations, or the type and amount of data necessary to gain approval is dependent on the specific product candidate and may change during the course of the product candidate's preclinical and clinical development. Furthermore, we have not obtained regulatory approval for an animal drug and it is possible that none of our existing animal drug candidates, or any future animal drug candidates, will ever obtain regulatory approval. The reasons our animal drug candidates could fail to receive regulatory approvals are generally the same as the reasons that human drug product candidates may fail to obtain approval. Our failure to obtain a regulatory approval for our animal drug candidates could significantly harm our business, the results of our operations and our prospects. Requests for additional information from a regulatory authority could delay or prevent approval, or result in our decision to abandon the development program entirely.

If we do receive regulatory approval of our animal drug candidates, then we will have ongoing responsibilities including registration, recordkeeping, filing supplements, and periodic reporting, which could reveal additional complications and threaten the ongoing approval of our animal drug candidates. Further, as our polyclonal antibody product candidates are regulated as biological products, such product candidates will also require the submission and approval of a BLA prior to marketing. In general, to commercialize any of our product candidates, we must obtain marketing authorization for both the therapeutic antibody product and the altered animal genomic DNA that enables production of the polyclonal antibodies.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

We are not permitted to market our product candidates in the United States until we receive approval of a NADA and BLA from the FDA or in other countries until we receive similar marketing authorization from applicable regulatory authorities outside the United States. We are also not permitted to promote our product candidates as safe and effective therapies until after receiving approval. Obtaining approval of a NADA or BLA can be a lengthy, expensive and uncertain process. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States, which will significantly impair our ability to generate any revenue. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products' marketing, promotion, distribution or manufacturing processes;
- warning letters or untitled letters alleging violations;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- suspension of substantive review of pending applications, such as NADAs, BLAs, INADs, or INDs, pending data validation; and
- refusal to approve pending NADAs or BLAs or supplements to approved NADAs or BLAs.

Even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations on the indicated uses for which we may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates, generating revenue and achieving and sustaining profitability.

If we encounter difficulties enrolling patients in clinical trials, clinical trials of our product candidates may be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for any product candidate we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until conclusion. We may experience difficulties in patient enrollment in clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the design of the trial, including the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- travel restrictions and other potential limitations by federal, state, or local governments affecting the workforce or affective clinical research policies implemented in response to the COVID-19 pandemic or similar public health emergencies that may arise in the future;
- delays in or temporary suspension of the enrollment of patients in our anticipated clinical trials due to the COVID-19 pandemic or similar public health emergencies that may arise in the future;
- proximity and availability of clinical trial sites for prospective patients;
- the risk that patients enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our product candidates.

If we experience delays or difficulties in the enrollment of subjects in our anticipated clinical trials, such clinical trials may be delayed or terminated. Even if we are able to enroll a sufficient number of subjects in our future clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of such trials may be delayed, or the trials could become too expensive to complete. Our failure to timely complete our current and planned clinical trials would delay the approval and commercialization of our product candidates, impair the commercial performance of our product candidates, may decrease the period of commercial exclusivity and consequently harm our business and results of operations.

Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase costs or necessitate the abandonment or limitation of the development of some of our product candidates.

To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

Success in preclinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of any product candidate we may develop. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in preclinical studies for our product candidates to date, results may not be replicated in subsequent studies, and we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to support regulatory approval of any current or future product candidate we develop. Moreover, later audits of earlier preclinical data may reveal inaccuracies or deviations impacting the integrity of those data.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in such studies or trials nonetheless failed to obtain FDA or other necessary regulatory agency approval.

We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and potent for their intended uses. If any future late-stage clinical trials we may conduct do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree with our interpretation of the relevant data and may require that we conduct additional preclinical studies or clinical trials to support the regulatory approval of any product candidate that we develop. If we fail to obtain results in our planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

We have not completed the development of any product candidates. Our future success and ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. Our lead product candidate, SAB-176, was evaluated in a Phase 2a challenge study in healthy volunteers that were challenged with the 2009 pandemic H1N1 influenza A strain and showed significant reduction of viral load, reduction of influenza systems at day 4 post challenge and a shorter period of viral shedding in SAB-176 treated patients compared to placebo controls. There is no guarantee that similar results will be seen in naturally infected patients with high risk of developing severe influenza symptoms in future anticipated Phase 2b or Phase 3 clinical trials or that the company will have sufficient financial resources to conduct these trials.

All of our other product candidates are in earlier stages of development and will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an INAD or IND or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- delays in enrolling subjects in our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all; and
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular.

The regulatory approval processes of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted a NADA or BLA to the FDA or similar drug or biological product approval submissions to comparable foreign regulatory authorities for any product candidate. With respect to our lead product, SAB-185, we must complete additional clinical trials to demonstrate the safety and efficacy of SAB-185 before we will be able to obtain these approvals.

We may never obtain FDA approval for any product candidates in the United States, and even if we do, we may never obtain approval for or commercialize any product candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In addition to regulations in the United States, to market and sell our product candidates in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure for complex therapeutic biological product candidates such as ours varies among countries and can involve additional testing and validation and additional administrative review periods. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries.

In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for future regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished. We do not have any product candidates approved for sale in any jurisdiction, including in the United States or in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

The general approach for FDA approval of a new drug is dispositive data from two or more well-controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may not file or accept our NADA, BLA or other marketing applications for substantive review;
- the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a NADA, BLA or other comparable submissions in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an INAD or IND, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards ("IRBs"), or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using an investigational product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process for product candidates is expensive, time-consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and successful inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delays.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities or a more restrictive label for any of our product candidates that may receive regulatory approval. In our planned and future clinical trials of our product candidates, we may observe a more unfavorable safety and tolerability profile than was observed in earlier-stage testing of these candidates.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be related to administration of our product candidates could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates.

Additionally, during the course of our product development programs, FDA or comparable foreign regulatory authority review teams may change, and new agency personnel may view the risk-benefit profile of any product candidates we may develop differently than prior agency review teams. Any negative views as to the risk-benefit profile of the product candidates we are developing for our lead programs or any product candidates we may develop in the future could lead FDA or comparable foreign regulatory authorities to require that we conduct additional clinical trials or could require more onerous clinical trial designs for any then-ongoing or future clinical trials. The product-related side effects also could result in potential product liability claims being asserted against us. Furthermore, we or others may later identify undesirable side effects caused by our products, including during any long-term follow-up observation period.

If any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused or risks exacerbated by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient; a REMS may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the biopharmaceutical industry. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to recall the product or remove it from the marketplace;
- regulatory authorities may withdraw or limit their approvals of that product;
- regulatory authorities may require additional statements, specific warnings or contraindications on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- we may be required to change the way the product is distributed or administered;
- we may be subject to regulatory investigations and government enforcement actions;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these occurrences could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities, and may adversely affect our business, financial condition and prospects significantly.

The future commercial success of our product candidates will depend on the degree of market acceptance of our potential products among physicians, patients, healthcare payers, and the medical community.

When available on the market, our products may not achieve an adequate level of acceptance by physicians, patients and the medical community, which may result in us failing to achieve profitability. In addition, efforts to educate the medical community and third-party payers on the benefits of our products may require significant resources and may never be successful, which would prevent us from generating significant revenues or becoming profitable.

Failure to successfully identify, develop and commercialize additional products or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of product candidates in our current pipeline, a key element of long-term growth strategy is to develop and market additional products and product candidates. Because we have limited financial and managerial resources, research programs to identify product candidates will require substantial additional technical, financial and human resources, whether or not any product candidates are ultimately identified. The success of this strategy depends partly upon our ability to identify, select and develop promising product candidates and products. Our technology platforms may fail to discover and to generate additional product candidates that are suitable for further development. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics that indicate that it is unlikely to be a product that will receive approval by the FDA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon its technological approach, we may not be able to obtain product or collaboration revenues in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

Our long-term growth strategy to develop and market additional products and product candidates is heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising pharmaceutical product candidates and products. Our business decisions may therefore be adversely influenced by improper or fraudulent scientific data sourced from third parties. Any irregularities in the scientific data used by us to determine our focus in research and development of product candidates and products could have a material adverse effect on our business, prospects, financial condition and results of operations.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize SAB176 and our other product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of SAB 176 and our other product candidates and other future product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- our inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer, and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payors, distributors, retailers, marketers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and similar state or foreign laws which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, or the knowing retention of an overpayment from government health care programs; HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and certain teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While our ability to promote the products is limited to those indications that are specifically approved by the FDA, physicians may choose to prescribe drugs for uses that are not described in the product's approved labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate a physician's use of professional judgment in prescribing treatments for patients. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use or off-label information. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or corrective advertising, institute fines, or could result in disgorgement of money, operating restrictions, injunctions or civil or criminal prosecution by the government, any of which could harm our reputation and business.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.

In the United States and certain non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our or our collaborators' ability to profitably sell any product candidates that obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our product candidates, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, expanded eligibility criteria for Medicaid programs, expanded the entities eligible for discounts under the Public Health program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, and created a licensure framework for follow-on biologic products.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take or how or whether such changes may affect the biopharmaceutical industry as a whole or our business in the future.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies, rebates and price negotiation for pharmaceutical products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we or our collaborators may receive for any approved or cleared product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, any of our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, recordkeeping, and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials and claims must be consistent with approved labeling and be in compliance with FDA regulations as well as other potentially applicable federal and state laws. In addition, biological product advertising and promotional materials intended to be used during the first 120 days after approval must be submitted to the FDA during the BLA review period. After approval, advertising and promotional materials must be submitted to the FDA 30 days prior to their intended use.

In addition, product manufacturers are subject to payment of program fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or with the integrity or sufficiency of data, records, or documentation, or disagrees with the promotion, marketing or labeling of that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or a regulatory agency later discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or if we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or labeling of the product;
- restrict manufacturing of the product, the approved manufacturers or the manufacturing process;
- restrict product distribution or use;
- demand a recall;
- seize or detain product or otherwise require the withdrawal of product from the market;
- impose fines, restitution or disgorgement of profits or revenues;
- impose consent decrees, injunctions or the imposition of civil or criminal penalties;
- refuse to permit the import or export of products; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

Advertising and promotion of any human therapeutic biological product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, other U.S. governmental authorities, or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to issue corrective information to healthcare practitioners and/or the general public, injunctions, or civil or criminal penalties.

In addition, the FDA's policies may change, and additional government laws may be enacted and implementing regulations promulgated, which could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products. Subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate.

As of early 2022, the FDA has resumed inspections of domestic and foreign facilities to ensure timely reviews of applications for all products lines. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required. On January 30, 2023, the Biden administration announced that it will end the public health emergency declarations related to COVID-19 on May 11, 2023. On January 31, 2023, the FDA indicated that it would soon issue a Federal Register notice describing how the termination of the public health emergency will impact the agency's COVID-19 related guidance. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the pandemic related to COVID-19 and its variants. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other

regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We need to attract and retain highly skilled personnel and strategic partners, and we may be unable to effectively manage our growth with our limited resources.

We have limited human resources and our future success will depend in part on our ability to attract, train, retain and motivate highly skilled executive level management, research and development, and sales personnel and to establish and maintain effective strategic alliances with key companies in our industry. Competition is intense for many of these types of personnel from other companies, consulting firms and more established organizations, many of which have significantly larger operations and greater financial, marketing, human, and other resources. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations may be materially adversely affected.

We anticipate adding new employees and we will have to integrate such new employees into our operations.

Our officers and directors may not possess all of the skills or experience necessary to successfully implement our business plan. Further, we anticipate hiring new employees. Failure to fully integrate new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations.

We depend upon our senior management and senior scientific staff, and their loss or unavailability could put us at a competitive disadvantage.

Our success depends largely on the skills, experience and reputation of certain key management and personnel, in particular our directors, executive officers and senior scientific staff. The loss or unavailability of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our employees and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could negatively impact our business, prospects, financial condition and operating results.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, suppliers and distributors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the rules and regulations of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.

We rely on third parties to perform some of our research and preclinical studies, and we plan to rely on third parties to conduct our clinical trials. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical studies or future clinical trials ourselves. As a result, we are, and expect to remain, dependent on third parties to perform some of our research and preclinical studies and any future clinical trials of our product candidates, including but not limited to governmental agencies and university laboratories, contract manufacturers, CROs, distribution and supply (logistics) services organizations, contract testing organizations (CTOs), consultants or consultant organization with specialized knowledge based expertise. The timing of the initiation and completion of our current and planned preclinical studies and clinical trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of future clinical trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, as the sponsor of the INADs, INDs and clinical protocols governing our future clinical trials, we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs, CTOs, and other third parties does not relieve us of our regulatory responsibilities. We, our CROs, CTOs, and clinical sites will be required to comply with GLP requirements for preclinical studies, as well as GCP requirements for clinical trials involving human subjects, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities, for all of our current product candidates and any future product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of trial sponsors, testing laboratories, clinical trial investigators, and clinical trial sites. If we or any of our CROs, CTOs, or clinical trial sites fail to adhere to our clinical trial protocols or to comply with applicable GLP or GCP requirements, as applicable, the data generated in our future preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before accepting for review or approving our marketing applications. In addition, our clinical trials must be conducted with product candidates produced under GMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial results or data. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates.

There is no guarantee that any such CROs, CTOs, clinical trial investigators or other third parties on which we plan to rely will devote adequate time and resources to our development activities or perform as contractually required. Further, the performance of our third parties on which we rely may be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic (similar public health emergencies that may arise in the future). If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our future clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

We are limited in our ability to manufacture pharmaceutical products.

To be successful, our products and the products of our partners must be manufactured in commercial quantities in compliance with regulatory requirements and at a commercially acceptable cost. We have not commercialized any pharmaceutical products, nor have we demonstrated an ability to manufacture commercial quantities of our or our partners' product candidates in accordance with regulatory requirements. If we are unable to produce suitable quantities of our or our partners' products, or contract third parties to do so, in accordance with regulatory standards at a commercially acceptable cost, our ability or the ability of our partners to conduct clinical trials, obtain regulatory approvals and market such products may be adversely affected, which could adversely affect our competitive position and our chances of achieving profitability. There can be no assurance that such products can be manufactured by us or any other party at a cost or in quantities which are commercially viable.

We intend to rely on third parties to produce commercial supplies of our product candidates.

We intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of drug substance or drug product. If we are not able to meet market demand for any approved product, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP requirements and other inspections by the FDA or other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

In addition, if we enter into a strategic collaboration with a third party for the commercialization of our current or any future product candidates, we will not be able to control the amount of time or resources that they devote to such efforts. If any strategic collaborator does not commit adequate resources to the marketing and distribution of our product candidates, it could limit our potential revenues.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

If we fail to successfully operate our animal production facility, it may adversely affect our clinical trials and the commercial viability of our product candidates.

We operate our own animal production facility, where we produce supplies of our product candidates for our preclinical and clinical studies, and such facility is currently subject to certain regulatory requirements and inspections, including by the USDA to ensure compliance with the Animal Welfare Act and other regulations relating to the care and welfare of laboratory and research animals.

Before approving any of our product candidates for commercialization, the FDA must conduct a pre-approval inspection of our animal production and manufacturing facilities to determine whether the manufacturing processes and facilities comply with GMPs. If and when we obtain regulatory approval for any of our product candidates, we would need to register our animal production and manufacturing facilities with the FDA and list all licensed biological products manufactured at such facilities. Even if the FDA determines that our facilities are in substantial compliance with applicable regulations and standards, we would be subject to ongoing periodic unannounced inspection by the FDA, the USDA, corresponding state agencies and potentially third-party collaborators to ensure strict compliance with GMPs, animal welfare requirements, and other applicable laws and government regulations. Our license to manufacture such future approved product candidates will be subject to continued regulatory review.

In addition, our animal production facility maintains detailed standard operating procedures and other documentation necessary to comply with the Animal Welfare Act and applicable regulations for the humane treatment of the pigs and piglets in our custody. We also maintain an Institutional Animal Care and Use Committee (IACUC) to provide ongoing oversight and to conduct assessments of the care and use of the animals in our research and development programs. If the USDA determines that our current equipment, facilities, or processes relating to donor animal production do not comply with applicable Animal Welfare Act standards, it may issue an inspection report documenting the deficiencies and setting deadlines for any required corrective actions. For continued noncompliance, the USDA may impose fines, suspend, or revoke animal research licenses or confiscate research animals.

There can be no assurance that we will not encounter difficulties in scaling up our manufacturing processes. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional inspections, permits, or other authorizations by the FDA, the USDA, or corresponding state agencies. We may encounter difficulties in scaling up production, including problems involving raw material suppliers, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. The actual cost to manufacture and process our product candidates could also be greater than we expect and could materially and adversely affect the commercial viability of any product candidates that we develop. Any of these difficulties, if they occur and are not resolved to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the future development or commercial program for such product candidate. These risks become more acute as we scale-up for commercial quantities, where a reliable source of product becomes critical to commercial success. The commercial viability of any of our product candidates, if approved, will depend on our ability to produce our product candidates at a large scale. Failure to achieve this level of supply could jeopardize the successful commercialization of our therapeutic product candidates, should any be approved for marketing.

The manufacture of polyclonal antibodies from transgenic animals is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of polyclonal antibody products often encounter difficulties in production, particularly in scaling out up and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate, quality assurance testing, operator error, shortages of qualified personnel, shortages of raw materials, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our animal production facility, it may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot ensure provide assurance that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

Our manufacturing capabilities could be affected by cost-overruns, resource constraints, unexpected delays, equipment failures, labor shortages or disputes, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, jeopardize our ability to produce our product candidates, and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our product candidates are uniquely manufactured, and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities.

The manufacturing process used to produce Tc Bovine is novel and has not been validated for commercial production.

There is a risk that of we may experience manufacturing issues associated with the differences in donor starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from our normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. Further, as product candidates advance through preclinical to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. We may not achieve our intended objectives and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of future clinical trials.

Although we continually attempt to optimize our manufacturing process, doing so is a difficult and uncertain task and there are risks associated with scaling to the level required for future initial clinical trials, advanced late-stage clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up our manufacturing processes, we may encounter lengthy delays in commercializing our product candidates.

The manufacturing process for any products candidates that we may develop is subject to the FDA and foreign regulatory authority approval processes and, if we choose to outsource our commercial production, we will need to contract with third-party manufacturers who we believe can meet applicable FDA, USDA, and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce any product candidate to specifications acceptable to the FDA, the USDA, or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or any third-party manufacturers we may contract with in the future will be able to manufacture the approved product to specifications and under GMPs acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of future clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our future success depends on our ability to manufacture our product candidates on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements. Our inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures.

We have not entered into definitive long term manufacturing and supply agreements with any producers.

On October 26, 2022, we entered into a Manufacturing Option Agreement (the "Emergent Manufacturing Agreement") and Right of First Refusal Agreement (the "Emergent RoFR Agreement," and together with the Emergent Manufacturing Agreement, the "Emergent Agreements") with Emergent BioSolutions Canada, Inc., a wholly-owned subsidiary of Emergent BioSolutions Inc. ("Emergent"). The Emergent Agreements contemplate that we will enter into one or more binding Master Manufacturing Services Agreements, whereby Emergent will provide contract development and manufacturing services to produce our fully-human polyclonal antibody products. Under the Emergent Manufacturing Agreement, we granted Emergent an exclusive option for the exclusive commercial manufacture of commercial stage product utilizing our humanized polyclonal antibodies. Pursuant to the terms of our arrangement, we will notify Emergent in advance of our first commercial manufacturing needs for any product and each additional product, and Emergent may then exercise the exclusive manufacturing option with respect to such product. Under the Emergent RoFR Agreement, we granted Emergent an exclusive right of first refusal to license and develop our products, developed using humanized polyclonal antibodies based on our platform to treat (i) botulism anti-toxin, (ii) pandemic influenza, or (iii) anti-fungal diseases. Any definitive manufacturing arrangement will be determined at the time any Master Manufacturing Services Agreement is entered into with Emergent, and there is no guarantee we will do so.

We intend to pursue agreements with contract manufacturers to produce the components and drug products that we will use in the future for the commercialization of products that make using of our technology, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. Components of our product candidates are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize any given product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of our product candidates may be delayed. If we are unable to obtain sufficient compounds and labeling services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of each component do not comply with applicable regulations for the manufacturing and production of drugs, our business, financial condition, and results of operations may be materially harmed.

We are subject to manufacturing risks that could substantially increase the costs and limit supply of product candidates or prevent us from achieving a commercially viable production process.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including:

- we do not have experience in manufacturing our product candidates at commercial scale.
- we plan to develop a larger scale manufacturing process for our product candidates.
- we may not succeed in scaling up the process.
- we may need a larger scale manufacturing process for certain product candidates than what has been planned.

Any changes in our manufacturing processes as a result of scaling up may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals as a result of scaling up could delay the development and regulatory approval of our product candidates and ultimately affect our success. We may not achieve the manufacturing productivity ("yield") required to achieve a commercially viable cost of goods. Low productivities may result in a cost of goods which is too high to allow profitable commercialization or give rise to the need for additional manufacturing process optimization which would require additional funding and time.

Additionally, the process of manufacturing biologics, such as our product candidates, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We and our contract manufacturers are subject to significant regulatory oversight with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and may have limited capacity.

All parties involved in the preparation of therapeutics for clinical trial or commercial sale are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with GMP requirements. These regulations govern manufacturing processes and procedures (including recordkeeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. In addition, due to our use of transgenic animals to manufacture our product candidates, we, and potentially our third-party manufacturers, are subject to animal welfare requirements as part of our production process. The FDA, the USDA, and comparable foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards, including for the manufacture, packaging or testing of biological products or for the care and welfare of research animals.

Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a NADA and BLA on a timely basis and must adhere to the FDA's GMP requirements and USDA animal welfare requirements enforced by each agency through its respective facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party manufacturers. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or our third-party manufacturers to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers or testing contractors fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions. Such an occurrence may cause our business, financial condition and results of operations to be materially harmed.

The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

We presently manufacture our product candidates at our lab facilities in South Dakota. If our lab facilities were to be damaged or destroyed by fire, flood, other natural disaster or other occurrences of any kind, it would have a material adverse effect on our ability to produce product candidates and on our business, financial condition and results of operations.

We must comply with applicable cGMP, regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, leading to significant delays in the availability of therapeutic product for clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

Our product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical studies or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates.

Outbreaks of livestock diseases and other events affecting the health of our bovine herd can adversely impact our ability to conduct our operations and production of our product candidates.

Our product candidates are based on materials produced by genetically engineered bovines. We maintain a herd of approximately 200 genetically engineered production animals at a single location in South Dakota and a larger herd of recipient animals at other locations. Our ability to produce product candidates is dependent on the continued health and productivity of these animals. The supply of our product candidates can be adversely impacted by outbreaks of livestock diseases, which can have a significant adverse impact on our financial condition. Our animals produced by the recipient herd do not typically become productive until 15-18 months from the start of gestation. If all or a material number of the productive herd were to become diseased, injured or die as a result of bacterial, fungal or viral infections, such as foot and mouth disease, or natural disaster or other occurrences of any kind, it would have a material adverse effect on our ability to produce product candidates and on our business, financial condition and results of operations

Extreme factors or forces beyond our control could negatively impact our business.

Natural disasters, fire, bioterrorism or other acts of terrorism or vandalism, animal activist activity or adverse public perception or media coverage or other public relations issues, pandemics or extreme weather, including droughts, floods, excessive cold or heat, hurricanes or other storms, could impair the health or growth of livestock or interfere with our operations due to power outages, fuel shortages, feed shortages, decrease in availability of water, damage to our production and manufacturing facilities or disruption of transportation channels which would delay the development, regulatory approval and manufacture of our product candidates and ultimately affect our success. Any of these factors could have an adverse effect on our financial condition and ability to operate.

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, along with our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants, utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyber-attacks.

There can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Collaborations with third parties may be important to our business. If these collaborations are not successful, our business could be adversely affected.

In addition to our current collaborations, we may in the future seek third-party collaborators for the development and commercialization of product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from any future collaboration or license agreement will depend on the collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any collaborators may have the right to abandon research or development projects and terminate applicable agreements, including any funding obligations, prior to or upon the expiration of the agreed upon terms.

Any collaboration that we enter into in the future may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may decide not to continue the development of collaboration products and could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing, distribution and commercialization rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, might cause delays or termination of the research, development or commercialization of such product candidates, might lead to additional responsibilities for us with respect to such product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborations may be terminated at the convenience of the collaborator or for a material breach by either party, and, if a collaboration is terminated, we could be required to make payments to the collaborator or have our potential payments under the collaboration reduced; and
- in the event of the termination of a collaboration, we could be required to raise additional capital to pursue further development or commercialization of the product candidates returned to us by our former collaborator.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We have historically relied on awards from, and contracts with, the U.S. Government to fund our business and operations, and will need to find new and alternative sources of funding following the discontinuance of certain such arrangements.

We have historically relied on awards from, and contracts with, the U.S. Government to fund our business and operations, but we have recently mutually agreed with the U.S. federal Government (USG) to discontinue Project Agreement No. 01; MCDC1902-007, an award agreement which represented a

substantial majority of our revenues. We therefore need to secure new and alternative sources of funding for our projects. There is no guarantee that we will find such other sources of funding on favorable terms or at all, which could have a direct adverse effect on our financial condition and ability to operate.

We operate in a highly competitive industry.

We are engaged in highly competitive industries. We compete with many public and private companies, including pharmaceutical companies, chemical companies, specialized biotechnology companies and academic institutions. Many of our competitors have substantially greater financial, scientific and technical resources, and manufacturing and marketing experience and capabilities than us. In addition, many of our competitors have significantly greater experience conducting preclinical studies and clinical trials of new pharmaceutical products, and in obtaining regulatory approvals for pharmaceutical products. Our competitors and competitors of our collaborators may develop and commercialize such products more rapidly than we and our collaborators do. Competition may increase further as a result of potential advances from the study of pharmaceutical products, and greater availability of capital for investment in this field. There can be no assurance that our competitors will not succeed in developing technologies and products that are more effective than any being developed by us or that would render our technology and products obsolete or noncompetitive. There can be no assurance that these and other efforts by potential competitors will not be successful, or that other methods will not be developed to compete with our technology. There are specific products and technologies that compete with our current product pipeline and that may outperform or be more competitive than our products. For example, there are multiple products that may be competitive with SAB-142 for T1D such as animal-derived polyclonal biologics Thymoglobulin (Sanofi Genzyme) and Atgam (Pfizer), and monoclonal antibody treatments such as teplizumab (Tzield), , Alefacept, and Orencia; there are other antibody technologies that may compete with our anti-influenza product, SAB-176 such as VIR-2482 (Vir), DAS-181 (Ansun) and FLU-IVIG (Emergent Biosolutions) and with our SAB-195 (anti-*C.diff*) such as bezlotoxumab (Zinplava).

We have no sales and marketing experience.

We have no experience in sales, marketing or distribution. Before we can market any of our product candidates directly, we must develop a substantial marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may obtain the assistance of a pharmaceutical company with a large distribution system and a large direct sales force. We do not have any existing distribution arrangements with any pharmaceutical company for our products. There can be no assurance that we will be able to establish sales and distribution capabilities or be successful in gaining market acceptance for our products.

We are subject to stringent environmental regulation and potentially subject to environmental litigation, proceedings, and investigations.

Our business operations and use of real property are subject to stringent federal, state, and local environmental laws and regulations pertaining to safe working conditions, ethical experimental use of animals, the discharge of materials into the environment, and the handling and disposition of wastes (including solid and hazardous wastes) or otherwise relating to protection of the environment. These laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Compliance with these laws and regulations, and the ability to comply with any modifications to these laws and regulations, is material to our business. New matters or sites may be identified in the future that will require additional investigation, assessment, or expenditures. In addition, some of our facilities have been in operation for some time and, over time, we and any other prior operators of these facilities may have generated and disposed of wastes that now may be considered hazardous. Future discovery of contamination of property underlying or in the vicinity of our present or former properties or manufacturing facilities and/or waste disposal sites could require us to incur additional expenses. In addition, claimants may sue us for injury or contamination that results from our use of or our handling of contaminants, and our liability may exceed our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts. The occurrence of any of these events, the implementation of new laws and regulations, or stricter interpretation of existing laws or regulations, could adversely affect our financial condition and ability to operate.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We may, now or in the future, be required to reimburse our counterparties in connection with costs incurred during performance of our contractual arrangements.

On August 3, 2022, we received notice from the DoD to terminate the Department of Defense, Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense Enabling Biotechnologies ("JPEO") Rapid Response contract, dated as of August 7, 2019 with the DoD most recently amended as of September 14, 2021, relating to a prototype research and development of a Rapid Response Antibody Program and advanced clinical development through licensure and commercial manufacturing for SAB-185 (the "JPEO Rapid Response Contract Termination"). A termination and settlement proposal (the "TSP") was submitted the DoD on September 9, 2022; we submitted a final invoice on December 15, 2022; and received payment from the DoD on or about January 12, 2023. The terms of the arrangement provide for a cost-reimbursable structure, and state that the parties will work in good faith equitable reimbursement for work performed toward accomplishment of the tasks provided in the agreement. At this time, other than certain deferred obligations potentially payable to the DoD solely due to subsequent negotiations with our third-party vendors**,** we believe and have been advised

there is a reasonable, good faith basis for the position that no present or future obligations exist by us in favor of our counterparties. However, if an alternative determination is made, we may become liable for costs incurred during the termination of the JPEO Rapid Response contract, which could have an adverse effect on our business and results of operations.

Risks Related to Our Intellectual Property

Our success depends on our ability to maintain the proprietary nature of our technology.

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third-parties or allowing third parties to infringe our rights. Patent issues relating to pharmaceuticals and biologics involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the U.S. Patent and Trademark Office ("USPTO") or enforced by the federal courts. Therefore, we do not know whether any particular patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

Third parties may claim we infringe their intellectual property rights.

Our research, development and commercialization activities may be found to infringe patents owned by third parties from whom we do not hold licenses or other rights to use their intellectual properties. There may be rights we are not aware of, including applications that have been filed, but not published that, when issued, could be asserted against us. These third parties could bring claims against us, and that may cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of potential patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third-party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us.

We may become involved in litigation to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time-consuming.

Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file suit to counter infringement for unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover our technology. An adverse determination of any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at the risk of not issuing.

Even if we are successful, litigation may result in substantial costs and distraction to our management. Even with a broad portfolio, we may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries.

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical products and processes in the U.S. and other important markets outside the U.S., such as Europe and Japan. In addition, foreign markets may not provide the same level of patent protection as provided under the U.S. patent system. Litigation or administrative proceedings may be necessary to determine the validity and scope of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to do one or more of the following: cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and redesign our products to avoid infringing the intellectual property rights of third-parties, which may be time-consuming or impossible to do. In addition, changes in, or different interpretations of, patent laws in the U.S. and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products. We cannot provide assurance that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

We have third party collaborators that might claim rights in or to our technology and/or assets.

We have extensive experience collaborating with multiple parties in Government and industry, and has agreements and collaborations that allow potential claims and actual rights, such as shared publication rights, shared inventions, access to assets, potential claims of co-inventorship, limited rights to data, general purpose rights to data, and other claims that may affect our business operations, intellectual property portfolio, interruption of operating assets or our ability to protect our own rights. There can be no assurance that our competitors, suppliers, service providers, collaborators or other parties will not succeed in asserting rights that are or become contrary to our interests.

Changes in patent law in the United States and in ex-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing and proposing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents, particularly those directed to pharmaceutical and biopharmaceutical products and uses could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how these decisions or any future decisions by the U.S. Congress, the federal courts or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world is expensive. While many of our licensed patents, including the patents covering our lead product candidates, have been issued in major markets and other countries, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States where we have issued patents, or from selling or importing products made using our inventions in other jurisdictions. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we do not have patent protection or where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical and biopharmaceutical products, which could make it difficult for us or our licensors to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings for infringement by third parties or by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could also result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and any related patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We may not prevail in any lawsuits that we initiate or are initiated against us, and the damages or other remedies awarded in lawsuits that we initiate, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per eligible drug may be extended and only those claims covering the approved drug, an approved method for using it or a method for manufacturing it may be extended. Patent term extensions tied to marketing approval in foreign jurisdictions may also be available for our patents. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

Risks Related to Being a Public Company

We incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, financial condition, and results of operations.

As a public company, we are and will continue to be subject to the reporting requirements of the Exchange Act, the listing standards of Nasdaq and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting, and financial compliance costs, make some activities more difficult, time-consuming and costly, and place significant strain on our personnel, systems, and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, financial condition, and results of operations, although we have already hired additional employees to assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our operating expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest substantial resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business operations to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

We also expect that being a public company and these new rules and regulations will make it increasingly expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of disclosure of information in filings required of a public company, our business and financial condition are more visible, which may result in an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business, financial condition, and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, financial condition, and results of operations.

We are an "emerging growth company," as well as a "smaller reporting company," and our election to comply with the reduced disclosure requirements as a public company may make our common stock less attractive to investors.

For so long as we remain an "emerging growth company" as defined in the Tax Cuts and Jobs Act of 2017 (the "JOBS Act"), we may take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies," including not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley-Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, being required to provide fewer years of audited financial statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

As an emerging growth company, we may choose to take advantage of some but not all of these reduced reporting burdens. Accordingly, the information we provide to our stockholders may be different than the information you receive from other public companies in which you hold stock. In addition, the JOBS Act also provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of this extended transition period under the JOBS Act. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock less attractive as a result, which may result in a less active trading market for our common stock and higher volatility in our stock price.

We may lose our emerging growth company status and become subject to the SEC's internal control over financial reporting management and auditor attestation requirements. If we are unable to certify the effectiveness of our internal controls, or if our internal controls have a material weakness, we could be subject to regulatory scrutiny and a loss of confidence by stockholders, which could harm our business and adversely affect the market price of our common stock. We will cease to be an "emerging growth company" upon the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a large accelerated filer, with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have, in any three-year period, issued more than $1.0 billion in non-convertible debt securities; and (iv) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of becoming a public company).

We are also a "smaller reporting company" as defined under the Securities Act and the Exchange Act. We may continue to be a smaller reporting company so long as either (i) the market value of shares of our common stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of shares of our common stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company under the requirements of (ii) above, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the applicable listing standards of Nasdaq. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place significant strain on our personnel, systems and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the U.S. Securities and Exchange Commission ("SEC") is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting, which includes hiring additional accounting and financial personnel to implement such processes and controls. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight. If any of these new or improved controls and systems do not perform as expected, we may experience material weaknesses in our controls.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until after we are no longer an "emerging growth company" as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock.

We have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of December 31, 2022. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations, and adversely affect the trading price of our common stock.

Under the supervision and with participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2022, and we have concluded that our internal controls over financial reporting were not effective as of December 31, 2022, due to the existence of material weaknesses in such controls. We have also concluded that our disclosure controls and procedures were not effective as of December 31, 2022, all as described in Item 9A, "Controls and Procedures," of this Annual Report on Form 10-K. Management is actively engaged in the planning for, and implementation of, remediation efforts to address our material weaknesses. Continuing costs to remedy these material weaknesses and to address inquiries from regulators may be significant and may require significant attention from our management and other personnel, and we cannot assure you that we will be able to remedy the material weaknesses.

The incurrence of significant additional expense, or the requirement that management and other personnel devote significant time to these matters could reduce the time available to execute on our business strategies and could have a material adverse effect on our business, financial condition and results of operations. We also cannot assure you that additional material weaknesses in our internal control over financial reporting will not arise or be identified in the future. If our remediation efforts are insufficient to address the identified deficiencies, or if additional deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results and may be unable to make our filings with the SEC on a timely basis. Moreover, because of the inherent limitations of any control system, material misstatements due to error or fraud may not be prevented or detected on a timely basis, or at all.

If we are unable to provide reliable and timely financial reports in the future, our business and reputation may be further harmed. Failures in internal controls may negatively affect investor confidence in our management and the accuracy of our financial statements and disclosures or result in adverse publicity and concerns from investors and commercial customers, any of which could have a negative effect on the price of our shares, subject us to regulatory investigations and penalties and/or shareholder litigation, and materially adversely impact our business and financial condition.

Our warrants are accounted for as liabilities and changes in value of the warrants could have a material effect on our financial results.

Prior to the Business Combination, on April 12, 2021, the staff of the SEC issued a Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs") (the "SEC Staff Statement"). The SEC Staff Statement focused on certain accounting and reporting considerations related to warrants of a kind similar to warrants that we issued prior to the Business Combination at the time of our initial public offering and the exercises by the underwriters of their over-allotment options in January 2021. In response to the SEC Staff Statement we determined to classify the warrants as derivative liabilities measured at fair value, with the initial valuation occurring on October 22, 2021, the "Closing Date" of the Business Combination, with changes in fair value each period reported in earnings.

As a result, included on our balance sheet are derivative liabilities related to embedded features contained within the warrants. Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in earnings in the statement of income. As a result of the recurring fair value measurement, our financial statements and results of operations may fluctuate quarterly based on factors which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non-cash gains or losses on the warrants each reporting period and that the amount of such gains or losses could be material.

Our business, financial condition, and results of operations may fluctuate on a quarterly and annual basis, which may result in a decline in our stock price if such fluctuations result in a failure to meet the expectations of securities analysts or investors.

Our operating results have in the past and could in the future vary significantly from quarter-to-quarter and year-to-year and may fail to match our past performance, our projections or the expectations of securities analysts because of a variety of factors, many of which are outside of our control and, as a result, should not be relied upon as an indicator of future performance. As a result, we may not be able to accurately forecast our operating results and growth rate. Any of these events could cause the market price of our common stock to fluctuate. Factors that may contribute to the variability of our operating results include, but are not limited to: our ability to attract new clients and partners, retain existing clients and partners and maximize engagement and enrollment with existing and future clients; changes in our sales and implementation cycles, especially in the case of our large clients; new solution introductions and expansions, or challenges with such introductions; changes in our pricing or fee policies or those of our competitors; the timing and success of new solution introductions by us or our competitors or announcements by competitors or other third parties of significant new products or acquisitions or entrance into certain markets; any other change in the competitive landscape of our industry, including consolidation among our competitors; increases in operating expenses that we may incur to grow and expand our operations and to remain competitive; our ability to successfully expand our business, whether domestically or internationally; breaches of security or privacy; changes in stock-based compensation expenses; the amount and timing of operating costs and capital expenditures related to the expansion of our business; adverse litigation judgments, settlements, or other litigation-related costs; changes in the legislative or regulatory environment, including with respect to privacy or data protection, or enforcement by government regulators, including fines, orders, or consent decrees; the cost and potential outcomes of ongoing or future regulatory investigations or examinations, or of future litigation; changes in our effective tax rate; our ability to make accurate accounting estimates and appropriately recognize revenue for our solutions for which there are no relevant comparable products; changes in accounting standards, policies, guidance, interpretations, or principles; instability in the financial markets; general economic conditions, both domestic and international; volatility in the global financial markets; political, economic, and social instability, including terrorist activities and health epidemics (including the recent outbreak of COVID-19), and any disruption these events may cause to the global economy; and changes in business or macroeconomic conditions. The impact of one or more of the foregoing or other factors may cause our operating results to vary significantly.

Changes in accounting principles may cause previously unanticipated fluctuations in our financial results, and the implementation of such changes may impact our ability to meet our financial reporting obligations.

We prepare our financial statements in conformity with accounting principles generally accepted in the U.S. ("U.S. GAAP"), which are subject to interpretation or changes by the FASB, the SEC, and other various bodies formed to promulgate and interpret appropriate accounting principles. New accounting pronouncements and changes in accounting principles have occurred in the past and are expected to occur in the future which may have a significant effect on our financial results. Furthermore, any difficulties in implementation of changes in accounting principles, including the ability to modify our accounting systems, could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us.

If our estimates or judgments relating to our critical accounting policies prove to be incorrect, our business, financial condition, and results of operations could be adversely affected.

The preparation of financial statements in conformity with U.S. GAAP and our key metrics require management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes and amounts reported in our key metrics. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities, and equity and the amount of revenue and expenses that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to allowance for doubtful accounts, assessment of the useful life and recoverability of long-lived assets, fair value of guarantees included in revenue arrangements and fair values of stock-based awards, warrants, contingent consideration, and income taxes. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

Risks Related to our Common Stock

Anti-takeover provisions contained in our certificate of incorporation as well as provisions of Delaware law, could impair a takeover attempt.

Our certificate of incorporation contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions include:

- the right of our board of directors to issue shares of preferred stock and to fix the terms of such shares;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; and
- requirement that a meeting of stockholders may only be called by members of our board of directors and the ability of our stockholders to call a special meeting is specifically denied, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors. These provisions, alone or together, could delay hostile takeovers and changes in control or changes in our board of directors and management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our common stock. Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of common stock and could also affect the price that some investors are willing to pay for our common stock.

The market price of our securities may be volatile, which could cause the value of any investment in our securities to decline.

The price of our securities may fluctuate significantly due to general market and economic conditions. An active trading market for our securities may not develop or, if developed, it may not be sustained. In addition, fluctuations in the price of our securities could contribute to the loss of all or part of your investment. Even if an active market for our securities develops and continues, the trading price of our securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on an investment in our securities and our securities may trade at prices significantly below the price paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline. Factors affecting the trading price of our securities may include, but are not solely limited to, the risk factors identified herein.

The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. In addition, our Business Combination resulted in our merging with a special purpose acquisition company, which can cause additional volatility in the price of our common stock and warrants. There has also been increased focus by government agencies on transactions such as our Business Combination in the last year, and we expect that increased focus to continue, and we may be subject to increased scrutiny by the SEC, other government agencies and holders of our securities, as a result. These market and industry factors may materially reduce the market price of our common stock and warrants regardless of our operating performance.

An investment in our common stock is extremely speculative and there can be no assurance of any return on any such investment.

An investment in our common stock is extremely speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in us, including the risk of losing their entire investment.

Our failure to meet the continuing listing requirements of Nasdaq could result in a de-listing of our securities.

On January 23, 2023, we received a written notification (the "Notice Letter") from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1), as the closing bid price for our common stock was below the $1.00 per share requirement for the last 30 consecutive business days. The Notice Letter stated that we have 180 calendar days, or until July 24, 2023 (the "Initial Compliance Period"), to regain compliance with the minimum bid price requirement. In the event that we do not regain compliance with Listing Rule 5450(a)(1) prior to the expiration of the Initial Compliance Period (or additional compliance period, if applicable), we will receive written notification that our securities are subject to delisting.

If we fail to satisfy the continuing listing requirements of Nasdaq, such as minimum closing bid price requirements, as discussed above, the corporate governance, or stockholders' equity or minimum closing bid price requirements, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock. In the event of a delisting, we would likely take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Because we have no current plans to pay cash dividends on our common stock for the foreseeable future, investors may not receive any return on their investment unless they sell their common stock for a price greater than the price paid.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. As a result, investors may not receive any return on an investment in our common stock unless they sell the common stock for a price greater than the price paid.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Sales of significant number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that it deems reasonable or appropriate and make it more difficult for you to sell shares of our common stock. Certain holders of our securities are entitled to rights with respect to the registration of the shares of our common stock under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner it determines from time to time. We may also sell our common stock as part of entering into strategic alliances, creating joint ventures or collaborations or entering into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

On December 7, 2022, we consummated a private placement with certain institutional and accredited investors, whereby we issued an aggregate of 7,363,377 shares of common stock and warrants to purchase up to 7,363,377 shares of common stock (the "PIPE Warrants"), each share and PIPE Warrant sold at a combined purchase price of $1.08. The PIPE Warrants become exercisable on the six-month anniversary of the date of grant for a price of $1.08 per share and are exercisable for five years from the date of issuance. We also issued our placement agent, Brookline Capital Markets, PIPE Placement Agent Warrants to purchase up to an aggregate of 210,913 shares of Common Stock (the "PIPE Placement Agent Warrants"). The Placement Agent Warrants have an exercise price equal to $1.35 per share and are exercisable six months from the date of issuance and expires five years from the date of issuance. The issuance of shares of common stock upon exercise of the PIPE Warrants or PIPE Placement Agent Warrants may result in material dilution to existing stockholders.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We have a significant number of warrants which are currently exercisable for shares of our common stock, and the exercise thereof would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

On January 15, 2022, outstanding warrants to purchase an aggregate of 5,958,600 shares of our common stock became exercisable, in accordance with the terms of the warrant agreement governing those securities. The exercise price of these warrants is $11.50 per share.

On June 7, 2023, outstanding PIPE Warrants and PIPE Placement Agent Warrants to purchase up to 7,363,377 and 210,913 shares, respectively, of our common stock will become exercisable, in accordance with the terms of the warrant agreement governing those securities. The respective exercise price of these warrants is $1.08 and $1.35.

To the extent such warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of shares of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of our common stock.

Risks Related to Capital Markets

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past, most recently as a result of the COVID-19 pandemic. These disruptions can result in severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Additionally, in March 2023 the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank, or SVB. We have no exposure to SVB. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. In addition, U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require it to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

If securities or industry analysts do not publish research or reports about our business or publish negative reports, the market price of our common stock could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If regular publication of research reports ceases, we could lose visibility in the financial markets, which in turn could cause the market price or trading volume of our common stock to decline. Moreover, if one or more of the analysts who cover us downgrade our common stock or if reporting results do not meet their expectations, the market price of our securities could decline.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock.

Securities research analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. The price of our common stock may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, the price of our common stock could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, the price or the trading volume of our common stock could decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our securities may be volatile and, in the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert management's attention from other business concerns, which could seriously harm our business.

Risks Related to Financing and Tax

We may require additional capital to support business growth, and this capital might not be available on acceptable terms, if at all.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges, advance or begin clinical trial and research initiatives, enhance our operating infrastructure, and acquire complementary businesses and technologies. In order to achieve these objectives, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters. In addition, we may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly limited.

Our ability to continue to operate as a going concern depends on our ability to obtain adequate financing in the future.

The ability of the Company to continue as a going concern is dependent, among other things, on the Company's ability to raise additional capital resources. The Company plans to seek additional funding through a combination of equity or debt financings, or other third-party financing, collaborative or other funding arrangements. Should the Company seek additional financing from outside sources, the Company may not be able to raise such financing on terms acceptable to the Company or at all. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Management believes there is substantial doubt about the Company’s ability to continue as a going concern for the one-year period following the date that the consolidated financial statements for December 31, 2022 were issued. The consolidated financial statements for December 31, 2022 have been prepared on the basis that the Company will continue as a going concern, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability for the Company to continue as a going concern.

Changes in legislation in U.S. and foreign taxation of international business activities or the adoption of other tax reform policies, as well as the application of such laws, could adversely impact our financial position and operating results.

As we expand the scale of our business activities, any changes in the U.S. or foreign taxation of such activities may increase our worldwide effective tax rate and harm our business, results of operations, and financial condition. For example, the Biden administration has proposed changes to federal income tax laws that would, among other things, impose a 15% minimum tax on corporate book income for certain taxpayers and strengthen the global intangible low-taxed income regime imposed by the Jobs Act of 2017 while eliminating related tax exemptions. The impact of future changes to U.S. and foreign tax law on our business is uncertain and could be adverse, and we will continue to monitor and assess the impact of any such changes.

Changes in tax laws and regulations or exposure to additional tax liabilities could adversely affect our financial results.

Beginning in 2022, the Jobs Act eliminated the option to deduct research and development expenditures and requires taxpayers to amortize them over five years pursuant to IRC Section 174. Although Congress is considering legislation that would defer the amortization requirement to later years, we have no assurance that the provision will be repealed or otherwise modified. If the requirement is not modified or deferred, it may materially reduce our cash flows beginning in 2023. Please refer to Note 15, *Income Taxes*, for additional information.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Research Center

As of December 31, 2022, our facilities include current Good Manufacturing Practice (cGMP) operations where drug products are manufactured in the clinical manufacturing facility located within the 60,000 square foot laboratory bay at the Sanford Research Center (the "Research Center") in Sioux Falls, South Dakota encompassing a 17,300 square foot manufacturing area that includes the clinical manufacturing facility, -20°C plasma storage, and a controlled warehouse.

The Research Center lease is currently set to expire in August 2024.

TC Cattle Facility

Transchromosomic (Tc) cattle used for hyperimmunization, and plasma collection are housed at our animal facilities which we refer to as the “Pharm”. The Pharm is a biosecure site dedicated to housing and rearing these animals. The physical surroundings are maintained in accordance with various governmental regulations. This site also includes surgical suite and plasma collection areas. Facilities are appropriate for cattle housing and give adequate protection from inclement weather conditions. Double barrier fencing (perimeter fencing and locked exterior gating) is designed to prevent Tc cattle from escaping or other unwanted animals from entering. Production animal pens consist of concrete feeding floors, water fountains and outdoor dirt lots. A biosecurity program is critical to the production of human pharmaceuticals from animals. The production herd is considered “closed” from a biosecurity perspective and inputs (feed, nutritional additives, medications, etc.) and outputs to the system are carefully monitored according to the appropriate regulations. A pest control program is instituted to control vermin. The biosecurity program is managed using a combination of procedural controls, facility design features (such as barriers, fencing and housing), controlled access and employee training into or out of the site. Tc Bovine plasma is collected from the animals in designated areas at the Pharm. The areas are cleaned and maintained per the rules and regulations of the FDA. The Fenwal Auto-C plasmapheresis machine (human device) is used to collect plasma. Plasma is collected aseptically under standard sanitary conditions using a closed system and sterile bags to avoid microbial contamination. Following plasmapheresis, the plasma bioprocessing bags are labeled and shipped to SAB manufacturing facility or to contract manufacturers.

The Pharm real property lease in Canton, South Dakota is currently set to expire in November 2038.

Corporate Headquarters

The Company leases its corporate headquarters located at 2100 East 54th Street North, Sioux Falls, SD 57104. The lease covers approximately 49,600 square feet of office and laboratory space, with approximately 18,400 square feet of space dedicated to research and development activities. The Company believes that its existing facilities and other available properties will be sufficient for its needs for the foreseeable future.

Item 3. Legal Proceedings.

We are not currently a party to any material litigation, nor are we aware of any pending or threatened litigation against us that we believe would materially affect our business, operating results, financial condition, or cash flows. Participants in our industry face frequent claims and litigation, including securities litigation, claims regarding patent and other intellectual property rights, and other liability claims. As a result, we may be involved in various legal proceedings from time to time in the future.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock and public warrants are listed on Nasdaq under the symbols "SABS" and "SABSW", respectively. On March 22, 2023, the closing price of our common stock was $0.51 per share and the closing price of our warrants was $0.05 per warrant.

Holders of Our Common Stock

As of March 28, 2023, we had 246 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

All sales of unregistered securities by us during the year ended December 31, 2022 have been included previously in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In the first quarter of 2022, the Company held $6.3 million in escrow pending the final settlement of the Forward Share Purchase Agreement; upon final settlement of the Forward Share Purchase Agreement, $817,060 in cash was released to the Company and the remaining $5.5 million was delivered to Radcliffe for the repurchase of 546,658 shares of the Company's common stock at a price of $10.10 per share—these shares are accounted for as treasury stock at cost within the consolidated statements of changes in stockholders' equity (deficit).

Item 6. [Reserved].

Not Applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in "Risk Factors" included elsewhere in this Annual Report. As used in this report, unless the context suggests otherwise, "we," "us," our" or "the Company" refer to SAB Biotherapeutics, Inc. and its subsidiaries.

Overview

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, including infectious diseases resulting from outbreaks and pandemics as well as immunology, gastroenterology, and respiratory diseases that have significant mortality and health impacts on immunocompromised patients. We have applied advanced genetic engineering and antibody science to develop transchromosomic (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. We currently have multiple drug development programs underway and collaborations with the US government and global pharmaceutical companies.

The platform has been expanded and validated through funding awarded from U.S. government emerging disease and medical countermeasures programs with cumulative grant award totals of approximately $203.6 million. We are advancing clinical programs in two indications, and preclinical development in three indications. In addition, we are executing on two research collaborations with global pharmaceutical companies, including CSL Behring and an undisclosed collaboration.

We generated total revenue of $23.9 million and $60.9 million for the years ended December 31, 2022 and 2021, respectively (60.7% decline). Our revenue to date has been primarily derived from government grants. As of December 31, 2022, $0.4 million in funding remains for our current government grants, with an additional $0.4 million remaining for our current government grants pending approval of extensions on the funding for two of the grants.

We plan to focus a substantial portion of our resources on continued research and development efforts towards deepening our technology and expertise with our platform and as well as indications in infectious disease and autoimmune indications. As a result, we expect to continue to make significant investments in these areas for the foreseeable future. We incurred research and development expenses of $36.4 million and $57.2 million for the years ended December 31, 2022 and 2021, respectively, and general and administrative expenses of $16.4 million and $17.1 million for the years ended December 31, 2022 and 2021, respectively. We expect to continue to incur significant expenses, and we expect such expenses to increase substantially in connection with our ongoing activities, including as we:

- invest in research and development activities to optimize and expand our DiversitAb platform;
- develop new and advance preclinical and clinical progress of pipeline programs;
- market to and secure partners to commercialize our products;
- expand and enhance operations to deliver products, including investments in manufacturing;
- acquire businesses or technologies to support the growth of our business;
- continue to establish, protect and defend our intellectual property and patent portfolio;
- operate as a public company.

To date, we have primarily financed our operations from government agreements and the issuance and sale of common stock.

Our net loss for the year ended December 31, 2022 was $18.7 million and our net loss for the year ended December 31, 2021 was $17.1 million. As of December 31, 2022, we had an accumulated deficit of $47.9 million, and cash and cash equivalents totaling $15.0 million.

Recent Developments

Private Placement

On December 7, 2022, we consummated a private placement with certain institutional and accredited investors, whereby we issued an aggregate of 7,363,377 shares of common stock and warrants to purchase up to 7,363,377 shares of common stock (the "PIPE Warrants"), each share and PIPE Warrant sold at a combined purchase price of $1.08. The PIPE Warrants become exercisable on the six-month anniversary of the date of grant for a price of $1.08 per share and are exercisable for five years from the date of issuance. The issuance of shares of common stock upon exercise of the PIPE Warrants may result in material dilution to existing stockholders.

Termination of Contract with US Department of Defense

On August 3, 2022, we received notice from the DoD to terminate the Department of Defense, JPEO Rapid Response contract, dated as of August 7, 2019 with the DoD most recently amended as of September 14, 2021, relating to prototype research and development of a Rapid Response Antibody Program and advanced clinical development through licensure and commercial manufacturing for SAB-185 (the "JPEO Rapid Response Contract Termination"). No termination penalties have been or will be incurred by us in connection therewith.

Business Combination

On October 22, 2021, we consummated the Business Combination pursuant to that certain Agreement and Plan of Merger, dated June 21, 2021 ("Business Combination Agreement"), by and among BCYP, Big Cypress Merger Sub Inc., a Delaware corporation and a direct wholly owned subsidiary of BCYP, and SAB Biotherapeutics, Inc., which changed its name to SAB Sciences, Inc. and became our wholly-owned subsidiary in connection with the Business Combination (and which we refer to now as Legacy SAB). Upon completion of the Business Combination, and pursuant to the terms of the Business Combination Agreement, the stockholders of Legacy SAB exchanged their Legacy SAB shares for our shares of common stock, and options to purchase shares of Legacy SAB were converted into options to purchase our shares of common stock. Additionally, (i) we issued 10,491,937 shares of common stock to the former stockholders of Legacy SAB, which are being held in escrow and which will be released if certain conditions are met prior to October 22, 2026, and (ii) we granted 1,508,063 contingently issuable restricted stock units to the holders of Legacy SAB options, which restricted stock units will be settled in our shares of common stock if the same conditions are met prior to October 22, 2026. For more information, see Note 1 to the Company's consolidated financial statements, *Nature of Business*.

Key Factors Affecting Our Results of Operations and Future Performance

We believe that our financial performance has been, and in the foreseeable future will continue to be, primarily driven by multiple factors as described below, each of which presents growth opportunities for our business. These factors also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address these challenges is subject to various risks and uncertainties, including those described in Part I, Item 1A of this Annual Report.

Components of Results of Operations

Revenue

Our revenue has historically been generated through grants from government and other (non-government) organizations. We currently have no commercially-approved products.

Grant revenue is recognized for the period that the research and development services occur, as qualifying expenses are incurred or conditions of the grants are met. We concluded that payments received under these grants represent conditional, nonreciprocal contributions, as described in ASC 958, *Not-for-Profit Entities*, and that the grants are not within the scope of ASC 606, *Revenue from Contracts with Customers*, as the organizations providing the grants do not meet the definition of a customer. Expenses for grants are tracked by using a project code specific to the grant, and the employees also track hours worked by using the project code.

For the years ended December 31, 2022 and 2021, we worked on the following grants:

Government grants

The total revenue for government grants was approximately $23.9 million and $60.9 million, respectively, for the years ended December 31, 2022 and 2021.

National Institute of Health – National Institute of Allergy and Infectious Disease (“NIH-NIAID”) (Federal Award #1R44AI117976-01A1) – this grant was for $1.4 million and started in September 2019 through August 2021. The grant was subsequently amended to extend the date through August 2022. For the years ended December 31, 2022 and 2021, there was approximately $182,000 and $518,000, respectively, in grant income recognized from this grant. This grant was completed in 2022.

NIH-NIAID (Federal Award #1R41AI131823-02) – this grant was for approximately $1.5 million and started in April 2019 through March 2021. The grant was subsequently amended to extend the date through March 2023. For the years ended December 31, 2022 and 2021, approximately $328,000 and $51,000, respectively, in grant income was recognized from this grant. Approximately $429,000 in funding remains for this grant as of December 31, 2022.

NIH-NIAID through Geneva Foundation (Federal Award #1R01AI132313-01, Subaward #S-10511-01) – this grant was for approximately $2.7 million and started in August 2017 through July 2021. The grant was subsequently amended to extend the date through July 2023. For the years ended December 31, 2022 and 2021, there was approximately $1,052,000 and $94,000, respectively, in grant income recognized from this grant. Approximately $0.4 million in funding remaining for this grant as of December 31, 2022.

DoD, JPEO through Advanced Technology International – this grant was for a potential of $25 million, awarded in stages starting in August 2019 and with potential stages running through February 2023. Additional contract modifications were added to this agreement in 2020 for work on a COVID therapeutic, bringing the agreement total to approximately $143 million. In September 2021, an additional modification for $60.5 million was added to the agreement for advanced clinical development through licensure and commercial manufacturing, bringing the agreement total to approximately $203.6 million. For the years ended December 31, 2022 and 2021, approximately $22.2 million and $60.2 million, respectively, in grant income was recognized from this grant. This grant was terminated in 2022.

The grants for JPEO Rapid Response contract are cost reimbursement agreements, with reimbursement of our direct research and development expense (labor and consumables) with an overhead charge (based on actual, reviewed quarterly) and a fixed fee (9%).

On August 3, 2022, we received noticed from the DoD to terminate the JPEO Rapid Response contract, dated as of August 7, 2019 with the DoD most recently amended as of September 14, 2021, relating to a prototype research and development of Rapid Response Antibody Program and advanced clinical development through licensure and commercial manufacturing for SAB-185 (the "JPEO Rapid Response Contract Termination"). We engaged in negotiations with the DoD to compensate us for services provided prior to the JPEO Rapid Response Contract Termination and costs we would be expected to bear in future periods.

Operating Expenses

Research and Development Expenses

Research and development expenses primarily consist of salaries, benefits, incentive compensation, stock-based compensation, laboratory supplies and materials for employees and contractors engaged in research and product development, licensing fees to use certain technology in our research and development projects, fees paid to consultants and various entities that perform certain research and testing on our behalf. Research and development expenses are tracked by target/project code. Indirect general and administrative costs are allocated based upon a percentage of direct costs. We expense all research and development costs in the period in which they are incurred.

Research and development activities consist of discovery research for our platform development and the various indications we are working on. We have not historically tracked our research and development expenses on a product candidate-by-product candidate basis.

For the years ended December 31, 2022 and 2021, we had contracts with multiple CRO to conduct and complete clinical studies. In the case of SAB-185, the CRO has been contracted and paid by the US government - as of December 31, 2022, there is no active CRO engaged by us in work on the SAB-185. For SAB-176, PPD Development, LP, acting as CRO oversaw the Phase 1 safety study. The terms of that agreement are subject to confidentiality, and the status of the agreement is that it is current, in good standing and approximately 95% of the contract has been paid through December 31, 2022. SAB has also contracted with hVIVO Services Limited to conduct the Phase 2a influenza study on SAB-176. The terms of that agreement are subject to confidentiality, and the status of the agreement is that it is current, in good standing and approximately 95% of the contract has been paid through December 31, 2022.

We expect to continue to incur substantial research and development expenses as we conduct discovery research to enhance our platform and work on our indications. We expect to hire additional employees and continue research and development and manufacturing activities. As a result, we expect that our research and development expenses will continue to increase in future periods and vary from period to period as a percentage of revenue.

Major components within our research and development expenses are salaries and benefits (laboratory & farm), laboratory supplies, animal care, contract manufacturing, clinical trial expense, outside laboratory services, project consulting, and facility expense. Our platform allows us to work on multiple projects with the same resources, as the research and development process of each product is very similar (with minimal differences in the manufacturing process). Research and development expenses by component for the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31,	
	2022	2021
Salaries & benefits	$ 12,032,720	$ 9,944,717
Laboratory supplies	6,441,181	14,471,878
Animal care	1,560,099	4,636,515
Contract manufacturing	5,256,518	12,665,794
Clinical trial expense	271,283	5,299,817
Outside laboratory services	4,561,696	4,735,373
Project consulting	805,994	1,812,292
Facility expense	5,354,356	3,415,518
Other expenses	154,666	201,685
Total research and development expenses	$ 36,438,513	$ 57,183,589

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, benefits and stock-based compensation costs for employees in our executive, accounting and finance, project management, corporate development, office administration, legal and human resources functions as well as professional services fees, such as consulting, audit, tax and legal fees, general corporate costs and allocated overhead expenses. We expect that our general and administrative expenses will continue to increase in future periods, primarily due to increased headcount to support anticipated growth in the business and due to incremental costs associated with operating as a public company, including costs to comply with the rules and regulations applicable to companies listed on a securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC and stock exchange listing standards, public relations, insurance and professional services. We expect these expenses to vary from period to period in absolute terms and as a percentage of revenue.

Nonoperating (Expense) Income

Gain on change in fair value of warrant liabilities

Gain on change in fair value of warrant liabilities consists of the changes in the fair value of the warrant liabilities.

Gain on debt extinguishment of Paycheck Protection Program SBA Loan

Gain on extinguishment of debt consists of the forgiveness of the PPP Loan, plus accrued interest.

Other income

Other income consists of primarily of gains on disposals of fixed assets.

Interest income

Interest income consists of interest earned on cash balances in our bank accounts.

Interest expense

Interest expense consists primarily of interest related to borrowings under notes payable for equipment.

Income Tax Expense

Income tax expense consists primarily of domestic federal and state income taxes.

Results of Operations

The following tables set forth our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	**2021**
Revenue		
Grant revenue	$ 23,904,181	$ 60,876,078
Total revenue	23,904,181	60,876,078
Operating expenses		
Research and development	36,438,513	57,183,589
General and administrative	16,383,285	17,085,692
Total operating expenses	52,821,798	74,269,281
Loss from operations	(28,917,617)	(13,393,203)
Other income (expense)		
Changes in fair value of warrant liabilities	10,399,200	(4,151,068)
Gain on debt extinguishment of Paycheck Protection Program SBA Loan	—	665,596
Other income	33,754	5,488
Interest expense	(301,584)	(294,459)
Interest income	71,072	23,115
Total other income	10,202,442	(3,751,328)
Loss before income taxes	(18,715,175)	(17,144,531)
Income tax expense	25,629	—
Net loss	$ (18,740,804)	$ (17,144,531)

Comparison of the Years Ended December 31, 2022 and 2021

Revenue

	Year Ended December 31,			
	2022	**2021**	**Change**	**% Change**
Revenue	$ 23,904,181	$ 60,876,078	$ (36,971,897)	(60.7)%
Total revenue	$ 23,904,181	$ 60,876,078		

Revenue decreased by $37.0 million, or 60.7%, in 2022, primarily due to the JPEO Rapid Response Contract Termination (year-over-year decrease of $38 million, (63.1)%). Included in revenues for the year ended December 31, 2022 are $5.3 million for contract manufacturing, $3.1 million for labor, and $5.4 million for supplies as compared to $12.7 million for contract manufacturing, $3.9 million for fixed asset reimbursement, $6.1 million for labor, and $16.7 million for supplies for the year ended December 31, 2021.

We anticipate future revenues will be substantially derived from current period directly reimbursable expenses such as laboratory supplies, labor costs, and consulting fees plus, when applicable, an overhead charge and a flat-rate fixed fee. As a result of the JPEO Rapid Response Contract Termination, we expect future revenues to be lower as our primary pipeline development targets of Clostridioides difficile Infection, influenza, and immune system disorders remain independently financed as we explore potential partnerships, co-development opportunities, and licensing arrangements

Research and Development

	Year Ended December 31,			
	2022	2021	Change	% Change
Research and development	$ 36,438,513	$ 57,183,589	$ (20,745,076)	(36.3)%
Total research and development expenses	$ 36,438,513	$ 57,183,589		

Research and development expenses decreased by $20.7 million, or (36.3)%, in 2022, primarily due to decrease in laboratory supplies (year-over-year decrease of $8.2 million, (42.7)%) , contract manufacturing costs (year-over-year decrease of $7.4 million, (58.3)%), clinical trial and project consulting expense (year-over-year decrease of $6.0 million, (84.5)%), and animal care costs (year-over-year decrease of $3.1 million, (65.2)%), offset by an increase in salaries and benefits (year-over-year increase of $2.1 million, 21.2%), and facility costs (year-over-year increase of $1.9 million, 52.8%). Please refer to the research and development expenses by component for the years ended December 31, 2022 and 2021 table above for additional information.

As a result of the JPEO Rapid Response Contract Termination and in tandem with our focus on primary pipeline development targets, future period research and development expenses will decrease as we no longer expect to incur costs of contract manufacturing, outside laboratory services, project consulting, and facilities costs related to the production of SABS-185.

General and Administrative

	Year Ended December 31,			
	2022	2021	Change	% Change
General and administrative	$ 16,383,285	$ 17,085,692	$ (702,407)	(4.1)%
Total general and administrative expenses	$ 16,383,285	$ 17,085,692		

General and administrative expenses decreased by $0.7 million, or (4.1)%, in 2022, primarily due to decreased administrative salaries and benefits (year-over-year decrease of $2.3 million), decreases in business, regulatory and marketing consulting (year-over-year decrease of $0.7 million), offset by an increase in insurance costs (year-over-year increase of $2.0 million), and public reporting expenses (year-over-year increase of $0.3 million).

Non-operating (Expense) Income

	Year Ended December 31,			
	2022	2021	Change	% Change
Changes in fair value of warrant liabilities	$ 10,399,200	$ (4,151,068)	$ 14,550,268	(350.5)%
Gain on debt extinguishment of Paycheck Protection Program SBA Loan	—	665,596	$ (665,596)	(100.0)%
Other income	33,754	5,488	$ 28,266	515.1%
Total non-operating (expense) income	$ 10,432,954	$ (3,479,984)		

Total non-operating (expense) income changed by $13.9 million in 2022, primarily due to changes in the fair value of the warrant liabilities, partially offset by the forgiveness of the PPP Loan, plus accrued interest, in the first quarter of 2021.

Interest Expense

	Year Ended December 31,			
	2022	2021	Change	% Change
Interest expense	$ 301,584	$ 294,459	$ 7,125	2.4%
Total interest expense	$ 301,584	$ 294,459		

Interest expense remained largely unchanged in 2022, driven by adding no new Finance Leases or other interest-bearing debt. We expect interest expense to increase in future periods as the accrued interest payable under the 8% Unsecured Convertible Note is realized over a full year.

Interest Income

	Year Ended December 31,			
	2022	2021	Change	% Change
Interest income	$ 71,072	$ 23,115	$ 47,957	207.5%
Total interest income	$ 71,072	$ 23,115		

Interest income increased by $47,957 in 2022, primarily due to higher average cash balances and higher interest rates on cash deposits.

Liquidity and Capital Resources

As of December 31, 2022 and December 31, 2021, we had $15.0 million and $33.2 million, respectively, of cash and cash equivalents. Additionally, as of December 31, 2021 we had $6.3 million in restricted cash held in escrow pending the final settlement of the Forward Share Purchase Agreement. Upon final settlement of the Forward Share Purchase Agreement during the first quarter of 2022, $817,060 in cash was released to us and the remaining $5.5 million was delivered to Radcliffe for the repurchase of 546,658 shares of our common stock. To date, we have primarily relied on grant revenue in the form of government grants and the sale of preferred stock.

Our standard repayment terms for accounts receivable are thirty days from the invoice date. As a majority of our accounts receivable is from work performed under government grants, we have not had an uncollectible accounts receivable amount in over 5 years. As of the date this annual report has been made available for issuance, our entire $5.6 million balance of accounts receivables as of December 31, 2022 has been fully collected.

We intend to continue to invest in our business and, as a result, may incur operating losses in future periods. We expect to continue to invest in research and development efforts towards expanding our capabilities and expertise along our platform and the primary pipeline development targets we are working on, as well as building our business development team and marketing our solutions to partners in support of the growth of the business.

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin commercialization of our products. As a result, we will require additional capital to fund our operations in order to support our long-term plans, in particular, following the JPEO Rapid Response Contract Termination.

We have incurred operating losses for the past several years. While we intend to continue to keep operating expenses at a reduced level there can be no assurance that our current level of operating expenses will not increase or that other uses of cash will not be necessary. Based on our current level of operating expenses, existing cash and cash equivalents may not be sufficient to cover operating cash needs through the twelve months following the date these financials are made available for issuance. We intend to seek additional capital through equity and/or debt financings, collaborative or other funding arrangements. Should we seek additional financing from outside sources, we may not be able to raise such financing on terms acceptable to us or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Sources of Liquidity

Since our inception, we have financed our operations primarily from revenue in the form of government grants and from equity financings.

Equity Financings and Option Exercises

As of December 31, 2022, we have raised approximately $90.2 million since our inception from the issuance and sale of convertible preferred shares, net of issuance costs associated with such financings, the Business Combination with BCYP, and exercises of employee stock options.

Notes payable and Convertible Debt

As of December 31, 2022 and 2021 we had total debt balances of $1,314,309 and $1,796,724, respectively.

8% Unsecured Convertible Note

Pursuant to the Fourth Amendment to our lease with Sanford Health, we agreed to a period of Abated Rent from October 1, 2022 to September 30, 2023 pertaining to our leased laboratory bay at the Sanford Research Center. In exchange for the Abated Rent, effective as of October 1, 2022, we issued to Sanford Health an 8% unsecured, convertible promissory note (the "8% Unsecured Convertible Note").

Pursuant to the 8% Unsecured Convertible Note, we shall pay the sum of $541,644 (the “Principal”) plus accrued and unpaid interest thereon on September 31, 2024 (the “Maturity Date”). Simple interest shall accrue on the outstanding Principal from and after the date of the October Note, and shall be payable on the Maturity Date. Sanford Health shall have the right, but not the obligation, to convert all or any part of the outstanding Principal of the 8% Unsecured Convertible Note, together with any accrued and unpaid interest thereon to the date of such conversion, into such number of fully paid and non-assessable shares of the Company’s common stock, at any time and from time to time, prior to the later of the Maturity Date and the date on which the 8% Unsecured Convertible Note is paid in full, subject to certain restrictions, at a conversion price per share of Common Stock equal to greater of (x) $1.50 and (y) the price at which the Company sells shares of common stock in any bona fide private or public equity financing prior to the Maturity Date.

Other Notes Payable

On March 27, 2020, President Trump signed into law the “Coronavirus Aid, Relief and Economic Security Act (“CARES Act”). In April 2020, we entered into the PPP Loan with First Premier Bank under the PPP, which is part of the CARES Act administered by the SBA. As part of the application for these funds, we, in good faith, certified that the current economic uncertainty made the loan request necessary to support our ongoing operations. The certification further requires us to take into account our current business activity and our ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. Under the PPP, we received proceeds of approximately $661,612. In accordance with the requirements of the PPP, we utilized the proceeds from the PPP Loan primarily for payroll costs. The PPP Loan has a 1.00% interest rate per annum, matures in April 2022 and is subject to the terms and conditions applicable to loans administered by the SBA under the PPP. Under the terms of PPP, all or certain amounts of the PPP Loan may be forgiven if they are used for qualifying expenses, as described in the CARES Act. We recorded the entire amount of the PPP Loan as debt. Under the terms of the PPP Loan, monthly payments of principal and interest were due to commence November 1, 2020, however, the SBA is deferring loan payments for borrowers who apply for loan forgiveness until the SBA remits the borrower’s loan forgiveness amount to the lender. An application for forgiveness of the PPP Loan was completed in February 2021. In March 2021, the SBA approved the forgiveness of the PPP Loan, plus accrued interest. We recorded a gain on extinguishment of PPP Loan of $665,596 for the forgiveness of the PPP Loan and accrued interest within gain on debt extinguishment of Paycheck Protection Program SBA Loan on the consolidated statement of operations for the year ended December 31, 2021.

Insurance Financing

We obtained financing for certain Director & Officer liability insurance policy premiums. The agreement assigns First Insurance Funding (Lender) a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies including (a) all returned or unearned premiums, (b) all additional cash contributions or collateral amounts assessed by the insurance companies in relation to the financed policies and financed by Lender, (c) any credits generated by the financed policies, (d) dividend payments, and (e) loss payments which reduce unearned premiums. If any circumstances exist in which premiums related to any Financed Policy could become fully earned in the event of loss, Lender shall be named a loss-payee with respect to such policy.

The total premiums, taxes and fees financed is approximately $1,236,000 with an annual interest rate of 5.47%. In consideration of the premium payment by Lender to the insurance companies or the Agent or Broker, we unconditionally promise to pay Lender the amount Financed plus interest and other charges permitted under the Agreement. At December 31, 2022 and 2021 we recognized approximately $773,000 and $1,772,000, respectively, as insurance financing note payable in its consolidated balance sheet. We will pay the insurance financing through installment payments with the last payment being on September 22, 2023.

In December 2017, we entered into a loan agreement with a financial institution for the purchase of a tractor for $116,661 at 3.6%. The loan included annual payments of $25,913 for the next five years starting in December 2018. The tractor was paid off in full in November 2022.

Please refer to Note 11 in our consolidated financial statements, *Notes Payable,* for additional information on our debt.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2022 and 2021:

	2022	2021
Net cash provided (used) by operating activities	$ (23,459,511)	$ 1,986,873
Net cash used in investing activities	(2,090,024)	(10,943,657)
Net cash provided by financing activities	1,051,411	35,891,419
Net decrease in cash, cash equivalents, and restricted cash	$ (24,498,124)	$ 26,934,635

Operating Activities

Net cash provided (used) by operating activities decreased by $25.4 million in 2022, primarily due to a $15.5 million decrease in operating income, an $11.9 million increase in non-cash working capital, offset by an increase of $2.7 million in non-cash expenses. Year-over-year changes in cash provided (used) by operating activities is explained by shifts in the company's non-cash working capital balances as we continue to advance our lead programs after the JPEO Rapid Response Contract Termination.

Investing Activities

Net cash used in investing activities increased by $8.9 million in 2022, primarily due to a decrease in purchases of equipment as new equipment purchases under the JPEO Rapid Response Contract were substantially completed in 2021. Capital asset purchases completed in 2022 relate substantially to leasehold improvements at the Corporate Headquarters and completion of the clinical manufacturing facility at the Sanford Research Center.

Financing Activities

Net cash provided by financing activities decreased by $34.8 million in 2022, primarily due to $34.4 million in proceeds from the Business Combination being fully realized in 2021. In 2022, we received $7.7 million of funds (net of issuance costs) from the issuance of common stock in a private placement, offset by utilizing $6.3 million of restricted cash to settle the Forward Share Purchase Agreement.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2022:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	Over 5 years
Notes payable	$ 1,314,309	$ 772,665	$ 541,644	$ —	$ —
Operating lease liabilities (1)	896,838	528,520	368,318	—	—
Finance lease liabilities (1)	6,395,321	406,339	802,992	802,992	4,382,998
Total	$ 8,606,468	$ 1,707,524	$ 1,712,954	$ 802,992	$ 4,382,998

(1) We are party to certain contractual arrangements for equipment, lab space, and an animal facility, which meet the definition of leases under FASB ASC Topic 842, *Leases* (“ASC 842”).

We enter into contracts in the normal course of business with third parties, including CROs. These payments are not included in the table above, as the amount and timing of such payments are not known.

As of December 31, 2022, there were no material changes outside of the ordinary course of business to our commitments and contractual obligations.

Income Taxes

We had $22.0 million of federal net operating loss carryforwards as of December 31, 2022. Our carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

These carryforwards may generally be utilized in any future period but may be subject to limitations based upon changes in the ownership of our shares in a prior or future period. We have not quantified the amount of such limitations, if any.

Going Concern

A fundamental principle of the preparation of financial statements in accordance with GAAP is the assumption that we will continue in existence as a going concern, which contemplates continuity of operations and the realization of assets and settlement of liabilities occurring in the ordinary course of business.

As of December 31, 2022, we have experienced net losses, negative cash flows from operations and had an accumulated deficit of $47.9 million. We anticipate we will continue to generate losses for the foreseeable future, and expects the losses to increase as we continue the development of, and seek regulatory approvals for, product candidates, and begin commercialization of products. As a result, we will require additional capital to fund operations in order to support long-term plans, in particular, following the JPEO Rapid Response Contract Termination. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the date that these financial statements were issued.

To continue as a going concern, we will need, among other things, to raise additional capital resources. We plan to seek additional funding through a combination of equity or debt financings, or other third-party financing, collaborative or other funding arrangements. Should we seek additional financing from outside sources, we may not be able to raise such financing on terms acceptable to us or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

The consolidated financial statements for December 31, 2022, have been prepared on the basis that we will continue as a going concern, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability for us to continue as a going concern.

Off-Balance Sheet Arrangements

We did not have, for the periods presented, and we do not currently have, any off-balance sheet financing arrangements or any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities, that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Estimates

We have prepared our consolidated financial statements in accordance with U.S. GAAP. Our preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 in our consolidated financial statements, *Summary of Significant Accounting Policies,* we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our revenue is primarily generated through grants from government and other (non-government) organizations.

Grant revenue is recognized for the period that the research and development services occur, as qualifying expenses are incurred or conditions of the grants are met. We concluded that payments received under these grants represent conditional, nonreciprocal contributions, as described in ASC 958, *Not-for-Profit Entities*, and that the grants are not within the scope of ASC 606, *Revenue from Contracts with Customers*, as the organizations providing the grants do not meet the definition of a customer. Expenses for grants are tracked by using a project code specific to the grant, and the employees also track hours worked by using the project code.

Stock-Based Compensation

We recognize compensation cost relating to stock-based payment transactions using a fair-value measurement method, which requires all stock-based payments to employees, directors, and non-employee consultants, including grants of stock options, to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. Prior to the Business Combination, the grant date fair value of our common stock was typically determined by our board of directors with the assistance of management and a third-party valuation specialist. Subsequent to the Business Combination, the board of directors elected to determine the fair value of our post-merger common stock based on the closing market price at closing on the date of grant. In determining the fair value of our stock-based awards, we utilize the Black-Scholes option-pricing model, which uses both historical and current market data to estimate fair value. The Black-Scholes option-pricing model incorporates various assumptions, such as the value of the underlying common stock, the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. For awards with performance-based vesting criteria, we estimate the probability of achievement of the performance criteria and recognize compensation expense related to those awards expected to vest. No awards may have a term in excess of ten years. Forfeitures are recorded when they occur. Stock-based compensation expense is classified in our consolidated statements of operations based on the function to which the related services are provided. We recognize stock-based compensation expense over the expected term.

In addition to considering the results of the independent third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common shares as of each grant date, which may be a date other than the most recent independent third-party valuation date, including:

- the prices at which we most-recently sold preferred shares and the superior rights and preferences of the preferred shares relative to our common shares at the time of each grant;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- our financial condition and operating results, including our levels of available capital resources and forecasted results;
- developments in our business, including the achievement of milestones such as entering into partnering agreements;
- the valuation of publicly traded companies in the life sciences, biopharmaceutical and healthcare technology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting our industry, and trends within our industry;
- the likelihood of achieving a liquidity event for the holders of our preferred shares and holders of our common shares, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in our industry.

The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, the fair value of our common shares and our stock-based compensation expense could be materially different.

See Note 13 in our consolidated financial statements, *Stock Option Plan,* for information concerning certain specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted for the years ended December 31, 2022 and 2021.

Stock-based compensation expense was $2.7 million and $2.3 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 we had $4.2 million of total unrecognized stock-based compensation cost related to non-vested options, which we expect to recognize in future operating results over a weighted-average period of 3.17 years. Total unrecognized compensation cost related to non-vested stock awards as of December 31, 2022, was approximately $0.5 million and is expected to be recognized within future operating results over a weighted-average period of 3.46 years.

Warrant Valuations

Liability Classified Warrants

We are required to periodically estimate the fair value of our Private Placement Warrant liabilities with the assistance of an independent third-party valuation firm. The assumptions underlying these valuations represented our best estimates, which involved inherent uncertainties and the application of significant levels of our judgment. The fair value of our Public Warrant liabilities is determined by reference to the quoted market price.

The warrants are accounted for as liabilities in accordance with ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity*, and were presented within warrant liabilities on the consolidated balance sheet as of December 31, 2022. The initial fair value of the warrant liabilities was measured at fair value on the Closing Date, and changes in the fair value of the warrant liabilities were presented within changes in fair value of warrant liabilities in the consolidated statement of operations for the year ended December 31, 2022.

On the Closing Date, we established the fair value of the Private Placement Warrants utilizing both the Black-Scholes Merton formula and a Monte Carlo Simulation ("MCS") analysis. Specifically, we considered a MCS to derive the implied volatility in the publicly-listed price of the Public Warrants. We then considered this implied volatility in selecting the volatility for the application of a Black-Scholes Merton model for the Private Placement Warrants. We determined the fair value of the Public Warrants by reference to the quoted market price.

The Public Warrants were classified as a Level 1 fair value measurement, due to the use of the quoted market price, and the Private Placement Warrants held privately by Big Cypress Holdings LLC, a Delaware limited liability company which acted as our sponsor in connection with the IPO (the "Sponsor"), were classified as a Level 3 fair value measurement, due to the use of unobservable inputs.

The measurement as of December 31, 2021 for the Public Warrant liability was approximately $428,000 and the change in fair value of the Public Warrant liability was approximately $417,000 for the year ended December 31, 2022.

The key inputs into the valuations as of the Closing Date and December 31, 2022 were as follows:

	December 31, 2022	December 31, 2021
Risk-free interest rate	4.00%	1.24%
Expected term remaining (years)	3.81	4.81
Implied volatility	82.0%	43.0%
Closing common stock price on the measurement date	$ 0.59	$ 7.81

Equity Classified Warrants

On December 7, 2022, as a part of our 2022 Private Placement, the Company issued PIPE Private Placement Warrants to investors to purchase up to 7,363,377 shares of Common Stock. The PIPE Private Placement Warrants, including those purchased by the participating directors of SAB are exercisable beginning six months from the date of issuance at an exercise price equal to $1.08 per share, and are exercisable for five years from the date of issuance. We also issued our placement agent, Brookline Capital Markets, PIPE Placement Agent Warrants to purchase up to an aggregate of 210,913 shares of Common Stock The Placement Agent Warrants have an exercise price equal to $1.35 per share and are exercisable six months from the date of issuance and expires five years from the date of issuance.

The PIPE Private Placement Warrants and PIPE Placement Agent Warrants met all necessary criteria to be accounted for as equity in accordance with ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity. As such, they are presented within additional paid-in capital within Company's Consolidated Statements of Changes in Stockholders' Equity (Deficit) and consolidated balance sheets as of December 31, 2022.

Warrants classified as equity are initially measured at fair value. Subsequent changes in fair value are not recognized as long as the warrants continue to be classified as equity. The initial fair value of each PIPE Private Placement Warrant and PIPE Placement Agent Warrant issued has been determined using the Black-Scholes option-pricing model. All relevant terms and conditions for the PIPE Private Placement Warrant and PIPE Placement Agent Warrant are identical with the exception of the exercise prices of $1.08 and $1.35, respectively; the key inputs into the valuations as of the initial measurement date were as follows:

	Initial Measurement
Risk-free interest rate	3.62%
Expected term remaining (years)	5.00
Implied volatility	89.0%
Closing common stock price on the measurement date, less discount for lack of marketability (1)	$ 0.66

(1) As the underlying shares are restricted from sale for a period of 180 days from the date of the 2022 Private Placement, the fair value of the warrants were estimated using the Black-Scholes option pricing model that uses several inputs, including market price of our common shares at the end of each reporting period (a level one input), less a discount for lack of marketability (a level two input). The discount for lack of marketability was estimated upon consideration of volatility and the length of the lock-up period.

See Note 14 in our consolidated financial statements, *Fair Value Measurements,* for information concerning certain specific assumptions we used in applying the Black-Scholes Merton formula and MCS to determine the estimated fair value of the Private Placement Warrants, PIPE Private Placement Warrants, and PIPE Placement Agent Warrants outstanding for the year ended December 31, 2022.

Common Stock Valuations

Prior to becoming a public company, we were required to periodically estimate the fair value of our common stock with the assistance of an independent third-party valuation firm, as discussed above, when issuing stock options and computing our estimated stock-based compensation expense. The assumptions underlying these valuations represented our best estimates, which involved inherent uncertainties and the application of significant levels of our judgment. In order to determine the fair value of our common stock, we considered, among other items, previous transactions involving the sale of our securities, our business, financial condition and results of operations, economic and industry trends, the market performance of comparable publicly traded companies, and the lack of marketability of our common stock.

Subsequent to the Business Combination, we now determine the fair value of our common stock based on the closing market price at closing on the date of grant.

Compensation expense related to stock-based transactions is measured and recognized in the financial statements at fair value of our post-merger common stock based on the closing market price at closing on the date of grant. Stock-based compensation expense is measured at the grant date based on the fair value of the equity award and is recognized as expense over the requisite service period, which is generally the vesting period, on the straight-line method. We estimate the fair value of each stock option award on the date of grant using the Black-Scholes option-pricing model. Determining the fair value of stock option awards at the grant date requires judgment, including estimating the expected volatility, expected term, risk-free interest rate, and expected dividends.

Lease Liabilities and Right-of-Use Assets

We are party to certain contractual arrangements for equipment, lab space, and an animal facility, which meet the definition of leases under ASC 842. In accordance with ASC 842, we, as of January 1, 2018 (the date of adoption), recorded right-of-use assets and related lease liabilities for the present value of the lease payments over the lease terms. We utilized the practical expedient regarding lease and non-lease components and have combined such items into a single combined component. Our incremental borrowing rate was used in the calculation of our right-of-use assets and lease liabilities.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 4 in our consolidated financial statements, *New Accounting Standards*.

Impact of the COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic, which continues to spread throughout the U.S. and worldwide. As with many companies around the world, our day-to-day operations were disrupted with the imposition of work from home policies and requirements for physical distancing for any personnel present in our offices and laboratories. The pandemic has also disrupted our activities as shelter-in-place orders, quarantines, supply chain disruptions, travel restrictions and other public health safety measures have impacted our ability to interact with our existing and potential partners for our activities. However, the COVID-19 pandemic did not materially impact our business, operating results or financial condition. There is significant uncertainty as to the trajectory of the pandemic and its impacts on our business in the future. We could be materially and adversely affected by the risks, or the public perception of the risks, related to the COVID-19 pandemic or similar public health crises. Such crises could adversely impact our ability to conduct on-site laboratory activities, expand our laboratory facilities, secure critical supplies such as reagents, laboratory tools or immunized animals required for discovery research activities, and hire and retain key personnel. The ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, among others. Accordingly, we cannot predict the extent to which our business, financial condition and results of operations will be affected. We remain focused on maintaining our operations, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from the COVID-19 pandemic.

JOBS Act Accounting Election

We qualify as an "emerging growth company" as defined in the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are not otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this Annual Report;
- not being required to comply with the auditor attestation requirements on the effectiveness of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis);
- reduced disclosure obligations regarding executive compensation arrangements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year in which the fifth anniversary of the completion of our initial public offering occurred. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this Annual Report and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our shareholders may be different than the information you receive from other public companies in which you hold stock.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, until those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an emerging growth company or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which we will adopt the recently issued accounting standard.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not Applicable.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required pursuant to this item are included in Part IV, Item 15 of this Annual Report, and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer has evaluated the effectiveness of our disclosure controls and procedures. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of the end of the fiscal year covered by this Annual Report as a result of the material weaknesses in Internal Control over Financial Reporting described below.

Management's Report on Internal Control over Financial Reporting

Management, including our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a- 15(f) and 15d-15(f) under the Exchange Act and based upon the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO framework"). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. GAAP.

An effective internal control system, no matter how well designed, has inherent limitations, including the possibility of human error or overriding of controls, and therefore can provide only reasonable assurance with respect to reliable financial reporting. Because of its inherent limitations, our internal control over financial reporting may not prevent or detect all misstatements, including the possibility of human error, the circumvention or overriding of controls, or fraud. Effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation of the effectiveness of our internal control over financial reporting based on the COSO framework. Based on evaluation under these criteria and based upon the existence of the material weakness described below, management determined, that we did not maintain effective internal control over financial reporting as of December 31, 2022.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis.

We identified deficiencies in the control environment component of the COSO Framework that constitute a material weakness:

- We lack sufficient appropriate accounting and reporting knowledge to effectively perform review controls surrounding technical accounting matters and significant and/or unusual transactions.

Management believes that the material weakness set forth above is the result of the scale of our operations, is intrinsic to our size, and intends to take remedial actions described below.

Plan for Remediation of Material Weakness

We continue to work to strengthen our internal control over financial reporting and are committed to ensuring that such controls are designed and operating effectively. We are implementing process and control improvements to address the above material weakness as follows:

- We have supplemented existing accounting resources with external advisors to assist with performing certain technical accounting activities. We have hired an additional full-time employee with technical accounting expertise and public company experience. Management will continue to supplement existing internal resources as needed. In addition, Management will continue to review the qualifications of our finance organization to ensure our personnel have the appropriate technical and SOX related expertise.
- We have begun the process of implementing a contract management platform that will integrate functions governing the initiation, authorization, and execution of contracts with enhancements for our existing contract review control. This tool will improve the ability of the finance organization to review new and renewed contracts for potential financial reporting implications.

We are committed to continuing to improve our internal control processes related to these matters and will continue to review our financial reporting controls and procedures. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address deficiencies or modify certain of the remediation measures described above.

Changes in Internal Control Over Financial Reporting

Other than as described above, there have been no changes in our internal control over financial reporting in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On March 21, 2023, the Company entered into a settlement agreement with Ladenburg (the "2023 Ladenburg Agreement", and the action brought by Ladenburg, the "Ladenburg Action"), effective March 23, 2023. In connection with the Ladenburg Agreement, on March 24, 2023, the Company (i) issued to Ladenburg a warrant to purchase up to 300,000 shares of common stock, exercisable for three years from the date of issuance at $0.5424 per share; and (ii) furnished to Ladenburg a one-time cash payment of $500,000. Pursuant to the terms and subject to the conditions set forth in the 2023 Ladenburg Agreement, the Company will (i) no later than June 30, 2023, pay $1.5 million to Ladenburg in cash or shares of common stock, at the Company's option; and (ii) no later than December 31, 2023, pay $1.1 million to Ladenburg in cash or shares of common stock, at the Company's option. Following the completion of the Company's obligations under the Ladenburg Agreement, Ladenburg has agreed to dismiss the Ladenburg Action with prejudice and extinguish any and all obligations of the Company in connection therewith. Any issuance of securities under the Ladenburg Agreement has been made or shall be made pursuant to exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering, and Rule 506 of Regulation D promulgated under the Securities Act.

The Company notes the consideration due to Ladenburg under the 2023 Ladenburg Agreement, excluding the warrants issuable thereunder, are contained within the 2021 and 2022 audited consolidated balance sheets within accrued expenses and other current liabilities.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Executive Officers

The following persons are serving as our executive officers and directors:

Name	Age	Position(s)
Samuel J. Reich	47	Class III Director and Executive Chairman of the Board
Christine Hamilton, MBA	67	Class III Director
Eddie J. Sullivan, PhD	57	Class III Director, President and Chief Executive Officer
Jeffrey G. Spragens	81	Class II Director
William Polvino, MD	62	Class I Director
David Link, MBA	67	Class II Director
Scott Giberson	53	Class I Director
Erick Lucera	55	Class I Director
Russell P. Beyer, MBA, CMA	68	Chief Financial Officer
Christoph Bausch, PhD	52	Chief Science Officer
Alexandra Kropotova, MD	50	Chief Medical Officer

Family Relationships

There are no family relationships among any of our directors or executive officers. Edward Hamilton, our former Executive Chairman, retired from such role as of the consummation of the Business Combination. Mr. Hamilton was named as a board observer in October 2021. Edward Hamilton is Christine Hamilton's husband.

Executive Officers

Samuel J. Reich has served as a member of our board of directors from November 2020 and was named executive chairman of our board of directors in October 2021. Mr. Reich served as our Chief Executive Officer and Chief Financial Officer from November2020 until October 2020 prior to the closing of our Business Combination. Mr. Reich co-founded Biscayne Neurotherapeutics, Inc. in 2011 and served as its Executive Chairman until its sale to Supernus Pharmaceuticals (Nasdaq: SUPN) in October 2018. Biscayne Neurotherapeutics was focused on novel treatments for seizure disorders. Previously, Mr. Reich was the Executive Vice President of OPKO Ophthalmologics, a division of OPKO Health, Inc. (Nasdaq: OPK) from March 2007 to November 2008, where Mr. Reich served on the executive committee and lead the Ophthalmologics business division. Prior to his position at OPKO, Mr. Reich was the Founder and Executive Vice President of Acuity Pharmaceuticals, Inc., where he worked from July 2002 through March 2007, at which time Acuity Pharmaceuticals merged with OPKO Health. Mr. Reich was a doctoral candidate in the Department of Ophthalmology at the University of Pennsylvania Medical School. He left graduate school prior to the completion of his Ph.D. to establish Acuity. Prior to that, he was a graduate student at the University of Pennsylvania in the Biomedical Studies graduate program. He has authored six peer- reviewed scientific publications and is currently an inventor on sixteen issued U.S. patents and over50 issued foreign patents. Mr. Reich holds a B.A. with High Honors in Biochemistry from Clark University, cum laude, Phi Beta Kappa.

Eddie J. Sullivan, PhD, is our co-founder and has served as our president and CEO since 2014. Dr. Sullivan has served in biopharma leadership positions for more than 25 years. Prior to joining us, he held the CEO role or other leadership roles in our predecessor entities, including CEO of Hematech, a subsidiary of Kyowa Hakko Kirin. During that time, he led initiatives to develop infectious disease, cancer, and autoimmune immunotherapies. In addition to raising over $250 million in capital to develop biopharmaceutical platform technologies, he has also led several successful mergers and acquisitions. A recognized thought leader in antibodies and transgenic animals, Dr. Sullivan serves on the board of directors for the Biotechnology Innovation Organization (BIO) and has served on its executive committee. He has worked with industry committees and discussion groups that have focused on animal biotechnology, regulatory framework, human immunotherapies, and global health threats. Dr. Sullivan was governor-appointed to South Dakota's Research Commercialization Council and is Chairman of the state's National Science Foundation-EPSCoR committee. He also founded, served as president, and remains an advisor to the state affiliate of BIO, South Dakota Biotech, and in 2014 was honored for his leadership, innovation, vision, and entrepreneurship with the inaugural LIVE award. He holds an undergraduate degree from the University of Arizona and graduate degrees from Brigham Young University, Kennedy-Western University, and Utah State University in both reproduction and business.

Russell P. Beyer, MBA, CMA, has served as our Chief Financial Officer since September 2021. Mr. Beyer is a global strategic business leader, bringing more than 20 years of experience working with Fortune 100 companies in the pharmaceutical industry, such as Teva, AstraZeneca, and IPR Pharmaceuticals. In addition to working in the pharmaceutical industry, Russell also served in strategic financial leadership roles for World Fuel Services and Hewlett-Packard. His professional background encompasses extensive experience in fostering a team-based approach to leading merger and post-merger integration activities, developing shared services operations, implementing global ERP platforms, and delivering strong profitability for the companies he served. He received his MBA from Simon School of Business at the University of Rochester, and his BA from St. Lawrence University.

Christoph Bausch, PhD, MBA, is our Chief Operating Officer as of May 2022, overseeing all Research & Manufacturing operations of the company. Prior to his role as COO, he served as Chief Science Officer since joining SAB in April 2017, providing leadership in all areas of Research & Development, and functioned as drug development lead for a Stage 3 clinically advanced drug product. Dr. Bausch is an experienced research scientist, biotech entrepreneur and business development executive who has led the successful discovery, development, biomanufacturing, and commercialization of platform technologies in the life sciences. Previously, Dr. Bausch has served as founder and director of a molecular diagnostic company and has provided life science consulting for Keion Group, LLC. Dr. Bausch held several science-based business development positions prior to joining SAB, most recently for multi-billion-dollar global industrial biomanufacturing leader POET, LLC, where he structured strategic partnerships, prospected, and vetted new technologies and streamlined research and development activities. He also worked in both research and commercialization roles for Fortune 500 life science and high technology company Sigma-Aldrich, now MilliporeSigma. Dr. Bausch received his PhD in Microbiology at The Ohio State University, Columbus, Ohio, completed Post-Doctoral Training at the Stowers Institute for Medical Research, Kansas City, Missouri and earned an MBA from St. Louis University, St. Louis, Missouri, in addition to a BA in Biology from the University of Nebraska-Lincoln, Lincoln, Nebraska.

Alexandra Kropotova, M.D., is our Executive Vice President & Chief Medical Officer, joining SAB in June, 2022 to lead the strategy, direction, and execution of the company's clinical development for the entire portfolio. Dr. Kropotova is a biopharmaceutical executive with expertise in all phases of global clinical development, translational medicine and medical affairs. Prior to joining SAB Biotherapeutics, as a Therapeutic Area Head of Global Specialty R&D at Teva Pharmaceuticals, Alexandra led innovative drug development focused on delivering a broad portfolio of immunology, respiratory, and immuno-oncology assets spanning from pre-IND to BLA/NDA filing of biologics and complex drug-device combination products. Prior to Teva, Dr. Kropotova served in various roles at Sanofi, including Vice President, Strategy & Strategic Planning Head, North American Medical Affairs; Associate Vice President and subsequently Vice President, Immuno-Inflammation, Global R&D Clinical Development; and Senior Medical Director, Respiratory, Allergy & Anti-Infectives. She also served in various roles at Pfizer Inc., most recently as Director & Head of Global Clinical Respiratory and Analgesics. She continues to serve on the Board of Directors at iBio, a global leader in plant-based biologics manufacturing and development of novel biopharmaceuticals. Dr. Kropotova received her MBA from Ohio University Graduate School of Business, Athens, Ohio; and her M.D. in Internal Medicine from the Vladivostok State Medical University, Vladivostok, Russia.

Non-Employee Directors

Biographical information for Eddie J. Sullivan, our President, Chief Executive Officer and Class III director, and Samuel J. Reich, our Executive Chairman of the Board and Class III director, is set forth above in "Item 10. Executive Officers".

Jeffrey G. Spragens has served as a member of our board of directors since November 2020. From 2005 through 2013, Mr. Spragens was a Co-Founder and the CEO of SafeStitch Medical, Inc., a medical device company that pioneered incisionless surgery techniques that helps to relieve GERD and obesity. In 2013, SafeStitch merged with TransEnterix, Inc. (NYSE: TRXC). In addition, Mr. Spragens was one of the three founding board members of North American Vaccine, which became a publicly traded company in 1990. At North American Vaccine, Mr. Spragens was responsible for securing initial financing and building a commercial manufacturing facility. Mr. Spragens was instrumental in North American Vaccine's acquisition by Baxter International (NYSE: BAX) in 1999. Mr. Spragens has also been a successful real estate developer and entrepreneur. Mr. Spragens was President of FCH services from 1973 until 1986. FCH developed and managed units of coop and condo housing financed with HUD financing with offices in several major cities. In 1986, Mr. Spragens converted to condo ownership 1,000 apartment units in San Mateo, California, resulting in one of the largest residential projects in California at that time. Mr. Spragens was Managing Partner of Gateway Associates, Inc. from 1990 to 2000. In addition, Mr. Spragens is President and 50% owner of Mint Management Company, a residential property management company he co-founded in 1987, which develops, owns and operates apartment units in New Jersey, Michigan and Kansas. Mr. Spragens developed and continues to own and operate Inman Grove Shopping Center in Edison, New Jersey. Mr. Spragens is also a well-known and respected philanthropist. Mr. Spragens is a Founding Board Member and Treasurer of Foundation for Peace. Foundation for Peace provides healthcare, education, and clean water to those in need in Dominican Republic and Haiti. He is also a member of the Board of Directors and Finance Committee of Hernia Help, which provides free hernia surgery to underserved children and adults in developing countries. Mr. Spragens has a BA from the University of Cincinnati, a Law Degree from George Washington University, and an MA from American University. Mr. Spragens is well qualified to serve on our board of directors because of his extensive public company management and multi-sector investment experience, and his public company board experience.

Christine Hamilton, MBA, is our co-founder and has served as a member of our board of directors since 2014. Ms. Hamilton is the owner and managing partner of Christiansen Land and Cattle, Ltd., a fourth-generation diversified farming and ranching enterprise. She also owns Dakota Packing, Inc., a wholesale company based in Las Vegas that provides high-end, "center-of-the-plate" protein products to a national customer base. Ms. Hamilton has served on the board of directors for several financial and public companies including HF Financial Corporation, Home Federal Bank (now Great Western Bancorp, NYSE: GWB) and, in 2018, was recognized for her exemplary service as a board member of the Federal Reserve Bank (Ninth District) after a four-year term. She currently serves as a board member for publicly traded Titan Machinery, Padlock Ranch, and Meadowlark Institute. Ms. Hamilton was a governor-appointed commissioner for South Dakota Game Fish & Parks and is a 2016 inductee to the South Dakota Hall of Fame for her contributions to the state and agribusiness. In 2000, Ms. Hamilton and her family formed the Matson Halverson Christiansen Hamilton Foundation (MHCH), a not-for-profit foundation with a mission to improve the quality of life and create opportunities for growth and enterprise development in South Dakota. Ms. Hamilton holds a philosophy degree from Smith College in Northampton, Massachusetts, and an MBA in entrepreneurship from the University of Arizona. Ms. Hamilton is well qualified to serve on our board of directors because of her extensive public company board experience.

Dr. William J. Polvino, MD, has served as a member of our board of directors since 2019, after having served as our business advisor for several years. Dr. Polvino is pharmaceutical entrepreneur with more than 25 years of experience in the healthcare arena. He is currently chief executive officer of Bridge Medicines, a pioneering drug discovery company focused on advancing promising early technologies from concept to clinic. Prior to Bridge Medicines, Dr. Polvino was president and chief executive officer of Veloxis Pharmaceuticals A/S (NASDAQ-OMX: VELO), a public biotechnology company that deployed proprietary formulation technology to develop and commercialize an innovative oral drug product for transplant patients. He also served as president and CEO of Helsinn Therapeutics (formerly Sapphire Therapeutics) and has held executive and senior-level positions in drug development at Merck, Wyeth and Theravance. Dr. Polvino earned his medical degree from Rutgers Medical School and a B.S. in Biology from Boston College. He trained in internal medicine at Massachusetts General Hospital and was a fellow in clinical pharmacology at the National Institutes of Health prior to entering the pharmaceutical and biotechnology industry. Dr. Polvino is well qualified to serve on our board of directors because of his extensive experience in the biotechnology industry and his extensive public company management experience.

David Link, MBA, has served as a member of our board of directors since 2018 and is currently Vice-Chairman. Mr. Link is the former executive vice president and chief strategy office at Sanford Health with more than three decades of experience in strategy, planning and financial operations. During his tenure, Mr. Link contributed significantly to growing the organization from a regional health system into one of the nation's largest non-profit, integrated health care delivery systems. He was also charged with overseeing Sanford Health Plan, Sanford Foundation and research and development, including Sanford Research. Under his leadership, the initial Sanford Clinic was created as well as the development of Sanford World Clinics, an initiative designed to provide communities around the world with permanent, sustainable health care infrastructure. Currently, Dave serves as an appointed program director in the President's Office at Dakota State University, one of the nation's leading programs in cyber security. Dave holds board or committee positions with Enterprise 605, the South Dakota REACH Committee, South Dakota Research and Commercialization Council and Sanford Research. In 2019, he was honored for his exemplary leadership and support of the state's bioscience industry with the LIVE Award at the South Dakota Biotech. Dave holds a bachelor's degree in data processing and computer science, an MBA from the University of South Dakota and a master's in healthcare administration from the University of Minnesota. Mr. Link is well qualified to serve on our board of directors because of his extensive experience in the biotechnology industry and his extensive public company board experience.

Scott Giberson, RPh, MPH, D.Sc., Rear Admiral (retired), joined the SAB board of directors in July 2022. He is currently the President of AMI Expeditionary Healthcare, a private global healthcare solutions company where he fosters global client relations at the highest levels. Clients include senior leadership of multiple U.S. and foreign government entities, the WHO, UN and private industry partners such as the Gates Foundation. RADM Giberson retired after 27 years as two-star admiral and as an Assistant U.S. Surgeon General. RADM (ret.) Giberson served as the acting Deputy Surgeon General of the United States (2013-2014), he was the Surgeon General's principal liaison with health leadership in multiple U.S. Departments. He also held executive positions as the Senior Advisor to the Office of Surgeon General, Director of Commissioned Corps Headquarters, Chief Pharmacist of the USPHS (2010-2014), Director of the IHS National HIV/AIDS Program and Senior Public Health Advisor for Pacific Command's Center of Excellence in Disaster Management and Humanitarian Assistance (2003-2006). He served as overall Commander of the Commissioned Corps' Ebola Response in West Africa. RADM Giberson has authored numerous articles and delivered well over 100 keynote lectures on leadership, global health, and public health at numerous venues both domestically and internationally. RADM Giberson has received many awards including the Presidential Unit Citation from President Obama in the Oval Office for leadership during the West African Ebola response. The Military Officers Association of America selected him as on the of the "Top 100 Veterans in the Last 100 Years You Need to Know". RADM Giberson is a graduate of Temple University and U. of Massachusetts/Amherst, holds a Pharmacy degree and licensure, MPH, and graduate certificate in Health Emergencies in Large Populations from the International Committee of the Red Cross. He has received three honorary Doctoral degrees (one for his pioneering work in interprofessional practice). He is also a Fellow of Wharton Business School (U. of Pennsylvania) Executive Leadership Program. Mr. Giberson is well qualified to serve on our board of directors because of his extensive experience in the medical industry.

Erick Lucera, joined the SAB board of directors in April 2023. From 2020 to February 2023, Mr. Lucera served as Chief Financial Officer of AVEO Oncology, a public biotech company, and subsequent to the close of its acquisition, worked on integration with LG Chem, Ltd. From 2016 to 2020, Mr. Lucera served as Chief Financial Officer, Treasurer and Secretary of VALERITAS, a publicly traded commercial-stage medical technology company where he led multiple successful public offerings. From 2017 to the present, Mr. Lucera has served as a member of the Board of Directors and Audit Committee Chairman of Beyond Air, a publicly held commercial-stage medical device and biopharmaceutical company developing a platform of nitric oxide generators and delivery systems. From 2021 to the present, Mr. Lucera has served as a member of the Board of Directors and Audit Committee Chairman of Bone Biologics Corporation, a publicly held company focusing on regenerative medicine therapies to treat bone disorders. From 2015 to 2016, Mr. Lucera served as Chief Financial Officer, Treasurer and Secretary of VIVENTIA Bio, acquired by Eleven Biotherapeutics, Inc., now Sesen Bio, a biotechnology company focused on developing targeted protein therapeutics for the treatment of cancer. Early in his career, Mr. Lucera spent more than 15 years covering healthcare and the life sciences in investment management. Given Mr. Lucera’s extensive experience in strategic planning and finance, we believe that Mr. Lucera is well qualified to serve as a member of the Board of Directors.

Director Independence

The listing rules of Nasdaq require us to maintain a board of directors comprised of a majority of independent directors, as determined affirmatively by our board of directors. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of our audit, compensation and nominating and corporate governance committees must be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the Nasdaq listing rules, a director will only qualify as an “independent director” if, in the opinion of our board of directors, the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out his or her responsibilities.

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of Christine Hamilton, Jeffrey Spragens, William Polvino, David Link, Scott Giberson. and Erick Lucera (representing six of our eight directors), has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that they each are an “independent director” as that term is defined under the Nasdaq listing rules.

In making these determinations, our board of directors considered the relationships that each nonemployee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including consulting relationships, family relationships and the beneficial ownership of our capital stock by each non-employee director.

Board Composition

Our business and affairs are organized under the direction of our board of directors. Our board currently consists of eight (8) directors divided into three classes as follows:

- each Class I director having a term that expires immediately following our first annual meeting of stockholders following the closing of the Business Combination, which shall be the annual meeting of stockholder for the calendar year ended December 31, 2025;
- each Class II director having a term that expires immediately following our annual meeting of stockholders for the calendar year ended December 31, 2023; and
- each Class III director having a term that expires immediately following our annual meeting of stockholders for the calendar year ended December 31, 2024

or, in each case, until their respective successor is duly elected and qualified, or until their earlier resignation, removal or death.

Messrs. Dr. Polvino, Mr. Lucera and Mr. Giberson currently serve as the Class I directors, Messrs. Link and Spragens currently serve as the Class II directors, and Mrs. Hamilton and Messrs. Reich and Sullivan currently serve as Class III directors.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of the board of directors will be fixed exclusively by resolutions of the board of directors. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in its control or management. Our board of directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of its voting stock.

Board Meetings

During 2022, our board of directors held 6 meetings, and each director attended at least 75% of the aggregate of (i) the total number of meetings of our board of directors held during the period for which he or she has been a director and (ii) the total number of meetings held by all committees of our board of directors on which he or she served during the periods that he or she served.

Committees of the Board of Directors

Our board of directors has three standing committees: an audit committee, a nominating and corporate governance committee ("nominating committee") and a compensation committee. Subject to phase-in rules and a limited exception, Nasdaq rules and Rule 10A-3 of the Exchange Act require that the audit committee of a listed company be comprised solely of independent directors, and Nasdaq rules require that the compensation committee and nominating committee of a listed company be comprised solely of independent directors. Each of our committees is comprised entirely of independent directors.

Audit Committee

On October 22, 2021, we established an audit committee of the board of directors. Jeffrey Spragens, William Polvino, David Link, and Erick Lucera serve as members of the audit committee, with Jeffrey Spragens serving as the Chairman of the audit committee. Under the Nasdaq listing standards and applicable SEC rules, we are required to have at least three members of the audit committee, all of whom must be independent. Each of Dr. Polvino and Messrs. Spragens and Link meet the independent director standard under Nasdaq listing standards and under Rule 10A-3(b)(1) of the Exchange Act.

Each member of the audit committee is financially literate, and our board of directors has determined that Mr. Spragens qualifies as an "audit committee financial expert" as defined in applicable SEC rules.

We adopted a restated audit committee charter on October 22, 2021 which details the principal functions of the audit committee, including:

- the appointment, compensation, retention, replacement, and oversight of the work of the independent registered public accounting firm engaged by us;
- pre-approving all audit and permitted non-audit services to be provided by the independent registered public accounting firm engaged by us, and establishing pre-approval policies and procedures;
- setting clear hiring policies for employees or former employees of the independent registered public accounting firm, including but not limited to, as required by applicable laws and regulations;
- setting clear policies for audit partner rotation in compliance with applicable laws and regulations;
- obtaining and reviewing a report, at least annually, from the independent registered public accounting firm describing (i) the independent registered public accounting firm's internal quality-control procedures, (ii) any material issues raised by the most recent internal quality-control review, or peer review, of the audit firm, or by any inquiry or investigation by governmental or professional authorities within the preceding five years respecting one or more independent audits carried out by the firm and any steps taken to deal with such issues and (iii)all relationships between the independent registered public accounting firm and us to assess the independent registered public accounting firm's independence;
- reviewing and approving any related party transaction required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC prior to us entering into such transaction; and
- reviewing with management, the independent registered public accounting firm, and our legal advisors, as appropriate, any legal, regulatory or compliance matters, including any correspondence with regulators or government agencies and any employee complaints or published reports that raise material issues regarding our financial statements or accounting policies and any significant changes in accounting standards or rules promulgated by the FASB, the SEC or other regulatory authorities.

The audit committee charter is available on the corporate governance section of our website, which is located at https://ir.sab.bio/static-files/a6bd0fd3-9f6f-4927-9a79-806338ec0ee9

Compensation Committee

On October 22, 2021, we established a compensation committee of the board of directors. Christine Hamilton, Scott Giberson and William Polvino serve as members of the compensation committee. Christine Hamilton serves as the Chairman of the compensation committee. Under the Nasdaq listing standards and applicable SEC rules, we are required to have at least two members of the compensation committee, all of whom must be independent. Each of Dr. Polvino and Ms. Hamilton are independent.

We adopted a restated compensation committee charter on October 22, 2021, which details the principal functions of the compensation committee, including:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, if any is paid by us, evaluating our Chief Executive Officer's performance considering such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;
- reviewing and approving on an annual basis the compensation, if any is paid by us, of all our other officers;
- reviewing on an annual basis our executive compensation policies and plans;
- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and Form 10-K disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our officers and employees;
- if required, producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing, evaluating, and recommending changes, if appropriate, to the remuneration for directors.

Notwithstanding the foregoing, other than as indicated in this Annual Report, no compensation of any kind, including finders, consulting, or other similar fees, will be paid to any of our existing stockholders, officers, directors, or any of their respective affiliates, prior to, or for any services they render to effectuate the offering.

The charter also provides that the compensation committee may, in its sole discretion, retain or obtain the advice of a compensation consultant, legal counsel or other adviser and will be directly responsible for the appointment, compensation and oversight of the work of any such adviser. However, before engaging or receiving advice from a compensation consultant, external legal counsel or any other adviser, the compensation committee will consider the independence of each such adviser, including the factors required by Nasdaq and the SEC.

Compensation Committee Interlocks and Insider Participation

No person who served as a member of the compensation committee during the fiscal year ended December 31, 2022 was a current or former officer or employee of the Company or engaged in certain transactions with the Company required to be disclosed by regulations of the SEC. Additionally, there were no compensation committee "interlocks" during the fiscal year ended December 31, 2022, which generally means that no executive officer of the Company served as a director or member of the compensation committee of another entity, one of whose executive officers served as a director or member of the compensation committee of the Company.

The compensation committee charter is available on the corporate governance section of our website, which is located at https://ir.sab.bio/static-files/3f29e14f-e5da-45b5-9844-20a98ba5f4cd

Nominating Committee

On October 22, 2021, we established a nominating committee of the board of directors. David Link, Christine Hamilton, Scott Giberson and Jeff Spragens serve as members of the Nominating and Governance Committee. David Link serves as the Chairman of the Nominating and Governance Committee. Under the Nasdaq listing standards and applicable SEC rules, we are required to have at least two members of the nominating committee, all of whom must be independent. Each of Ms. Hamilton, Mr. Link and Mr. Spragens are independent.

We adopted a restated nominating committee charter on October 22, 2021, which details the purpose and responsibilities of the nominating committee, including:

- screening and reviewing individuals qualified to serve as directors, consistent with criteria approved by the board, and recommending to the board of directors' candidates for nomination for election at the annual meeting of stockholders or to fill vacancies on the board of directors;
- developing and recommending to the board of directors and overseeing implementation of our corporate governance guidelines; and
- reviewing on a regular basis our overall corporate governance and recommending improvements as and when necessary.

The nominating committee will consider several qualifications relating to management and leadership experience, diversity, background and integrity and professionalism in evaluating a person's candidacy for membership on the board of directors. The nominating committee may require certain skills or attributes, such as financial or accounting experience, to meet specific board needs that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of board members. The nominating committee does not distinguish among nominees recommended by stockholders and other persons.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the board of directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

The nominating committee charter is available on the corporate governance section of our website, which is located at https://ir.sab.bio/static-files/3f29e14f-e5da-45b5-9844-20a98ba5f4cd

Director Nominations

The process of recommending director nominees for selection by the board of directors is undertaken by the nominating committee (see above).

The board of directors will also consider director candidates recommended for nomination by our stockholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of stockholders (or, if applicable, a special meeting of stockholders). Our stockholders that wish to nominate a director for election to our board of directors should follow the procedures set forth in our bylaws.

Board Diversity

Effective corporate governance is critical for both our long-term performance and maintaining stockholder trust. Our board of directors is responsible for overseeing the governance, strategy and operation of the Company. Our eight directors come from diverse backgrounds, drawing on their substantial experience across industries and professional designations, including experience related to: biotechnology and pharmaceutical; finance, including investment management and capital markets; healthcare and medical services and operations; philanthropy; public accounting; and higher education.

Board Leadership Structure

Our board of directors is currently chaired by Samuel Reich. Our board of directors believes that we and our stockholders are currently best served by this leadership structure. As Executive Chairman, Mr. Reich promotes unified leadership and direction for our board of directors and management and provides the critical leadership necessary for carrying out our strategic initiatives. Mr. Reich, together with our board of director's strong committee system and independent directors, allows our board of directors to maintain effective oversight of our business operations, including independent oversight of our financial statements, executive compensation, selection of director candidates, and corporate governance programs. We believe our current board of director's leadership structure enhances its ability to effectively carry out its roles and responsibilities on behalf of our stockholders.

Role of Board in Risk Oversight Process

Our board of directors has an active role, as a whole and also at the committee level, in overseeing risk management. Our board of directors is responsible for general oversight and regular review of risk management, including financial, strategic, and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and whether our compensation policies and programs have the potential to encourage excessive risk taking. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating committee is responsible for overseeing our corporate governance practices and the management of risks associated with board of director independence and potential conflicts of interest. Although each committee is responsible for evaluating and overseeing the management of certain risks, the entire board of directors is regularly informed through discussions from committee

members about such risks. The board of directors believes its leadership structure is consistent with and supports the administration of its risk oversight function.

Section 16 Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires certain of our officers and our directors, and persons who own more than 10 percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors, and greater than 10 percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of copies of such forms received by us, we believe that during the year ended December 31, 2022, all filing requirements applicable to all of our officers, directors, and greater than 10% beneficial stockholders were timely complied with.

Code of Ethics

We adopted a restated Code of Conduct and Ethics (the "Code of Ethics") applicable to our directors, officers, and employees. A copy of our Code of Ethics is available on our website at https://ir.sab.bio/static-files/cf6414d7-b1d5-40d6-83f9-f7598094d99.

In addition, a copy of the Code of Ethics will be provided without charge by making a written request and mailing it to our corporate headquarters offices to the attention of the Investor Relations Department.

We intend to disclose any amendments to or waivers of certain provisions of our Code of Ethics in a Current Report on Form 8-K. Please see "*Where You Can Find Additional Information*" for additional information.

Item 11. Executive Compensation.

The following is a discussion and analysis of compensation arrangements of the Company's named executive officers. This discussion may contain forward-looking statements that are based on the Company's current plans, considerations, expectations and determinations regarding future compensation programs. The actual compensation programs that the Company adopts may differ materially from the currently planned programs that are summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Summary Executive Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by or paid to Our named executive officers for the fiscal years ended December 31, 2022 and 2021.

Name and Principal Position	Year	Salary ($)	Option Awards (1) ($)	Stock Awards (2) ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Eddie J. Sullivan, PhD.	2022	377,200	44,725 (3)	—	42,435	10,982	475,342
President and Chief Executive Officer	2021	376,154	—	—	140,000	9,750	525,904
Samuel J. Reich	2022	350,000	304,600 (4)	—	14,000	12,200	680,800
Executive Chairman of the Board of Directors	2021	52,731	2,741,235	—	—	1,660	2,795,626
Alexandra Kropotova, MD	2022	282,692	13,029	567,000 (5)	—	2,423	865,144
EVP, Chief of Medical Officer	2021	—	—	—	—	—	—

(1) Represents the aggregate grant date fair value of stock option awards granted in the respective fiscal year as computed in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation*. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option valuation model. A discussion of the assumptions used in calculating the amounts in this column may be found in the Notes to our audited consolidated financial statements for the year ended December 31, 2022 set forth in this Annual Report. These amounts do not represent the actual amounts paid to or realized by the executives during the fiscal years presented.

(2) Represents the aggregate grant date fair value of restricted stock units granted in the respective fiscal year as computed in accordance with FASB ASC Topic 718, Compensation — Stock Compensation. Restricted stock units are valued at market price of the Company's common stock at the closing price at the date of grant. These amounts do not represent the actual amounts paid to or realized by the executives during the fiscal years presented.

(3) We granted Eddie Sullivan a stock option to purchase up to 21,218 shares of our common stock at an exercise price of $1.78 per share, the closing price of our common stock on March 16, 2022. The shares subject to this stock option award will vest 100% of the shares on the one-year anniversary of the grant date and We granted Eddie Sullivan a stock option to purchase up to 35,000 shares of our common stock at an exercise price of $0.71 per share, the closing price of our common stock on September 13, 2022. The shares subject to this stock option will vest as to 25% of the shares one-year anniversary of the grant date, and vest as to the remainder of the shares in 36 equal monthly installments thereafter.

(4) We granted Samuel J. Reich a stock option to purchase up to 7,000 shares of our common stock at an exercise price of $1.78 per share, the closing price of our common stock on March 16, 2022. The shares subject to this stock option award will vest 100% of the shares on the one-year anniversary of the grant date and We granted Samuel J. Reich a stock option to purchase up to 525,000 shares of our common stock at an exercise price of $0.71 per share, the closing price of our common stock on September 13, 2022. The shares subject to this stock option will vest as to 25% of the shares one-year anniversary of the grant date, and vest as to the remainder of the shares in 36 equal monthly installments thereafter.

(5) We granted Alexandra Kropotova 300,000 restricted shares of our common stock under our 2021 Equity Incentive Plan. The shares subject to this stock award will vest as to 25% of the RSU's on the one-year anniversary of the grant date, and the remainder of the RSU's in 36 equal monthly installments thereafter.

Outstanding Equity Awards at Fiscal 2022 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2022.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#) Exercisable	Market Value of Shares or Units of Stock That Have Not Vested ($)
Eddie J. Sullivan, PhD.	139,585	—	0.54	8/4/2024	—	—
	162,850	—	0.54	12/11/2024	—	—
	162,850	—	0.54	12/11/2024	—	—
	23,264	—	2.69	4/26/2030	—	—
	—	21,218 (1)	1.78	3/16/2032	—	—
	—	35,000 (2)	0.71	9/13/2032	—	—
Samuel J. Reich	136,110	213,890 (3)	11.17	11/16/2031	—	—
	—	7,000 (4)	1.78	3/16/2032	—	—
	—	525,000 (5)	0.71	9/13/2032	—	—
Alexandra Kropotova, MD	—	18,325 (6)	0.71	9/13/2032	—	—
	—	—	—	—	300,000 (7)	177,000

(1) The shares subject to this stock option award will vest 100% of the shares on the one-year anniversary of the grant date.

(2) The shares subject to this stock option award will vest as to 25% of the shares on one-year anniversary of the grant date, and vest as to the remainder of the shares in 36 equal monthly installments thereafter.

(3) The shares subject to this stock option award will vest in 22 equal monthly installments.

(4) The shares subject to this stock option award will vest 100% of the shares on the one-year anniversary of the grant date.

(5) The shares subject to this stock option award will vest as to 25% of the shares on one-year anniversary of the grant date, and vest as to the remainder of the shares in 36 equal monthly installments thereafter.

(6) The shares subject to this stock option award will vest as to 25% of the shares on one-year anniversary of the grant date, and vest as to the remainder of the shares in 36 equal monthly installments thereafter.

(7) The shares subject to this stock award will vest as to 25% of the RSU's on the one-year anniversary of the grant date, and the remainder of the RSU's in 36 equal monthly installments thereafter.

Named Executive Officer Employment Arrangements

Below are descriptions of the current employment agreements with our named executive officers.

Eddie J. Sullivan

On March 1, 2021, we entered into an Executive Employment Agreement with Dr. Sullivan to continue to serve as our President & Chief Executive Officer. The agreement provides Dr. Sullivan an annual base salary of $377,200, and his eligibility to participate in the Company's benefit plans generally. The agreement also subjects Dr. Sullivan to standard nondisclosure, invention assignment, and arbitration provisions. If Dr. Sullivan's employment is terminated by the Company without Cause (as defined in the employment agreement) (other than for death or disability) or the term of his employment is not renewed, Dr. Sullivan will receive (i) a severance payment equal to 1 year of his then base salary, payable either in a lump sum or in accordance with the Company's then-current payroll practices and (ii) the applicable bonus amounts prorated for the portion of the calendar year Dr. Sullivan was employed so long as he was employed by the Company as of April 1st of the year of termination and the board of directors has approved a bonus plan for that year (such bonus amount payable by the end of the Company's fiscal year following the termination).

Samuel J. Reich

On November 17, 2021, we entered into an Executive Employment Agreement with Mr. Reich to serve as our Executive Chairman of the Board of Directors. The agreement provides Mr. Reich an annual base salary of $350,000, and his eligibility to participate in the Company's benefit plans generally. The agreement also subjects Mr. Reich to standard nondisclosure, invention assignment, and arbitration provisions. If Mr. Reich's employment is terminated by the Company without Cause (as defined in the employment agreement) (other than for death or disability) or the term of his employment is not renewed, Mr. Reich will receive (i) a severance payment equal to 1 year of his then base salary, payable in a lump sum five business days after his release becomes final, (ii) the applicable accrued but unpaid annual bonus, if any, for the fiscal year ended prior to his date of termination, payable at the same time annual bonuses for such fiscal year are paid to other key executives of the Company, (iii) one hundred percent of his outstanding unvested equity awards as of the date of termination will be fully vested and exercisable, and (iv) reimbursement of the COBRA premiums, if any, for continuation coverage for Mr. Reich, his spouse and dependents under the Company's group health, dental and vision plans for a twelve month period from the date of termination.

Alexandra Kropotova

On May 20, 2022, we entered into an Executive Employment Agreement with Dr. Kropotova to serve as our Executive Vice President – Chief Medical Officer. The agreement provides Dr. Kropotova an annual base salary of $525,000, and her eligibility to participate in the Company's benefit plans generally. The agreement also subjects Dr. Kropotova to standard nondisclosure, invention assignment, and arbitration provisions. If Dr. Kropotova's employment is terminated by the Company without Cause (as defined in the employment agreement) (other than for death or disability) or the term of her employment is not renewed, Dr. Kropotova will receive (i) the applicable accrued but unpaid Annual Bonus, if any, for the calendar year ended prior to her Date of Termination payable at the same time annual bonuses for such calendar year are paid to other key Employees of the Company pursuant to the terms of the Bonus Plan (ii) one hundred percent (100%) of the Employee's outstanding unvested Equity Awards as of the Date of Termination will be fully vested and exercisable (iii) a severance payment payable in a single lump sum within five (5) business days after the Employee's Release becomes final, binding and irrevocable in accordance with Section 10 of the Employment Agreement, in an amount equal to twelve (12) months of Base Salary (iv) Reimbursement of the COBRA premiums, if any, paid by the Employee for continuation coverage for the Employee, her spouse and dependents under the Company's group health, dental and vision plans for six (6) month period from the Date of Termination.

Summary Director Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by or paid to our directors for the fiscal year ended December 31, 2022.

Name	Fees Earned or Paid in Cash ($)	Option Awards (1) ($)	Stock Awards (2) ($)	Total ($)
Samuel J. Reich	—	304,600	—	304,600
Christine Hamilton, MBA	25,000	—	—	25,000
Eddie J. Sullivan, PhD	—	44,725	—	44,725
Jeffrey G. Spragens	23,408	—	—	23,408
William Polvino, MD	25,000	—	—	25,000
David Link, MBA	25,000	—	—	25,000
Scott Giberson	5,928	14,000	—	19,928
Erick Lucera	—	—	—	—

(1) Represents the aggregate grant date fair value of stock option awards granted in the respective fiscal year as computed in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation*. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option valuation model. A discussion of the assumptions used in calculating the amounts in this column may be found in the Notes to our audited consolidated financial statements for the year ended December 31, 2022 set forth in this Annual Report. These amounts do not represent the actual amounts paid to or realized by the executives during the fiscal years presented.

(2) Represents the aggregate grant date fair value of restricted stock units granted in the respective fiscal year as computed in accordance with FASB ASC Topic 718, Compensation — Stock Compensation. Restricted stock units are valued at market price of the Company's common stock at the closing price at the date of grant. These amounts do not represent the actual amounts paid to or realized by the executives during the fiscal years presented.

SAB Biotherapeutics, Inc. 2021 Omnibus Equity Incentive Plan

The SAB Biotherapeutics, Inc. 2021 Omnibus Equity Incentive Plan (the "Incentive Plan") was adopted in connection with, and become effective at the closing of, the Business Combination.

Summary of the Incentive Plan

General

The Incentive Plan covers the grant of awards to our employees (including officers), non-employee consultants and non-employee directors and those of our affiliates. For purposes of the Incentive Plan, our affiliates include any corporation, partnership, limited liability company, joint venture or other entity, with respect to which we, directly or indirectly, own either (i) stock possessing more than fifty percent (50%) of the total combined voting power of all classes of stock entitled to vote, or more than fifty percent (50%) of the total value of all shares of all classes of stock of such corporation, or (ii) an aggregate of more than fifty percent (50%) of the profits interest or capital interest of any non-corporate entity.

The compensation committee administers the Incentive Plan. The full Board must approve all decisions regarding awards to non-employee directors.

Up to a maximum of 11,000,000 shares of our common stock may be delivered in settlement of awards granted under the Incentive Plan initially. The number of shares authorized for issuance will increase each fiscal year, beginning this fiscal year 2022 and occurring each year thereafter through 2031, by 2.0% of the number of our shares of common stock issued and outstanding on a fully-diluted basis as of the last day of the preceding fiscal year (such lesser number of shares as determined by our board of directors in its sole discretion). In no event, however, shall the aggregate number of shares that may be issued pursuant to this annual increase under the Incentive Plan exceed 5,000,000.

Up to a maximum of 11,000,000 shares of our common stock may be issued under the Incentive Plan pursuant to the exercise of incentive stock options. The stock delivered to settle awards made under the Incentive Plan may be authorized and unissued shares or treasury shares, including shares repurchased by us for purposes of the Incentive Plan. If any shares subject to any award granted under the Incentive Plan (other than a substitute award as described below) is forfeited or otherwise terminated without delivery of such shares (if such shares are returned to us due to a forfeiture restriction under such award), the shares subject to such awards will again be available for issuance under the Incentive Plan. However, any shares that are withheld or applied as payment for shares issued upon exercise of an award or for the withholding or payment of taxes due upon exercise of an award will continue to be treated as having been delivered under the Incentive Plan and will not again be available for grant under the Incentive Plan. Upon settlement of any stock appreciation rights ("SARs"), the number of shares underlying the portion of the SARs that is exercised will be treated as having been delivered for purposes of determining the maximum number of shares available for grant under the Incentive Plan and shall not again be treated as available for issuance under the Incentive Plan.

If a dividend or other distribution (whether in cash, shares of common stock or other property), recapitalization, forward or reverse stock split, subdivision, consolidation or reduction of capital, reorganization, merger, consolidation, scheme of arrangement, split-up, spin-off or combination involving us or repurchase or exchange of our shares or other securities, or other rights to purchase shares of our securities or other similar transaction or event affects our common stock such that the compensation committee determines that an adjustment is appropriate in order to prevent dilution or enlargement of the benefits (potential benefits) provided to grantees under the Incentive Plan, the compensation committee will make an equitable change or adjustment as it deems appropriate to the number of type of securities with respect to which awards may be granted, (ii) the number and type of securities subject to outstanding awards, (iii) the exercise price with respect to any option or SAR or, if deemed appropriate, make provision for a cash payment to the holder of such outstanding award, and (iv) the number and kind of outstanding restricted shares, or the shares underlying any other form of award.

Types of Awards

The Incentive Plan permits the granting of any or all of the following types of awards to all grantees:

- stock options, including incentive stock options, or ISOs;
- SARs;
- restricted shares;
- deferred stock;
- restricted stock units;
- performance units and performance shares;
- dividend equivalents;
- bonus shares; and
- other stock-based awards.

Generally, awards under the Incentive Plan are granted for no consideration other than prior and future services. Awards granted under the Incentive Plan may, in the discretion of the committee, be granted alone or in addition to, in tandem with or in substitution for, any other award under the Incentive Plan; provided, however, that if an SAR is granted in tandem with an ISO, the SAR and ISO must have the same grant date and term and the exercise price of the SAR may not be less than the exercise price of the ISO. The material terms of each award will be set forth in a written award agreement between the grantee and us.

Stock Options and SARs

The committee is authorized to grant SARs and stock options (including incentive stock options (ISOs) except that an ISO may only be granted to an employee of ours or one of our subsidiary corporations). A stock option allows a grantee to purchase a specified number of shares of our common stock at a predetermined price per share (the "exercise price") during a fixed period measured from the date of grant. An SAR entitles the grantee to receive the excess of the fair market value of a specified number of shares on the date of exercise over a predetermined exercise price per share. The exercise price of an option or an SAR will be determined by the committee and set forth in the applicable award agreement but the exercise price may not be less than the fair market value of a share of common stock on the grant date. The term of each option or SAR is determined by the committee and set forth in the applicable award agreement, except that the term may not exceed ten (10) years (five (5) years if the grantee holds more than 10% of the total combined voting power of all classes of our capital
stock).

Options may be exercised by payment of the purchase price through one or more of the following means: payment in cash (including personal check or wire transfer); delivering shares of our common stock previously owned by the grantee; or, with the approval of the compensation committee, (i) delivery of shares of our common stock acquired upon the exercise of such options, or (ii) the sale of shares acquired upon exercise of the options through a broker-dealer to whom the grantee has delivered irrevocable notice of exercise and instructions to deliver sales proceeds sufficient to pay us the exercise price.

Following shareholder approval of the Incentive Plan on October 20, 2021, ISOs may be granted pursuant to the terms of the Incentive Plan.

Restricted Shares

The committee may award restricted shares consisting of shares of our common stock which remain subject to a risk of forfeiture and may not be disposed of by grantees until certain restrictions established by the committee lapse. The vesting conditions may be service-based (i.e., requiring continuous service for a specified period) or performance-based (i.e., requiring achievement of certain specified performance objectives) or both. A grantee receiving restricted shares will have all of the rights of a stockholder, including the right to vote the shares and the right to receive any dividends, except as otherwise provided in the applicable award agreement. Upon termination of the grantee's affiliation with us during the restriction period (or, if applicable, upon the failure to satisfy the specified performance objectives during the restriction period), the restricted shares will be forfeited as provided in the applicable award agreement.

Deferred Stock and Restricted Stock Units

The committee may also grant deferred stock awards and/or restricted stock unit awards. A deferred stock award is the grant of a right to receive a specified number of shares of our common stock at the end of specified deferral periods or upon the occurrence of a specified event, which satisfies the requirements of Section 409A of the Internal Revenue Code. A restricted stock unit award is the grant of a right to receive a specified number of shares of our common stock upon lapse of a specified forfeiture condition (such as completion of a specified period of service or achievement of certain specified performance objectives). If the service condition and/or specified performance objectives are not satisfied during the restriction period, the award will lapse without the issuance of the shares underlying such award.

Restricted stock units and deferred stock awards carry no voting or other rights associated with stock ownership until the shares underlying the award are delivered in settlement of the award. Unless otherwise determined by the compensation committee, grantees will have the rights to receive dividend equivalents in respect of deferred stock and/or restricted stock units, which dividend equivalents shall be deemed reinvested in additional shares of deferred stock or restricted stock units, as applicable, which shall remain subject to the same forfeiture conditions applicable to the deferred stock or restricted stock units to which such dividend equivalents relate.

Performance Units

The committee may grant performance units, which entitle a grantee to cash or shares conditioned upon the fulfillment of certain performance conditions and other restrictions as specified by the committee and reflected in the applicable award agreement. The initial value of a performance unit will be determined by the committee at the time of grant. The committee will determine the terms and conditions of such awards, including performance and other restrictions placed on these awards, which will be reflected in the applicable award agreement.

Performance Shares

The committee may grant performance shares, which entitle a grantee to a certain number of shares of common stock, conditioned upon the fulfillment of certain performance conditions and other restrictions as specified by the committee and reflected in the applicable award agreement. The committee will determine the terms and conditions of such awards, including performance and other restrictions placed on these awards, which will be reflected in the applicable award agreement.

Bonus Shares

The committee may grant fully vested shares of our common stock as bonus shares on such terms and conditions as specified in the applicable award agreement.

Dividend Equivalents

The committee is authorized to grant dividend equivalents, which provide a grantee the right to receive payment equal to the dividends paid on a specified number of shares of our common stock. Dividend equivalents may be paid directly to grantees or may be deferred for later delivery under the Incentive Plan. If deferred, such dividend equivalents may be credited with interest or may be deemed to be invested in shares of our common stock, other awards under the Incentive Plan or in other property.

Other Stock-Based Awards

The Incentive Plan authorizes the committee to grant awards that are valued in whole or in part by reference to or otherwise based on certain other securities. The committee determines the terms and conditions of such awards, including whether awards are paid in shares or cash.

Business Combination, Consolidation or Similar Corporate Transaction

If there is a merger or consolidation of us with or into another corporation or a sale of substantially all of our stock (a “Corporate Transaction”), and the outstanding awards are not assumed by surviving company (its parent company) or replaced with equivalent awards granted by the surviving company(its parent company),the committee will cancel any outstanding awards that are not vested and nonforfeitable as of the consummation of such Corporate Transaction (unless the committee accelerates the vesting of any such awards) and with respect to any vested and nonforfeitable awards, the committee may either (i) allow all grantees to exercise options and SARs within a reasonable period prior to the consummation of the Corporate Transaction and cancel any outstanding options or SARs that remain unexercised upon consummation of the Corporate Transaction, or (ii) cancel any or all of such outstanding awards (including options and SARs) in exchange for a payment (in cash, or in securities or other property) in an amount equal to the amount that the grantee would have received (net of the exercise price with respect to any options or SARs) if the vested awards were settled or distributed or such vested options and SARs were exercised immediately prior to the consummation of the Corporate Transaction. If an exercise price of an option or SAR exceeds the fair market value of our common stock and the option or SAR is not assumed or replaced by the surviving company (its parent company),such options and SARs will be cancelled without any payment to the grantee.

Amendment to and Termination of the Incentive Plan

The Incentive Plan may be amended, altered, suspended, discontinued or terminated by our board of directors without further stockholder approval, unless such approval is required by law or regulation or under the rules of any stock exchange or automated quotation system on which our common stock is then listed or quoted. Thus, stockholder approval will not necessarily be required for amendments which might increase the cost of the Incentive Plan or broaden eligibility. Stockholder approval will not be deemed to be required under laws or regulations that condition favorable treatment of grantees on such approval, although our board of directors may, in its discretion, seek stockholder approval in any circumstance in which it deems such approval advisable.

In addition, subject to the terms of the Incentive Plan, no amendment or termination of the Incentive Plan may materially and adversely affect the right of a grantee under any award granted under the Incentive Plan.

Unless earlier terminated by our board of directors, the Incentive Plan will terminate when no shares remain reserved and available for issuance or, if earlier, on the tenth anniversary of the effective date of the Incentive Plan.

SAB Biotherapeutics, Inc. 2021 Employee Stock Purchase Plan

The SAB Biotherapeutics, Inc. 2021 Employee Stock Purchase Plan, (the "ESPP") was adopted in connection with, and became effective at the closing of, the Business Combination. The ESPP provides eligible employees an opportunity to purchase shares of common stock at a discount through accumulated contributions of their earned compensation. The ESPP's initial share reserve is one million shares of SAB Biotherapeutics common stock. Offering periods will not commence under the ESPP until determined by the board of directors or compensation committee.

Summary of the Employee Stock Purchase Plan

Administration

The ESPP will be administered by the board of directors, or a committee appointed by the board of directors, which may be the compensation committee. The board of directors or committee administering the ESPP (the "Administrator") has authority to construe and interpret the ESPP and to establish rules and regulations for the administration of the ESPP.

Eligibility

Eligible employees of the Company or a participating subsidiary may participate in the ESPP. One is an eligible employee for an accumulation period if he or she is an employee of the Company or a participating subsidiary both on the date determined by the ESPP administrator that enrollment forms must be received for an accumulation period and on the first day of the accumulation period. Notwithstanding the preceding sentences, an employee is not eligible to participate in the ESPP if on the first day of the accumulation period (1) such employee is a member of a collective bargaining unit whose benefits were the subject of good faith bargaining; (2) such employee is customarily employed 20 or less hours per week or five months or less per year; or (3) such employee is an employee of a participating subsidiary who is a resident of a foreign jurisdiction and

(i) participation is prohibited under the laws of such foreign jurisdiction or (ii) compliance with the laws of such foreign jurisdiction would violate Section 423 of the Code. An employee is also not eligible to participate if immediately after any purchase of shares under the ESPP, the employee would own capital stock of the Company and/or hold outstanding options to purchase such stock constituting five percent (5%) or more of the total combined voting power or value of all classes of the capital stock of the Company or of any subsidiary of the Company.

As of December 31, 2022, the Company had approximately 53 employees that would be eligible to participate in the ESPP.

Shares Available for Issuance

As noted above, the maximum aggregate number of shares of Company stock that may be issued under the ESPP is one million shares.

Enrollment Dates, Accumulation Periods and Purchase Dates

The accumulation periods under the ESPP will generally be a specified one-year period, or such other period, not to exceed twenty-seven (27) months, as determined by the Administrator. The first trading day of each accumulation period is the enrollment date, which is the date as of which eligible employees are granted contractual rights to purchase shares of Company stock under the ESPP. Payroll deductions may be made during the accumulation period by eligible employee selecting to participate as described below. The last trading day of each accumulation period will be the Company stock purchase date (unless the Administrator selects a different date) and on such date any contractual rights remaining outstanding will be deemed to be exercised and shares of Company stock will be purchased, as described below.

Participation in the ESPP

An eligible employee may become a participant in the ESPP by submitting an enrollment form, and payroll deductions for such employee will begin as soon as administratively feasible after such form is received in good order, subject to compliance with such policies, rules and procedures as we may establish in connection therewith.

As of each purchase date (which is the last trading day of an accumulation period as stated above), an employee's payroll deductions made during the accumulation period and not withdrawn by the employee or otherwise paid to the employee are used to buy shares of Company stock. The per share purchase price on the purchase date is 85% of the lower of (1) the fair market value of a share of Company stock on the purchase date, or (2) the fair market value of a share of Company stock on the first trading day of the accumulation period.

An employee will not be permitted to purchase more than 25,000 shares of Company stock on any purchase date, or such lower maximum number as may be determined by the Administrator. An employee's right to purchase shares under the ESPP in any calendar year cannot exceed $25,000, as measured by the fair market value of such shares (determined for each accumulation period as of the first trading day of the accumulation period).

An employee can invest any amount from 1% to 15% of his or her base earnings in Company stock through payroll deductions under the ESPP. Payroll deductions are credited to recordkeeping accounts. No earnings are credited to the accounts.

Withdrawal from the ESPP, Cessation of Payroll Deductions, Mandatory Cessation of Participation

An employee may withdraw from the ESPP in full (but not in part) during any accumulation period by delivering a notice of withdrawal to us (in a manner prescribed by the Administrator) at any time prior to the first day of the last calendar month immediately preceding the purchase date for such accumulation period, or at such shorter time in advance of the purchase date as the Administrator may permit. If notice of withdrawal is timely received, all funds then accumulated in the employee's account will not be used to purchase shares, but will instead be distributed to the employee as soon as administratively practical, and the employee's payroll deductions will cease as soon as administratively practical.

An employee also may cease payroll deductions as of the last day of any month during an accumulation period by delivering a notice of cessation to us at the time and in the manner prescribed by the Administrator. Unless the employee also withdraws from the ESPP as described in the preceding paragraph, the employee's accumulated payroll deductions will be applied to purchase shares of Company stock on the purchase date as described above.

Participation in the ESPP immediately terminates when an employee ceases to be an eligible employee for any reason, including voluntary or involuntary termination of employment. Upon the termination of an employee's participation in the ESPP, all accumulated payroll deductions of the employee will be returned to the employee.

Amendment and Termination

The board of directors or the compensation committee may amend or alter any provision of the ESPP and may terminate the ESPP at any time. Under certain circumstances, an amendment to the ESPP may require the approval of our stockholders. In addition, if the ESPP is amended to change the aggregate number of shares issuable thereunder or the provisions regarding eligible employees, certain tax advantages under the Code as discussed below (see "Certain Federal Income Tax Consequences Relating to the ESPP") will only continue if we obtain stockholder approval of such amendment. Certain amendments to the ESPP may be made by the Administrator without stockholder approval.

In the event of any Company reorganization, recapitalization, stock split, reverse stock split, stock dividend, combination of shares, merger, consolidation, acquisition of property or shares, separation, asset spin-off, stock rights offering, liquidation or other similar change in the capital structure of the Company, the shares subject to an employee's election to purchase Company stock during an accumulation period will be adjusted and the aggregate number and kind of shares available under the ESPP and the purchase price of shares will also be adjusted, in each case to the extent deemed appropriate by the Administrator. Generally, if a dissolution or liquidation of the Company occurs during an accumulation period, any rights an employee has to acquire Company stock under the ESPP will be terminated, but an employee will have the right to acquire Company stock before the dissolution or liquidation.

Certain Federal Income Tax Consequences Relating to the ESPP

The following summary of the income tax consequences of the ESPP is based on current provisions of the Code and regulations thereunder. The summary does not address tax rates or state or local income taxes or taxes in jurisdictions other than the United States, nor does it address employment tax.

Enrollment or Purchase of Company Stock under the ESPP. No federal income tax consequences arise at the time of an employee's enrollment in the ESPP or upon the purchase of Company stock under the ESPP. However, as discussed below, if an employee disposes of Company stock acquired under the ESPP, such employee will have the federal income tax consequences described below in the year such employee disposes of the stock. Amounts withheld by payroll deduction are subject to federal income tax as though those amounts had been paid in cash. Whenever an employee transfers any shares of Company stock in a manner which may constitute a disposition, such employee must promptly advise the Secretary of the Company of the facts concerning that transfer.

Early Dispositions. If an employee disposes of Company stock purchased under the ESPP within two years after the first trading day of an accumulation period or within one year after the shares of Company stock are transferred to such employee or to an account in such employee's name (the "Tax Holding Period"), such employee will recognize compensation income in the year of disposition in an amount equal to the excess of (A) the lesser of the fair market value of the Company stock on the purchase date or the proceeds from the sale or exchange of the shares over (B) the price such employee paid for the Company stock. The Company must report such compensation as taxable ordinary income to the Internal Revenue Service on such employee's annual Form W-2. The amount, if any, that is taxable as ordinary income is added to the purchase price and becomes part of the cost basis for that Company stock for federal income tax purposes. If the disposition of the Company stock involves a sale or exchange, such employee generally may also realize a short-term capital gain or loss equal to the difference between such employee's cost basis (calculated pursuant to the preceding sentence) and the proceeds from the sale or exchange of the shares.

Later Dispositions. If an employee disposes of Company stock purchased under the ESPP on a date after the Tax Holding Period, or if such employee dies at any time while owning Company stock, such employee (such employee's estate) will have included in such employee's compensation as taxable ordinary income in the year of disposition or death, an amount equal to the lesser of

(1) the excess of the fair market value of the Company stock on the first trading day of the accumulation period over the purchase price paid by such employee (the employee's estate) for the shares, or

(2) the excess of the fair market value of the Company stock on the date of disposition or death over the purchase price paid by such employee (the estate) for the shares.

The amount which is taxable as ordinary income is added to the cost basis of that Company stock for federal income tax purposes. The cost basis is therefore the sum of the purchase price of the Company stock and the ordinary income recognized from the formula above. If the disposition of the Company stock involves a sale or exchange, such employee will also realize a long-term capital gain or loss equal to the difference between such employee's cost basis (calculated pursuant to the preceding sentence) and the proceeds from the sale or exchange of the shares.

The Company is not entitled to a deduction for amounts taxed as ordinary income or capital gain to an employee except to the extent of ordinary income recognized upon a sale or disposition during the Tax Holding Period (an early disposition).

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. For more information, see "Certain Relationships and Related Transactions, and Director Independence - Indemnification Agreements."

Agreements Related to the Business Combination

We have entered into certain agreements with certain of our named executive officers and directors in connection with the Business Combination. For more information, see (a) "Certain Relationships and Related Transactions, and Director Independence - Indemnification Agreements" and " - Amended and Restated Registration Rights Agreement," and (b) "Certain Relationships and Related Transactions, and Director Independence - Indemnification Agreements - Pre-Business Combination Related Party Transactions – BCYP."

Potential Payments upon Termination or Change in Control

The table below reflects, as applicable, amounts payable to our current named executive officers in connection with a termination by the Company without cause. For purposes of our agreements with our named executive officers, "cause" means, in the judgement of the Company: (i) executive engages in any act or omission which is in bad faith and to the detriment of the Company; (ii) executive willfully and materially violates any of the Company's then-current policies and procedures; (iii) executive's willful failure to perform his or her duties under the employment agreement; (iv) executive exhibits unfitness for service, dishonesty, habitual neglect, persistent and serious deficiencies in performance, or incompetence; (v) executive is convicted of, or there is an entry of guilty (or a nolo contender) plea by executive to, a crime (other than a minor traffic violation); (vi) executive materially breaches provision of the agreement related to nondisclosure, assignment of inventions and/or non-solicitation; or (vii) executive refuses or fails to act on any reasonable or lawful directive or order from the Board or executive's supervisor.

A summary of the potential payments that each of our current named executive officers would have received upon the occurrence of these events, assuming that each triggering event occurred on December 31, 2022, is set forth below.

Name and Principal Position	Salary ($)	Equity ($)	Perquisites / Benefits ($)	Other ($)	Total ($)
Eddie J. Sullivan, PhD. *President and Chief Executive Officer*	377,200	—	—	—	377,200
Samuel J. Reich *Executive Chairman of the Board of Directors*	350,000	—	—	—	350,000
Alexandra Kropotova, MD *EVP, Chief of Medical Officer*	525,000	—	—	—	525,000

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information regarding the beneficial ownership of our common stock as of March 28. 2023, by:

- each person known to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days. Shares subject to options that are currently exercisable or exercisable within 60 days are considered outstanding and beneficially owned by the person holding such options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the Company believes that the persons and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise noted, the business address of each of the directors and executive officers of the Company is 2100 East 54th Street North, Sioux Falls, SD 57104.

The percentage of beneficial ownership of the Company is calculated based on 50,397,762 shares of common stock outstanding as of March 28, 2023. Shares of common stock subject to warrants, options or rights currently exercisable, or exercisable within 60 days of March 28, 2023 are counted as beneficially owned by the selling stockholder.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
Five Percent Stockholders		
Christine Hamilton, MBA (1)	8,717,861	17.1%
Eddie J. Sullivan, PhD (2)	5,740,331	11.3%
Executive Officers and Directors		
Christine Hamilton, MBA (1)	8,717,861	17.1%
Eddie J. Sullivan, PhD (2)	5,740,331	11.3%
Samuel J. Reich (3)	957,388	1.9%
Jeffrey G. Spragens (4)	414,925	*%
William Polvino, MD (5)	116,320	*%
David Link, MBA (6)	150,834	*%
Scott Giberson (7)	6,944	*%
Erick Lucera	—	*%
All current executive officers and directors as a group (11)	**16,451,442**	**31.5%**

(1) Consists of (i) 4,993,090 shares of common stock held by Ms. Hamilton; (ii) 174,248 shares of common stock held as a co-owner by Ms. Hamilton with her spouse, Dr. Edward Hamilton; (iii) 2,909,022 shares of common stock held by Ms. Hamilton's spouse, Dr. Edward Hamilton; (iv) 25,000 shares held by Christiansen Investments; (v) 151,216 shares of common stock underlying stock options held by Ms. Hamilton exercisable within 60 days of March 28, 2023; and (vi) 465,285 shares of common stock underlying stock options held by her spouse, Dr. Edward Hamilton, exercisable within 60 days of March 28, 2023. Ms. Hamilton is a control person with voting and dispositive power over shares of Christiansen Investments and is deemed to have beneficial ownership of the shares held by Christiansen Investments. Ms. Hamilton disclaims beneficial ownership of such securities except to the extent of her pecuniary interest therein, directly or indirectly.

(2) Consists of (i) 5,230,564 shares of common stock held by Dr. Sullivan; and (ii) 509,767 shares of common stock underlying stock options held by Dr. Sullivan exercisable within 60 days of March 28, 2023.

(3) Consists of (i) 207,001 shares of common stock held by Mr. Reich; (ii) 1,000 shares of common stock held jointly by Mr. Reich and Mr. Reich's spouse; (iii) 547,698 of shares of common stock held by Big Cypress Holdings, LLC that are subject to vesting during a period of up to five years after October 22, 2021, which is the Business Combination Closing Date; (iv) 9,968 shares of common stock underlying warrants that are currently exercisable; and (v) 191,721 shares of common stock underlying stock options held by Mr. Reich exercisable within 60 days of March 28, 2023. Mr. Reich is a managing member with voting and dispositive power over shares of Big Cypress Holdings, LLC and is deemed to have beneficial ownership of the shares held by Big Cypress Holdings, LLC. Mr. Reich disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein, directly or indirectly.

(4) Consists of (i) 95,987 shares of common stock held by Mr. Spragens; (ii) 299,002 shares of common stock distributed to Mr. Spragens as a member of Big Cypress Holdings, LLC; and (iii) 19,936 shares of common stock underlying warrants that are currently exercisable.

(5) Consists of 116,320 shares of common stock underlying stock options held by Dr. Polvino exercisable within 60 days of March 28, 2023.

(6) Consists of (i) 57,313 shares of common stock held by Mr. Link; (ii) 12,097 of shares of common stock held by Iron Horse Investments, LLC; and (iii) 81,424 shares of common stock underlying stock options held by Mr. Link exercisable within 60 days of March 28, 2023. Mr. Link is a control person with voting and dispositive power over shares of Iron Horse Investments, LLC and is deemed to have beneficial ownership of the shares held by Iron Horse Investments, LLC. Mr. Link disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein, directly or indirectly

(7) Consists of 6,944 shares of common stock underlying stock options held by Mr. Giberson exercisable within 60 days of March 28, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following includes a summary of transactions since January 1, 2021 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "*Executive Compensation*."

Amended and Restated Registration Rights Agreement

In connection with the completion of the Business Combination, we entered into an amended and restated registration rights agreement with the Sponsor, certain of our stockholders, certain stockholders of Legacy SAB and Ladenburg Thalmann & Co. Inc. (Ladenburg), pursuant to which, among other things, Sponsor, certain of our stockholders and certain stockholders of Legacy SAB (i) agreed not to effect any sale or distribution of our common stock held by any of them during the specified lock-up period of 180 days after the closing of the Business Combination and (ii) were granted certain registration rights with respect to their shares of our common stock. We also agreed that Edward Hamilton will be entitled to have a board observer attend meetings of our board of directors (and any committee thereof) for so long as certain of his affiliates continue to own at least 75% of the shares held by such affiliates on the closing date of the Business Combination. The amended and restated registration rights agreement will terminate on the earlier of (i) the date that all registrable securities covered by the amended and restated registration rights agreement have sold pursuant to a registration statement effected pursuant to the terms of the amended and restated registration rights agreement or (ii) the date that all registrable securities covered by the amended and restated registration rights agreement are permitted to be sold under Rule 144 promulgated by the SEC under the Securities Act.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides for indemnification and advancements by us of certain expenses and costs relating to claims, suits or proceedings arising from his or her service to us or, at our request, service to other entities, as officers or directors to the maximum extent permitted by applicable law.

Sponsor Support Agreement

Concurrently with the execution of the Business Combination Agreement, we entered into a sponsor support agreement with Sponsor, Ladenburg and certain of our stockholders, pursuant to which Sponsor, Ladenburg and certain of our stockholders agreed to, among other things, (i) vote in favor of the Business Combination Agreement and the transactions contemplated thereby (including the Business Combination) and against any competing transaction, (ii) waive any anti-dilution or similar protection that could be triggered in connection with the Business Combination, (iii) be bound by certain transfer restrictions with respect to our shares of common stock prior to the closing of the Business Combination and (iv) agree to certain forfeiture provisions with respect to up to 598,580 of the shares owned by them (Restricted Shares) during a period of up to five years from the closing of the Business Combination (Vesting Period) as follows:

- 149,645 of the Restricted Shares will become fully vested and unrestricted if, within the Vesting Period, the volume weighted share price of the Company's common stock equals or exceeds $15.00 during at least 20 trading days within a 30-day trading period;
- 149,645 of the Restricted Shares will become fully vested and unrestricted if, within the Vesting Period, the volume weighted share price of the Company's common stock equals or exceeds $20.00 during at least 20 trading days within a 30-day trading period;
- 149,645 of the Restricted Shares will become fully vested and unrestricted if, within the Vesting Period, the volume weighted share price of the Company's common stock equals or exceeds $25.00 during at least 20 trading days within a 30-day trading period; and
- 149,645 of the Restricted Shares will become fully vested and unrestricted if, within the Vesting Period, the volume weighted share price of the Company's common stock equals or exceeds $30.00 during at least 20 trading days within a 30-day trading period.

Each tranche of Restricted Shares will also become fully vested and unrestricted in the event of a change in control of the Company during the Vesting Period that results in the holders of the Company's common stock receiving a per-share aggregate consideration equal to or in excess of the applicable tranche of Restricted Shares.

The sponsor support agreement terminated upon the closing of the Business Combination, other than with respect to the Restricted Shares, which will continue to become vested and unrestricted as described above.

Pre-Business Combination Related Party Transactions – BCYP

Founder Shares

On January 3, 2021, our legal predecessor, BCYP, effected a stock dividend of 1/3 of a share of common stock for every share of common stock outstanding, resulting in an aggregate of 2,875,000 founder shares outstanding (including up to 375,000 shares subject to forfeiture to the extent that the underwriters' over-allotment was not exercised in full or in part). As a result of the underwriters' election to fully exercise their over-allotment option on January 14, 2021, the 375,000 shares were no longer subject to forfeiture.

As discussed further below, on January 4, 2021, Sponsor forfeited 28,750 founder shares to BCYP and Ladenburg and certain of its employees purchased an aggregate of 28,750 shares from BCYP at an average purchase price of approximately $0.008 per share, for an aggregate purchase price of $230.

Private Placement

Simultaneously with the closing of our initial public offering of units, consisting of one share of common stock and one-half of a detachable warrant (the "Public Warrants") to purchase shares of common stock, on January 14, 2021, Sponsor purchased an aggregate of 417,200 private placement units, at a price of $10.00 per private placement unit, for an aggregate purchase price of $4,172,000, in a private placement. Each private placement unit was identical to the units sold in our legal predecessor's initial public offering, except that the detachable private warrants (the "Private Placement Warrants") are exercisable on a cashless so long as they are held by the initial purchasers or their permitted transferees.

Promissory Note

On November 19, 2020, Sponsor agreed to loan BCYP an aggregate of up to $250,000 to cover expenses related to the initial public offering pursuant to a promissory note (the "Sponsor Note"). This loan was non-interest bearing and payable on the earlier of December 31, 2021 or the completion of the initial public offering. Sponsor paid an aggregate of approximately $150,000 to cover for expenses on our behalf under the Note. On January 14, 2021, we repaid the Sponsor Note in full.

Administrative Services

BCYP agreed to pay an affiliate of Sponsor a monthly fee of an aggregate of $10,000 for office space, utilities and secretarial and administrative support. Upon completion of the Business Combination, the Company ceased paying these monthly fees.

Policies and Procedures for Transactions with Related Parties

The Company has adopted a written Related Party Transaction Policy that set forth its procedures for the identification, review, consideration and approval or ratification of related person transactions. A related person includes directors, executive officers, beneficial owners of 5% or more of any class of the Company's voting securities, immediate family members of any of the foregoing persons, and any entities in which any of the foregoing is an executive officer or is an owner of 5% or more ownership interest. Under the Related Party Transaction Policy, if a transaction involving an amount in excess of $120,000 has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, information regarding the related person transaction must be reviewed and approved by the Company's audit committee

In considering related person transactions, the Company's audit committee will take into account the relevant available facts and circumstances including, but not limited to:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of business of the Company;
- whether the transaction with the related person is proposed to be, or was, entered into on terms no less favorable to the Company than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to the Company of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The Related Party Transaction Policy requires that, in determining whether to approve, ratify or reject a related person transaction, the audit committee must review all relevant information available to it about such transaction, and that it may approve or ratify the related person transaction only if it determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, the best interests of the Company.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2022 and 2021 by Mayer Hoffman McCann P.C. ("MHM"), the Company's independent registered public accounting firm. Substantially all of MHM's personnel, who work under the control of MHM shareholders, are employees of wholly-owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure.

(US Dollars)	**2022**	**2021**
Audit fees	$ 710,644	$ 662,887
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total	$ 710,644	$ 662,887

Audit fees for the fiscal years ended December 31, 2022 and 2021 rendered by MHM relate to professional services rendered for the audits of our financial statements, quarterly reviews, issuance of consents, the Business Combination and review of documents filed with the SEC.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The policy generally provides that we will not engage MHM to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the Audit Committee ("specific pre-approval") or (ii) entered into pursuant to the pre-approval policies and procedures described in the policy ("general pre-approval"). Unless a type of service to be provided by MHM has received general pre-approval under the policy, it requires specific pre-approval by the Audit Committee or by a designated member of the Audit Committee to whom the committee has delegated the authority to grant pre-approvals. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the Audit Committee will consider whether such services are consistent with the SEC's rules on auditor independence.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description	Schedule/ Form	File No.	Exhibit	Filing Date
2.1+	Agreement and Plan of Merger, dated as of June 21, 2021, by and among Big Cypress Acquisition Corp., Big Cypress Merger Sub Inc, SAB Biotherapeutics, Inc., and Shareholder Representative Services LLC as the Stockholders' Representative	8-K	001-39871	2.1+	October 28, 2021
2.2+	First Amendment to Agreement and Plan of Merger, dated August 12, 2021, by and among Big Cypress Acquisition Corp. and SAB Biotherapeutics, Inc.	8-K	001-39871	2.2+	October 28, 2021
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-39871	3.1	October 28, 2021
3.2	Amended and Restated Bylaws.	8-K	001-39871	3.2	October 28, 2021
4.1	Specimen common stock Certificate of Registrant.	S-1/A	333-258869	4.2	January 4, 2021
4.2	Specimen Warrant Certificate of Registrant (incorporated by reference to Exhibit 4.3 of Form S-1/A.)	S-1/A	333-258869	4.3	January 4, 2021
4.3	Form of Warrant Agreement between Registrant and Continental Stock Transfer & Trust Company.	S-1/A	333-258869	4.4	January 4, 2021
4.4*	Description of Registrant's Securities				
10.1	Amended and Restated Registration Rights Agreement.	8-K	001-39871	10.1	October 28, 2021
10.2¥	Employment Agreement, dated March 1, 2021, by and between SAB Biotherapeutics, Inc. and Eddie J. Sullivan.	8-K	001-39871	10.2¥	October 28, 2021
10.3¥	Executive Employment Agreement, dated November 17, 2021, by and between SAB Biotherapeutics, Inc. and Samuel J. Reich	8-K	001-39871	10.1¥	November 12, 2021
10.4¥	Employment Agreement, dated September 15, 2021, by and between SAB Biotherapeutics, Inc. and Russell Beyer.	8-K	001-39871	10.5¥*	October 28, 2021
10.5¥*	A. Kropotova Agreement.				
10.6	Form of Indemnification Agreement.	8-K	001-39871	10.6	October 28, 2021
10.7¥	SAB Biotherapeutics, Inc. 2021 Omnibus Equity Incentive Plan.	8-K	001-39871	10.7 ¥	October 28, 2021
10.8¥	SAB Biotherapeutics, Inc. 2021 Employee Stock Purchase Plan.	8-K	001-39871	10.8 ¥	October 28, 2021
10.9	Form of Securities Subscription Agreement, dated November 12, 2020, between BCYP and Big Cypress Holdings LLC.	S-4	333-258869	10.3	September 22, 2021
10.10	Securities Purchase Agreement, dated December 7, 2020, between BCYP and Ladenburg Thalmann & Co. Inc. and certain of its employees.	S-4	333-258869	10.4	September 22, 2021
10.11	Placement Unit Subscription Agreement dated January 11, 2021 between the Company and Big Cypress Holdings LLC.	S-4	333-258869	10.5	September 22, 2021

10.11	BCYP Stockholders Support Agreement.	S-4	333-258869	10.7	September 22, 2021
10.13	SAB Stockholders Support Agreement.	S-4	333-258869	10.8	September 22, 2021
10.14	Third Amendment to Amended and Restated Lease Agreement				
10.15	Fourth Amendment to Amended and Restated Lease Agreement	8-K	001-39871	10.1	October 13, 2022
10.16***	Manufacturing Option Agreement, dated October 26, 2022	8-K	001-39871	10.1	November 1, 2022
10.17***	Right of First Refusal Agreement, dated October 26, 2022	8-K	001-39871	10.2	November 1, 2022
10.18	Securities Purchase Agreement dated December 6, 2022, by and between the Company and the purchasers thereto	8-K	001-39871	10.1	December 12, 2022
16.1	Letter to SEC from Marcum LLP	8-K	001-39871	16.1	October 28, 2021
21.1	List of Subsidiaries	8-K	001-39871	21.1	October 28, 2021
23.1*	Consent of Mayer Hoffman McCann P.C.				
24.1*	Power of Attorney (included on a signature page of the initial filing of this Annual Report)				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

**In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

**** Certain portions of this exhibit (indicated by "[***]") have been redacted pursuant to Regulation S-K, Item 601(b)(10)(iv).

+ Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

¥ Denotes management contract or any compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

SAB BIOTHERAPEUTICS, INC.

Date: April 14, 2023

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Eddie J. Sullivan **Eddie J. Sullivan**	Director and Chief Executive Officer (Principal Executive Officer)	April 14, 2023
/s/ Russell Beyer **Russell Beyer**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 14, 2023
/s/ Samuel J. Reich **Samuel J. Reich**	Director and Executive Chairman	April 14, 2023
/s/ Christine Hamilton, MBA **Christine Hamilton, MBA**	Director	April 14, 2023
/s/ David Charles Link **David Charles Link**	Director	April 14, 2023
/s/ William Polvino, MD, PhD **William Polvino, MD, PhD**	Director	April 14, 2023
/s/ Jeffrey G. Spragens **Jeffrey G. Spragens**	Director	April 14, 2023
/s/ Scott Giberson **Scott Giberson**	Director	April 14, 2023
/s/ Erick Lucera **Erick Lucera**	Director	April 14, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
SAB Biotherapeutics, Inc. and Subsidiaries

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of **SAB Biotherapeutics, Inc. and Subsidiaries** ("Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company does not generate sufficient cash flows from operations to maintain operations and, therefore, is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Restatement of 2021 Financial Statements

As discussed in Note 2 to the financial statements, the 2021 financial statements have been restated to correct certain misstatements.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2019.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
April 14, 2023

SAB Biotherapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021 (Restated)
Assets		
Current assets		
Cash and cash equivalents	$ 15,046,894	$ 33,206,712
Restricted cash	—	6,338,306
Accounts receivable, net	5,556,577	8,010,708
Prepaid expenses	1,493,982	2,636,224
Total current assets	22,097,453	50,191,950
Long-term prepaid insurance	467,694	—
Operating lease right-of-use assets	1,192,054	2,615,204
Financing lease right-of-use assets	3,896,873	4,019,322
Property, plant and equipment, net	23,250,853	24,314,455
Total assets	$ **50,904,927**	$ **81,140,931**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,679,116	$ 4,458,525
Forward share purchase liability	—	6,338,306
Notes payable	772,665	1,796,724
Operating lease liabilities, current portion	490,794	1,142,413
Finance lease liabilities, current portion	132,788	161,050
Due to related party	—	2,367
Deferred grant income	—	100,000
Accrued expenses and other current liabilities	9,917,981	12,455,888
Total current liabilities	14,993,344	26,455,273
Operating lease liabilities, noncurrent	361,225	1,653,185
Finance lease liabilities, noncurrent	3,629,642	3,762,430
Warrant liabilities	320,930	10,720,130
Convertible Debt	541,644	—
Total liabilities	19,846,785	42,591,018
Commitments and contingencies (Note 18)		
Stockholders' equity		
Preferred stock; $0.0001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Common stock; $0.0001 par value; 490,000,000 shares authorized at December 31, 2022 and December 31, 2021; 50,940,920 and 43,487,279 shares issued, respectively, and 50,394,262 and 43,487,279 outstanding at December 31, 2022 and December 31, 2021, respectively	5,094	4,349
Treasury stock, at cost; 546,658 and 0 shares held at December 31, 2022 and December 31, 2021, respectively	(5,521,246)	—
Additional paid-in capital	84,444,049	67,674,515
Accumulated deficit	(47,869,755)	(29,128,951)
Total stockholders' equity	31,058,142	38,549,913
Total liabilities and stockholders' equity	$ **50,904,927**	$ **81,140,931**

See accompanying notes to the consolidated financial statements

SAB Biotherapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations

	Year Ended December 31,	
	2022	**2021**
Revenue		
Grant revenue	$ 23,904,181	$ 60,876,078
Total revenue	23,904,181	60,876,078
Operating expenses		
Research and development	36,438,513	57,183,589
General and administrative	16,383,285	17,085,692
Total operating expenses	52,821,798	74,269,281
Loss from operations	(28,917,617)	(13,393,203)
Other income (expense)		
Changes in fair value of warrant liabilities	10,399,200	(4,151,068)
Gain on debt extinguishment of Paycheck Protection Program SBA Loan	—	665,596
Other income	33,754	5,488
Interest expense	(301,584)	(294,459)
Interest income	71,072	23,115
Total other income (expense)	10,202,442	(3,751,328)
Loss before income taxes	(18,715,175)	(17,144,531)
Income tax expense	25,629	—
Net loss	$ (18,740,804)	$ (17,144,531)
Loss per common share attributable to the Company's shareholders		
Basic and diluted loss per common share	$ (0.43)	$ (0.63)
Weighted-average common shares outstanding – basic and diluted	43,524,971	27,339,180

See accompanying notes to the consolidated financial statements.

SAB Biotherapeutics, Inc. and Subsidiaries
Consolidated Statements of Changes In Stockholders' Equity (Deficit)
For the years ended December 31, 2022 and 2021

	Common stock			Treasury Stock			
	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	**25,973,406**	**$ 2,598**	**$ 50,989,657**	**—**	**$ —**	**$ (11,984,420)**	**$ 39,007,835**
Effect of Business Combination and recapitalization, net of redemptions and issuance costs of $3,294,096	7,009,436	701	7,603,133	—	—	—	7,603,834
Issuance of restricted stock, subject to forfeiture	10,491,937	1,049	—	—	—	—	1,049
Forward Share Purchase Agreement, partial settlement	—	—	6,760,294	—	—	—	6,760,294
Stock-based compensation	—	—	2,314,682	—	—	—	2,314,682
Issuance of common stock for exercise of stock options	12,500	1	6,749	—	—	—	6,750
Net loss	—	—	—	—	—	(17,144,531)	(17,144,531)
Balance at December 31, 2021	**43,487,279**	**$ 4,349**	**$ 67,674,515**	**—**	**$ —**	**$ (29,128,951)**	**$ 38,549,913**
Forward Share Purchase Agreement, final settlement	—	—	817,060	—	—	—	817,060
Repurchase of common stock pursuant to the Forward Share Purchase Agreement	—	—	5,521,246	(546,658)	(5,521,246)	—	—
Stock-based compensation	—	—	2,674,204	—	—	—	2,674,204
Issuance of common stock for exercise of stock options	90,264	9	76,962	—	—	—	76,971
Issuance of common stock and warrants under private placement offering, net of issuance costs of $0.3 million	7,363,377	736	7,680,062	—	—	—	7,680,798
Net loss	—	—	—	—	—	(18,740,804)	(18,740,804)
Balance at December 31, 2022	**50,940,920**	**$ 5,094**	**$ 84,444,049**	**(546,658)**	**$ (5,521,246)**	**$ (47,869,755)**	**$ 31,058,142**

See accompanying notes to the consolidated financial statements.

SAB Biotherapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2022	**2021 (Restated)**
Cash flows from operating activities:		
Net loss	$ (18,740,804)	$ (17,144,531)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Gain on debt extinguishment of Paycheck Protection Program SBA Loan	—	(665,596)
Depreciation and amortization	3,169,429	1,488,614
Amortization of right-of-use assets	122,449	164,983
Stock-based compensation expense	2,674,203	2,314,682
Gain on sale of equipment	(15,805)	(5,488)
Gain on partial lease termination	(32,208)	—
Changes in fair value of warrant liabilities	(10,399,200)	4,151,068
Changes in operating assets and liabilities		
Accounts receivable	2,454,131	12,558,790
Prepaid expenses	674,552	(1,258,348)
Operating lease right-of-use assets	53,441	(63,626)
Accounts payable	(779,425)	(2,935,521)
Due to related party	(2,367)	(2,727)
Deferred grant income	(100,000)	—
Accrued expense and other current liabilities	(2,537,907)	3,384,573
Net cash (used in) provided by operating activities	**(23,459,511)**	**1,986,873**
Cash flows from investing activities:		
Proceeds from the sale of property, plant and equipment	76,390	—
Purchases of property, plant and equipment	(2,166,414)	(10,943,657)
Net cash used in investing activities	**(2,090,024)**	**(10,943,657)**
Cash flows from financing activities:		
Proceeds from Business Combination, net of transaction costs	—	34,340,225
Proceeds from issuance of notes payable	1,236,125	2,840,619
Payments on notes payable	(2,260,183)	(1,093,051)
Payments related to the Forward Share Purchase Agreement	(5,521,246)	—
Principal payments on finance leases	(161,055)	(203,124)
Proceeds from exercise of stock options	76,971	6,750
Proceeds from issuance of common stock	7,680,799	—
Net cash used in financing activities	**1,051,411**	**35,891,419**
Net increase (decrease) in cash, cash equivalents, and restricted cash	(24,498,124)	26,934,635
Cash, cash equivalents, and restricted cash		
Beginning of year	39,545,018	12,610,383
End of period	$ 15,046,894	$ 39,545,018

See accompanying notes to the consolidated financial statements.

(1) Nature of Business

On October 22, 2021 (the "Closing Date"), the Company consummated the business combination contemplated by the agreement and plan of merger, dated as of June 21, 2021, as amended on August 12, 2021, made by and among BCYP, Big Cypress Merger Sub Inc., a Delaware corporation ("Merger Sub"), SAB Biotherapeutics, Inc., a Delaware corporation ("SAB" or the "Company"), and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the representative, agent and attorney-in-fact of the SAB Stockholders. Upon closing of the Business combination, Big Cypress Merger Sub merged with SAB Biotherapeutics, with SAB Biotherapeutics as the surviving company of the merger. Upon closing of the business combination, BCYP changed its name to "SAB Biotherapeutics, Inc.".

SAB Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of products from its proprietary immunotherapy platform to produce fully targeted human polyclonal antibodies, without using human plasma or serum. SAB's novel DiversitAb platform enables the rapid production of large amounts of targeted human polyclonal antibodies, leveraging transchromosomic cattle (Tc Bovine™) that have been genetically designed to produce human antibodies (immunoglobulin G) rather than bovine in response to an antigen. Animal antibodies have been made in rabbits, sheep and horses. However, SAB's platform is the first to produce fully human antibodies in large animals.

The COVID-19 pandemic continues to evolve, and the extent to which it may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions, and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease. The Company is following, and will continue to follow, recommendations from the U.S. Centers for Disease Control and Prevention, as well as federal, state, and local governments. To date, the Company has not experienced material business disruptions, but it cannot be certain of the future impact of the COVID-19 pandemic on its business and consolidated financial statements.

Going Concern

As of December 31, 2022, the Company has experienced net losses, negative cash flows from operations and had an accumulated deficit of $47.9 million. The Company anticipates to continue to generate losses for the foreseeable future, and expects the losses to increase as the Company continues the development of, and seek regulatory approvals for, product candidates, and begin commercialization of products. As a result, the Company will require additional capital to fund operations in order to support long-term plans, in particular, following the JPEO Rapid Response Contract Termination. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these financial statements were issued.

To continue as a going concern, the Company will need, among other things, to raise additional capital resources. The Company plans to seek additional funding through a combination of equity or debt financings, or other third-party financing, collaborative or other funding arrangements. Should the Company seek additional financing from outside sources, the Company may not be able to raise such financing on terms acceptable to the Company or at all. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate the Company's assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

The consolidated financial statements as of December 31, 2022, have been prepared on the basis that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability for the Company to continue as a going concern.

(2) Restatement of Financial Statements

In March 2023, the Audit Committee of the Company's Board of Directors and the Company's management concluded that the Company's previously issued audited financial statements contained within the Annual Report on Form 10-K for the year ended December 31, 2021 (the "Prior Year Financial Statements"), and the Company's previously issued interim financial statements included in the Company's Quarterly Reports on Forms 10-Q for the three months ended March 31, 2022, the six months ended June 30, 2022, and nine months ended September 30, 2022 (the "Prior Period Interim Financial Statements"), should no longer be relied upon as a result of the following accounting errors:

- The Company concluded that it did not correctly account for a financed insurance premium whereby a third-party lender prepaid the Company's annual insurance premiums to our insurance companies in exchange for a short-term interest bearing note (the "Insurance Financing Agreement"). The Company previously recognized, on its consolidated balance sheet, a current prepaid asset for the amount paid by the Company under the Insurance Financing Agreement in excess of the total amortized value of the prepaid insurance policy. The Company reassessed its accounting for the Insurance Financing Agreement and determined that the Insurance Financing Agreement should be classified as a current note payable with the full amount of the insurance premium recognized as current prepaid asset at the time the Company entered into the Insurance Financing Agreement.

- The Company concluded that the Insurance Financing Agreement and corresponding payment to the third-party lender constitutes a constructive receipt and disbursement of cash. As a result, the Company determined the cash flows from financing activities contained within the Prior Year Financial Statements is understated—this error is accompanied by a corresponding overstatement in cash flows from operating activities due to an understated prepaid asset.

- Similar to the above assessment, the Company concluded that the cash payments to the third-party lender should be presented within cash flows from financing activities. As a result, the Company determined the cash flows from financing activities contained within the Prior Period Interim Financial Statements are overstated—this error is accompanied by a corresponding understatement in cash flows from operating activities due to the derecognition of the previously unrecognized prepaid asset.

Impact of the Restatement

The Company has restated herein its audited financial statements at December 31, 2022 for the year ended December 31, 2021. We have also restated interim financial statement periods for the three months ended March 31, 2022, the six months ended June 30, 2022, and nine months ended September 30, 2022, See Note 21, *Quarterly Financial Information (Unaudited)*.

	December 31, 2021		
	As Previously Reported	**Adjustment**	**As Restated**
Assets			
Current assets			
Cash and cash equivalents	$ 33,206,712	$ —	$ 33,206,712
Restricted cash	6,338,306	—	6,338,306
Accounts receivable, net	8,010,708	—	8,010,708
Prepaid expenses	864,513	1,771,711	2,636,224
Total current assets	48,420,239	1,771,711	50,191,950
Operating lease right-of-use assets	2,615,204	—	2,615,204
Financing lease right-of-use assets	4,019,322	—	4,019,322
Equipment, net	24,314,455	—	24,314,455
Total assets	$ **79,369,220**	$ **1,771,711**	$ **81,140,931**
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable	$ 4,458,525	$ —	$ 4,458,525
Forward share purchase liability	6,338,306	—	6,338,306
Notes payable – current portion	25,013	1,771,711	1,796,724
Operating lease liabilities, current portion	1,142,413	—	1,142,413
Finance lease liabilities, current portion	161,050	—	161,050
Due to related party	2,367	—	2,367
Deferred grant income	100,000	—	100,000
Accrued expenses and other current liabilities	12,455,888	—	12,455,888
Total current liabilities	24,683,562	1,771,711	26,455,273
Operating lease liabilities, noncurrent	1,653,185	—	1,653,185
Finance lease liabilities, noncurrent	3,762,430	—	3,762,430
Warrant liabilities	10,720,130	—	10,720,130
Notes payable, noncurrent	—	—	—
Total liabilities	40,819,307	1,771,711	42,591,018
Commitments and contingencies (Note 17)			
Stockholders' equity			
Preferred stock; $0.0001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2021 and 2020	—	—	—
Common stock; $0.0001 par value; 490,000,000 shares authorized at December 31, 2021 and 2020; 43,487,279 and 25,973,406 shares issued and outstanding at December 31, 2021 and 2020, respectively	4,349	—	4,349
Additional paid-in capital	67,674,515	—	67,674,515
Accumulated deficit	(29,128,951)	—	(29,128,951)
Total stockholders' equity	38,549,913	—	38,549,913
Total liabilities and stockholders' equity	$ **79,369,220**	$ **1,771,711**	$ **81,140,931**

	Year Ended December 31, 2021		
	As Previously Reported	Adjustment	As Restated
Cash flows from operating activities:			
Net (loss) income	$ (17,144,531)	$ —	$ (17,144,531)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Gain on debt extinguishment of Paycheck Protection Program SBA Loan	(665,596)	—	(665,596)
Depreciation and amortization	1,488,614	—	1,488,614
Amortization of right-of-use assets	164,983	—	164,983
Stock-based compensation expense	2,314,682	—	2,314,682
Gain on sale of equipment	(5,488)	—	(5,488)
Changes in fair value of warrant liabilities	4,151,068	—	4,151,068
Changes in operating assets and liabilities			
Accounts receivable	12,558,790	—	12,558,790
Prepaid expenses	513,363	(1,771,711)	(1,258,348)
Right-of-use assets – operating lease	(63,626)	—	(63,626)
Accounts payable	(2,935,521)	—	(2,935,521)
Deferred income	—	—	—
Due to related party	(2,727)	—	(2,727)
Accrued expense and other current liabilities	3,384,573	—	3,384,573
Net cash provided by operating activities	**3,758,584**	**(1,771,711)**	**1,986,873**
Cash flows from investing activities:			
Proceeds from the sale of equipment	—	—	—
Purchases of equipment	(10,943,657)	—	(10,943,657)
Net cash used in investing activities	**(10,943,657)**	—	**(10,943,657)**
Cash flows from financing activities:			
Proceeds from Business Combination, net of transaction costs	34,340,225	—	34,340,225
Proceeds from issuance of notes payable	—	2,840,619	2,840,619
Payments of notes payable	(24,143)	(1,068,908)	(1,093,051)
Principal payments on finance leases	(203,124)	—	(203,124)
Proceeds from exercise of stock options	6,750	—	6,750
Net cash provided by financing activities	**34,119,708**	**1,771,711**	**35,891,419**
Net increase in cash, cash equivalents, and restricted cash	26,934,635	—	26,934,635
Cash, cash equivalents, and restricted cash			
Beginning of year	12,610,383	—	12,610,383
End of year	$ 39,545,018	$ —	$ 39,545,018

(3) Summary of Significant Accounting Policies

A summary of the significant accounting policies applied in preparation of the accompanying consolidated financial statements is set forth below.

Basis of presentation

The financial statements have been prepared in conformity with U.S. GAAP and include all adjustments necessary for the fair presentation of the Company's financial position for the years presented.

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. GAAP (the "Reverse Recapitalization"). Under this method of accounting, BCYP is treated as the "acquired" company and SAB Biotherapeutics is treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Reverse Recapitalization was treated as the equivalent of SAB Biotherapeutics issuing stock for the net assets of BCYP, accompanied by a recapitalization. The net assets of BCYP are stated at historical cost, with no goodwill or other intangible assets recorded. SAB Biotherapeutics was determined to be the accounting acquirer based on the following predominant factors:

- SAB Biotherapeutics' shareholders have the largest portion of voting rights in the Company;
- the Board and Management are primarily composed of individuals associated with SAB Biotherapeutics; and
- the operations of SAB comprise the ongoing operations of the Company.

Emerging growth company status

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Principles of consolidation

The accompanying consolidated financial statements include the results of the Company and its wholly owned subsidiaries, SAB Capra, LLC and Aurochs, LLC. Intercompany balances and transactions have been eliminated in consolidation.

Significant risks and uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to, the results of research and development efforts, clinical trial activities of the Company's product candidates, the Company's ability to obtain regulatory approval to market its product candidates, competition from products manufactured and sold or being developed by other companies, and the Company's ability to raise capital.

The Company currently has no commercially approved products and there can be no assurance that the Company's research and development will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and obtaining and protecting intellectual property. Additional funding may be needed to cover operational costs as the Company moves forward with the Company's efforts to develop a commercially approved product.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the financial statements. The Company has used significant estimates in its determination of stock-based compensation assumptions, determination of the fair value of the Company's common stock prior to becoming a public company, determination of the fair value of the Company's warrants, determination of the incremental borrowing rate ("IBR") used in the calculation of the Company's right of use assets and lease liabilities, and the valuation allowance on deferred tax assets. Actual amounts realized may differ from these estimates.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The following fair value hierarchy classifies the inputs to valuation techniques that would be used to measure fair value into one of three levels:

Level 1: Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs that reflect the reporting entity's own assumptions

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to the short-term nature of their maturities, such as cash and cash equivalents, accounts receivable, accounts payable and accrued expenses.

The Company accounts for warrants to purchase its common stock pursuant to ASC Topic 470, *Debt*, and ASC Topic 480, *Distinguishing Liabilities from Equity*, and classifies warrants for common stock as liabilities or equity. The warrants classified as liabilities are reported at their estimated fair value (see Note 14 - *Fair Value Measurements*) and any changes in fair value are reflected in other income and expense. The warrants classified as equity are reported at their estimated relative fair value with no subsequent remeasurement. The Company's outstanding warrants are discussed in more detail in Note 14 - *Fair Value Measurements*.

Cash, cash equivalents, and restricted cash

Cash equivalents include short-term, highly liquid instruments, consisting of money market accounts and short-term investments with original maturities at the date of purchase of 90 days or less.

Amounts held in escrow by the Company pursuant to the Forward Share Purchase Agreement were reported as restricted cash on the consolidated balance sheet as of December 31, 2021.

The reconciliation of cash, cash equivalents, and restricted cash as of the years ended December 31, 2022 and 2021 was as follows:

	2022	2021
Cash and cash equivalents	$ 15,046,894	$ 33,206,712
Restricted cash	—	6,338,306
Total cash, cash equivalents, and restricted cash	$ 15,046,894	$ 39,545,018

Accounts receivable

Accounts receivable are carried at original invoice amount, less an allowance for doubtful accounts. The Company estimates an allowance for doubtful accounts for potential credit losses that are expected to be incurred, based on management's assessment of the collectability of specific accounts, the aging of the accounts receivable, historical information and other currently available evidence. Receivables are written off when deemed uncollectible. To date, no receivables have been written off. The Company had no allowance for doubtful accounts as of December 31, 2022 and 2021.

Concentration of credit risk

The Company maintains its cash and cash equivalent balances in the form of business checking accounts and money market accounts, the balances of which, at times, may exceed federally insured limits. Exposure to credit risk is reduced by placing such deposits in high credit quality federally insured financial institutions.

The Company received 100% of its total revenue through grants from government organizations during the years ended December 31, 2022 and 2021, respectively.

Lease liabilities and right-of-use assets

The Company is party to certain contractual arrangements for equipment, lab space, and an animal facility, which meet the definition of leases under FASB ASC Topic 842, *Leases* ("ASC 842"). In accordance with ASC 842, the Company recorded right-of-use assets and related lease liabilities for the present value of the lease payments over the lease terms. The Company's IBR was used in the calculation of its right-of-use assets and lease liabilities.

Research and development expenses

Expenses incurred in connection with research and development activities are expensed as incurred. These include licensing fees to use certain technology in the Company's research and development projects, fees paid to consultants and various entities that perform certain research and testing on behalf of the Company, and expenses related to salaries, benefits, and stock-based compensation granted to employees in research and development functions.

During the years ended December 31, 2022 and 2021, the Company had contracts with multiple CRO to complete studies as part of research grant agreements. In the case of SAB-185, the CRO was contracted and paid by the US government - as of December 31, 2022, there is no active CRO engaged by the Company in work on the SAB-185. For SAB-176, PPD Development, LP acting as the CRO oversaw the Phase 1 safety study. The terms of that agreement are subject to confidentiality, and the status of the agreement is that it is current, in good standing and approximately 95% of the contract has been paid as of December 31, 2022. SAB has also contracted with hVIVO Services Limited to conduct the Phase 2a influenza study on SAB-176. The terms of that agreement are subject to confidentiality, and the status of the agreement is that it is current, in good standing and approximately 95% of the contract has been paid as of December 31, 2022.

Property, plant and equipment, net

The Company records equipment at cost less depreciation. Depreciation is calculated using straight-line method over the following estimated useful lives:

(in years)	
Animal facility equipment	7
Laboratory equipment	7
Leasehold improvements	Shorter of asset life or lease term
Office furniture & equipment	5
Vehicles	5

Repairs and maintenance expenses are expensed as incurred.

Impairment of long-lived assets

The Company reviews the recoverability of long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. If necessary, the Company compares the estimated undiscounted future net cash flows to the related asset's carrying value to determine whether there has been an impairment. If an asset is considered impaired, the asset is written down to fair value, which is based either on discounted cash flows or appraised values in the period the impairment becomes known. The Company believes that long-lived assets are recoverable, and no impairment was deemed necessary, during the years ended December 31, 2022 and 2021.

Stock-based compensation

FASB ASC Topic 718, *Compensation – Stock Compensation*, prescribes accounting and reporting standards for all share-based payment transactions in which employee and non-employee services are acquired. The Company recognizes compensation cost relating to stock-based payment transactions using a fair-value measurement method, which requires all stock-based payments to employees, directors, and non-employee consultants, including grants of stock options, to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. Prior to the Business Combination, the grant date fair value of the Company's common stock was typically be determined by the Company's board of directors with the assistance of management and a third-party valuation specialist.

Subsequent to the Business Combination, the board of directors elected to determine the fair value of the Company's post-merger common stock based on the closing market price at closing on the date of grant. In determining the fair value of stock-based awards, the Company utilizes the Black-Scholes option-pricing model, which uses both historical and current market data to estimate fair value. The Black-Scholes option-pricing model incorporates various assumptions, such as the value of the underlying common stock, the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. For awards with performance-based vesting criteria, the Company estimates the probability of achievement of the performance criteria and recognizes compensation expense related to those awards expected to vest. No awards may have a term in excess of ten years. Forfeitures are recorded when they occur. Stock-based compensation expense is classified in the consolidated statements of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense over the expected term.

Income taxes

Deferred income taxes reflect future tax effects of temporary differences between the tax and financial reporting basis of the Company's assets and liabilities measured using enacted tax laws and statutory tax rates applicable to the periods when the temporary differences will affect taxable income. When necessary, deferred tax assets are reduced by a valuation allowance, to reflect realizable value, and all deferred tax balances are reported as long-term on the consolidated balance sheet. Accruals are maintained for uncertain tax positions, as necessary.

The Company uses a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The Company has elected to treat interest and penalties related to income taxes, to the extent they arise, as a component of income taxes.

Revenue recognition

The Company's revenue is primarily generated through grants from government and other (non-government) organizations.

Grant revenue is recognized during the period that the research and development services occur, as qualifying expenses are incurred or conditions of the grants are met. The Company concluded that payments received under these grants represent conditional, nonreciprocal contributions, as described in ASC 958, *Not-for-Profit Entities*, and that the grants are not within the scope of ASC 606, *Revenue from Contracts with Customers*, as the organizations providing the grants do not meet the definition of a customer. Expenses for grants are tracked by using a project code specific to the grant, and the employees also track hours worked by using the project code.

Comprehensive income

The Company had no items of comprehensive income other than its net loss.

Litigation

From time to time, the Company is involved in legal proceedings, investigations and claims generally incidental to its normal business activities. In accordance with U.S. GAAP, the Company accrues for loss contingencies when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Legal costs in connection with loss contingencies are expensed as incurred.

Earnings per share

In accordance with ASC 260, *Earnings per Share* ("ASC 260"), basic net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common stock outstanding during the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted-average number of common stock outstanding for the period including potential dilutive common shares such as stock options.

Segment reporting

In accordance with ASC 280, *Segment Reporting*, the Company's business activities are organized into one reportable segment, as only the Company's operating results in their entirety are regularly reviewed by the Company's chief operating decision maker to make decisions about resources to be allocated and to assess performance.

Common stock valuations

Prior to the Business Combination, the Company was required to periodically estimate the fair value of its common stock with the assistance of an independent third-party valuation firm, as discussed above, when issuing stock options and computing estimated stock-based compensation expense. The assumptions underlying these valuations represented the Company's best estimates, which involved inherent uncertainties and the application of significant levels of judgment. In order to determine the fair value of its common stock, the Company considered, among other items, previous transactions involving the sale of the Company's securities, the Company's business, financial condition and results of operations, economic and industry trends, the market performance of comparable publicly traded companies, and the lack of marketability of the Company's common stock.

Subsequent to the Business Combination, the Company now determines the fair value of common stock based on the closing market price at closing on the date of grant.

Compensation expense related to stock-based transactions is measured and recognized in the financial statements at fair value of the post-merger common stock based on the closing market price at closing on the date of grant. Stock-based compensation expense is measured at the grant date based on the fair value of the equity award and is recognized as expense over the requisite service period, which is generally the vesting period, on the straight-line method. The Company estimates the fair value of each stock option award on the date of grant using the Black-Scholes option-pricing model. Determining the fair value of stock option awards at the grant date requires judgment, including estimating the expected volatility, expected term, risk-free interest rate, and expected dividends.

(4) New accounting standards

Recently-adopted standards

In May 2021, FASB issued Accounting Standards Update ("ASU") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The amendments in ASU 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this ASU 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, including interim periods within those fiscal years. The Company adopted ASU 2021-04 at January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*. This ASU increases the transparency of government assistance to include the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. The guidance in ASU 2021-10 is effective for financial statements of all entities, including private companies, for annual periods beginning after December 15, 2021, with early application permitted. Entities are required to provide the new disclosures prospectively for all transactions with a government entity that are accounted for under either a grant or a contribution accounting model and are reflected in the financial statements at the date of initially applying the new amendments, and to new transactions entered into after that date. The Company adopted ASU 2021-10 at January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

(5) Reverse Recapitalization and Business Combination

On the Closing Date, BCYP closed the Business Combination with SAB Biotherapeutics, as a result of which SAB Biotherapeutics became a wholly-owned subsidiary of BCYP. While BCYP was the legal acquirer of SAB Biotherapeutics in the Business Combination, for accounting purposes, the Business Combination is treated as a Reverse Recapitalization. SAB Biotherapeutics is treated as the accounting acquirer with historical financial statements of SAB Biotherapeutics becoming the historic financial statements of BCYP (renamed SAB Biotherapeutics, Inc.) upon consummation of the Business Combination. Under this method of accounting, BCYP is treated as the "acquired" company and SAB Biotherapeutics is treated as the acquirer for financial reporting purposes. For accounting reporting purposes, the Business Combination was treated as the equivalent of SAB Biotherapeutics issuing stock for the net assets of BCYP, accompanied by a recapitalization. The net assets of BCYP were stated at historical cost, with no goodwill or other intangible assets recorded.

Pursuant to the Business Combination Agreement, the aggregate consideration payable to stockholders of SAB Biotherapeutics at the Closing Date consisted of 36,465,343 shares of New SAB Biotherapeutics common stock, par value $0.0001 per share ("Common Stock"). Each option of SAB Biotherapeutics that was outstanding and unexercised immediately prior to the Effective Time (whether vested or unvested) was assumed by BCYP and converted into an option to acquire an adjusted number of shares of Common Stock at an adjusted exercise price per share, in each case, pursuant to the terms of the Business Combination Agreement (the "Rollover Options").

Additionally, the Business Combination Agreement included an earnout provision whereby the shareholders of SAB Biotherapeutics shall be entitled to receive additional consideration (“Earnout Shares”) if the Company meets certain Volume Weighted Average Price (“VWAP") thresholds, or a change in control with a per share price exceeding the VWAP thresholds within a five-year period immediately following the Closing.

The Earnout Shares shall be released in four equal increments as follows:

- 25% of the Earnout Shares shall be released if, at any time during the five (5)-year period immediately following the Closing Date, the VWAP of the Company's publicly traded common stock is greater than or equal to $15.00 for any twenty (20) trading days within a period of thirty (30) consecutive trading days (the “First Earnout”).

- 25% of the Earnout Shares shall be released if, at any time during the five (5)-year period immediately following the Closing Date, the VWAP of the Company's publicly traded common stock is greater than or equal to $20.00 for any twenty (20) trading days within a period of thirty (30) consecutive trading days (the “Second Earnout”).

- 25% of the Earnout Shares shall be released if, at any time during the five (5)-year period immediately following the Closing Date, the VWAP of the Company's publicly traded common stock is greater than or equal to $25.00 for any twenty (20) trading days within a period of thirty (30) consecutive trading days (the “Third Earnout”).

- 25% of the Earnout Shares shall be released if, at any time during the five (5)-year period immediately following the Closing Date, the VWAP of the Company's publicly traded common stock is greater than or equal to $30.00 for any twenty (20) trading days within a period of thirty (30) consecutive trading days (the “Fourth Earnout” and together with the First Earnout, the Second Earnout and the Third Earnout, the “Earnouts”).

At the Effective Time, each outstanding share of SAB Biotherapeutics common stock, including shares of SAB Biotherapeutics common stock resulting from the conversion of outstanding shares of SAB Biotherapeutics preferred stock (as calculated pursuant to the SAB Biotherapeutics certificate of incorporation), immediately prior to the Effective Time, was converted into the right to receive a pro rata portion of the total consideration and the contingent right to receive a pro rata portion of the Earnout Shares.

Pursuant to the terms of the Business Combination Agreement, SAB Biotherapeutics’ securityholders (including vested option holders) who own SAB Biotherapeutics securities immediately prior to the Closing Date will have the contingent right to receive their pro rata portion of (i) an aggregate of 12,000,000 shares of Common Stock (“Earnout Shares”), of which 1,508,063 are contingently issuable based upon future satisfaction of the aforementioned VWAP thresholds. The remaining 10,491,937 are legally issued and outstanding, if the Company does not meet the above VWAP thresholds, or a change in control with a per share price below the VWAP thresholds occurs within a five-year period immediately following the Closing Date, the shares will be returned to the Company.

The Earnout Shares are indexed to the Company's equity and meet the criteria for equity classification. On the Closing Date, the fair value of the 12,000,000 Earnout Shares was $101.3 million. The Company reflected the Earnout Shares in the consolidated balance sheet at December 31, 2021 as a stock dividend by reducing additional paid-in capital, which was offset by the increase in additional paid-in capital associated with the Business Combination.

Preceding the Business Combination, on October 12, 2021, BCYP entered into a Forward Share Purchase Agreement (the “Forward Share Purchase Agreement”) with Radcliffe SPAC Master Fund, L.P., a Cayman Islands exempted limited partnership (“Radcliffe”). Under the Forward Share Purchase Agreement, Radcliffe shall sell and transfer to BCYP, and BCYP shall purchase from Radcliffe, up to 1,390,000 shares of common stock owned by Radcliffe at the closing of the Business Combination at a per Share price (the “Purchase Price”) equal to $10.10 per share (the "Market Sales Price"). Further, BCYP shall purchase the remaining shares held by Radcliffe not sold in the open market in excess of the Market Sales Price at the later of (a) the 90th day after the closing of the Business Combination, or (b) the first business day following the 95th day after the closing of the Business Combination if BCYP directs Radcliffe to sell shares at a mutually agreed upon price other than the Market Sales Price. As of the Closing Date, 1,296,891 shares of common stock were held by Radcliffe under the Forward Share Purchase Agreement.

Pursuant to the treatment of the Business Combination as a reverse recapitalization, SAB Biotherapeutics assumed the liability position as it existed as of the Effective Time. The net assets of the acquired entity were adjusted to include a forward share purchase liability of $13,098,599. In connection with the Business Combination, an amount matching the assumed forward share purchase liability was transferred into escrow, pending final settlement of the Forward Share Purchase Agreement in January 2022. Given the short-term nature of the Forward Share Purchase Agreement, the Company did not present value the forward share purchase liability. Subsequent settlements whereby Radcliffe sold shares in the open market in excess of the Market Sales Price were treated as a reduction in the assumed forward share purchase liability, with an offsetting increase in equity of the Company. Prior to December 31, 2021, a portion of the forward share purchase liability was settled. As of December 31, 2021, the forward share purchase liability balance was $6,338,306 on the consolidated balance sheet. The forward share purchase liability was fully settled during the year ended December 31, 2022.

The following table reconciles the elements of the Business Combination to the consolidated statement of cash flows for the year ended December 31, 2021:

	Recapitalization
Cash - BCYP trust and cash, net of redemptions	$ 22,535,723
Plus: restricted cash - Forward Share Purchase Agreement	13,098,599
Less: cash transaction costs allocated to the Company's equity	(1,294,097)
Total	$ 34,340,225

The following table reconciles the elements of the Business Combination to the consolidated statement of changes in redeemable preferred stock and stockholders' equity for the year ended December 31, 2021:

	Recapitalization
Cash - BCYP trust and cash, net of redemptions	$ 22,535,723
Plus: restricted cash - Forward Share Purchase Agreement	13,098,599
Less: non-cash net working capital assumed from BCYP	(5,067,682)
Less: forward share purchase liability assumed from BCYP	(13,098,599)
Less: fair value of redeemable warrants	(6,569,062)
Less: transaction costs allocated to the Company's equity	(3,294,096)
Total	$ 7,604,883

The following table details the number of shares of common stock issued immediately following the consummation of the Business Combination:

	Shares
Common stock, redeemable and outstanding prior to Business Combination	11,500,000
Less: redemption of BCYP shares	(8,030,289)
Common stock of BCYP	3,469,711
BCYP Founder and private shares	3,292,200
Shares issued for services	247,525
Total BCYP shares	7,009,436
SAB Biotherapeutics, Inc and subsidiaries shareholders	36,465,343
Total shares of common stock immediately after Business Combination	43,474,779

The following table details the allocated assets acquired and liabilities assumed as follows:

Assets Acquired	
BCYP trust and cash, net of redemptions	$ 22,535,723
Restricted cash - Forward Share Purchase Agreement	13,098,599
Other assets	102,742
Assets acquired	$ 35,737,064
Liabilities Assumed	
Forward share purchase liability	$ 13,098,599
Fair value of redeemable warrants	6,569,062
Other liabilities and accrued expenses	5,170,424
Liabilities assumed	24,838,085
Net Assets Acquired	$ 10,898,979

(6) Revenue

During the years ended December 31, 2022 and 2021, the Company worked on the following grants:

Government grants

The total revenue for government grants was approximately $23.9 million and $60.9 million respectively, for the years ended December 31, 2022 and 2021.

NIH-NIAID (Federal Award #1R44AI117976-01A1) – this grant was for $1.4 million and started in September 2019 through August 2021. The grant was subsequently amended to extend the date through August 2022. For the years ended December 31, 2022 and 2021, there was approximately $182,000 and $518,000, respectively, in grant income recognized. This grant was completed in 2022.

NIH-NIAID (Federal Award #1R41AI131823-02) – this grant was for approximately $1.5 million and started in April 2019 through March 2021. The grant was subsequently amended to extend the date through March 2023. For the years ended December 31, 2022 and 2021, there was approximately $328,000 and $51,000 respectively, in grant income recognized. There is approximately $429,000 in funding remaining for this grant as of December 31, 2022.

NIH-NIAID through Geneva Foundation (Federal Award #1R01AI132313-01, Subaward #S-10511-01) – this grant was for approximately $2.7 million and started in August 2017 through July 2021. This grant was subsequently amended to extend the date through July 2023. For the years ended December 31, 2022 and 2021, there was approximately $1,052,000 and $94,000, respectively, in grant income recognized from this grant. The corporation applied for an extension on the grant funding, and the extension is pending approval. If approved, there is approximately $0.4 million in funding remaining for this grant as of December 31, 2022.

DoD, JPEO through Advanced Technology International – this grant was for a potential of $25 million, awarded in stages starting in August 2019 and with potential stages running through February 2023. Additional contract modifications were added to this contract in 2020 and 2021 for work on a COVID therapeutic, bringing the contract total to $203.6 million. For the years ended December 31, 2022 and 2021, there was approximately $22.2 million and $60.2 million, respectively, in grant income recognized from this grant. This grant was terminated in 2022.

The grants for the JPEO contract are cost reimbursement agreements, with reimbursement of our direct research and development expense (labor and consumables) with an overhead charge (based on actual, reviewed quarterly) and a fixed fee (9%).

On August 3, 2022, the Company received noticed from the DoD to terminate the JPEO Rapid Response contract, dated as of August 7, 2019 with the DoD most recently amended as of September 14, 2021, relating to a prototype research and development of Rapid Response Antibody Program and advanced clinical development through licensure and commercial manufacturing for SAB-185 (the "JPEO Rapid Response Contract Termination"). The Company engaged in negotiations with the DoD to compensate the Company for services provided prior to the JPEO Rapid Response Contract Termination and costs the Company would be expected to bear in future periods.

(7) Earnings per share

Since the Company reported a net loss for the years ended December 31, 2022 and 2021, it was required by ASC 260 to use basic weighted-average shares outstanding when calculating diluted net loss per share for the years ended December 31, 2022 and 2021, as the potential dilutive securities are anti-dilutive.

	2022	2021
Calculation of basic and diluted loss per share attributable to the Company's shareholders		
Net loss attributable to the Company's shareholders	$ (18,740,804)	$ (17,144,531)
Weighted-average common shares outstanding – basic and diluted	43,524,971	27,339,180
Net loss per share, basic and diluted	$ (0.43)	$ (0.63)

The shares in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Year Ended December 31,	
	2022	2021
Stock options and awards	2,193,365	3,724,957
Convertible debt	368,298	—
Common stock warrants (1)	5,958,600	5,958,600
Earnout Shares (2)	10,491,937	10,491,937
Contingently issuable Earnout Shares from unexercised Rollover Options	1,508,063	1,508,063
Total	20,520,263	21,683,557

(1) The PIPE Warrants and Placement Agent Warrants to purchase 7,363,377 and 210,193 shares of common stock, respectively, are excluded from the calculation of diluted earnings per share as they are not exercisable until June 7, 2023.

(2) As the Earnout shares are subject to certain vesting requirements not satisfied as of the year ended December 31, 2022, the Earnout Shares held in escrow are excluded from calculating both basic and diluted earnings per share.

(8) Property, plant and equipment, net

As of December 31, 2022 and 2021, the Company's equipment was as follows:

	2022	2021
Laboratory equipment	$ 9,000,114	$ 7,431,988
Animal facility	8,357,667	8,357,667
Animal facility equipment	1,141,213	1,253,879
Construction-in-progress	308,317	4,608,778
Leasehold improvements	9,296,343	5,700,364
Vehicles	192,683	135,593
Office furniture and equipment	1,233,038	46,202
Less: accumulated depreciation and amortization	6,278,522	3,220,016
Property, plant and equipment, net	$ 23,250,853	$ 24,314,455

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $3,169,429 and $1,488,614, respectively.

All tangible personal property with a useful life of at least three years and a unit acquisition cost of $5,000 or more will be capitalized and depreciated over its useful life using the straight-line method of depreciation. The Company will expense the full acquisition cost of tangible personal property below these thresholds in the year of purchase. The basis of accounting for depreciable fixed assets is acquisition cost and any additional expenditures required to make the asset ready for use. The carrying amount at the balance sheet date of long-lived assets under construction-in-progress includes assets purchased, constructed, or being developed internally that are not yet in service. Depreciation commences when the assets are placed in service.

The Company has several ongoing construction projects related to the expansion of its operating capacity. As of December 31, 2022 and 2021, the Company's construction-in-progress was as follows:

	2022	2021
New office space at Headquarters	$ 85,767	$ 11,183
Laboratory space at Headquarters	—	2,506,482
Laboratory equipment at Headquarters	—	246,801
IT equipment at Headquarters	84,739	212,209
Software	137,811	137,811
Bioreactors	—	1,280,728
Other	—	213,564
Total construction-in-progress	$ 308,317	$ 4,608,778

(9) Leases

The Company has an operating lease for lab space from Sanford Health, under a lease that started in June 2014 and ran through June 2019, at which time the lease was amended to run through August 2024. This lease can be terminated with one year advance written notice. This lease was amended again in October 2022 to reduce the Company's leased area to 21,014 square feet. Additionally, pursuant to the amendment in October 2022, the Company and Sanford Health agreed for the period of October 2022 to September 2023, the Company's obligation to pay the Annual Rent shall be abated and not required to be paid when normally due (the "Abated Rent"). In exchange for the Abated Rent, effective October 1, 2022, the Company issued Sanford Health an 8% unsecured, convertible promissory note (see Note 11, *Notes Payable* for further discussion). The October 2022 amendment was accounted for as a lease modification under ASC 842 - *Leases* and the right-of-use asset and lease liability were remeasured at the modification date of October 1, 2022. The re-measurement of the lease resulted in a $480,000 decrease in the noncurrent portion of the operating lease liability, a $448,000 decrease in the operating right-of-use asset and a $32,000 gain reflected in other income. The October 2022 lease amendment reduced the lease payment to $44,252 per month. The lease does not provide an implicit rate, and, therefore, the Company used an IBR of 6.92% as the discount rate when measuring the operating lease liability. The operating lease does not include an option to extend beyond the life of the current term. The Company estimated the incremental borrowing rate based upon comparing interest rates available in the market for similar borrowings and the credit quality of the Company.

The Company entered into a lease for office, laboratory, and warehouse space in November 2020, the lease was amended in July 2022 to add additional administrative and lab space. This amended lease has a 3-year term, with options to extend for 3 additional periods of 3 years each. The options were not included in the right of use calculation as it is unclear as to whether or not the location will meet the Company's requirements beyond the next three years. The July 2022 amendment was accounted for as a separate contract under ASC 842 – *Leases*. The lease costs are $36,125 and $2,747 per month for the original leased space on November 2020 and the amendment on July 2022, respectively. The Company used an IBR of 4.69% and 6.60% as the discount rate when measuring the operating lease liability for the original leased space on November 2022 and the amended on July 2022, respectively. The Company estimated the incremental borrowing rate based upon comparing interest rates available in the market for similar borrowings and the credit quality of the Company.

The Company entered into a lease for barn space for the housing of goats in April 2020. This lease has a 2-year term, with automatic renewals for a one-year period after the initial term expires until either party terminates. The options were not included in the right of use calculation, as the goat project is mostly funded by government grants, and those grants do not currently extend beyond the initial lease term. The lease cost is $665 per month for the first year, then $678 per month for the second year. The Company used an IBR of 4.08% as the discount rate when measuring the operating lease liability. The Company estimated the incremental borrowing rate based upon comparing interest rates available in the market for similar borrowings and the credit quality of the Company. The operating lease ended in 2022 and is now classified as a short-term lease with a one-year annual renewal.

The Company has the following finance leases:

- In December 2018, the Company entered into a finance lease with Dakota Ag Properties for a new animal facility which includes the surrounding land. The facility and the land have been accounted for as separate lease components. The lease is based upon payback of $4,000,000 in construction costs, with a 20-year term at an interest rate of 8%. The monthly payment for this lease is $33,458. The Company has the option to purchase the asset at any time during the term of the lease for the balance of the unamortized lease payments.
- In December 2018, the Company entered into an equipment lease for a 12,000-gallon propane tank that is located on the Company's animal facility. The lease is for five years, with an annual payment of $8,199. The Company purchased the propane tank in November 2022.
- In July 2018, the Company entered into a lease agreement with a bank, for a Ruby Cell Analyzer. The lease agreement is for a five-year term. The monthly payment for this lease is $807. The Company purchased the Ruby Cell Analyzer in December 2022.
- In March 2019, the Company entered into two lease agreements for laboratory equipment. The leases are each for a 3-year term and a combined monthly payment of $5,956. Both leases have a $1 purchase option at the end of the lease term.

The lease agreements do not require material variable lease payments, residual value guarantees or restrictive covenants.

The amortizable lives of the operating lease assets are limited by their expected lease terms. The amortizable lives of the finance lease assets are limited by their expected lives, as the Company intends to exercise the purchase options at the end of the leases. The following is the estimated useful lives of the finance lease assets:

(in years)	
Animal Facility	40
Equipment	3 –7
Land	Indefinite

The Company's weighted-average remaining lease term and weighted-average discount rate for operating and finance leases as of December 31, 2022 are:

	Operating	Finance
Weighted-average remaining lease term (in years)	1.30	15.90
Weighted-average discount rate	6.00%	7.72%

The table below reconciles the undiscounted future minimum lease payments under non-cancelable leases with terms of more than one year to the total lease liabilities recognized on the consolidated balance sheet as of December 31, 2022:

	Operating	Finance
2023 - remaining	$ 528,520	$ 406,339
2024	368,318	401,496
2025	—	401,496
2026	—	401,496
2027	—	401,496
Thereafter	—	4,382,998
Undiscounted future minimum lease payments	896,838	6,395,321
Less: Amount representing interest payments	(44,819)	(2,632,891)
Total lease liabilities	852,019	3,762,430
Less current portion	(490,794)	(132,788)
Noncurrent lease liabilities	$ 361,225	$ 3,629,642

Operating lease expense was approximately $1.2 million and $1.1 million, respectively, for the years ended December 31, 2022 and 2021. Operating lease costs are included within research and development expenses on the consolidated statements of operations.

Finance lease costs for the years ended December 31, 2022 and 2021 included approximately $122,000 and $165,000, respectively, in right-of-use asset amortization and approximately $284,000 and $296,000, respectively, of interest expense. Finance lease costs are included within research and development expenses on the consolidated statements of operations.

Cash payments under operating and finance leases were approximately $1.2 million and $0.4 million, respectively, for the year ended December 31, 2022. Cash payments under operating and finance leases were approximately $1.1 million and $0.5 million, respectively, for the year ended December 31, 2021.

(10) Accrued Expenses and Other Current Liabilities

As of December 31, 2022 and 2021, accrued expenses and other current liabilities consisted of the following:

	2022	2021
Accrued vacation	$ 511,849	$ 552,629
Accrued payroll	357,390	674,858
Accrued construction-in-progress	85,767	548,988
Accrued supplies	—	709,027
Accrued consulting	186,833	179,082
Accrued clinical trial expense	355,479	423,634
Accrued outside laboratory services	1,106,903	128,752
Accrued bonus & severance	950,324	1,804,288
Accrued contract manufacturing	25,129	1,000,824
Accrued legal	856,505	833,646
Accrued financing fees payable	4,910,500	5,100,000
Accrued franchise tax payable	50,000	216,251
Accrued interest	8,192	—
Other accrued expenses	513,110	283,909
	$ 9,917,981	$ 12,455,888

(11) Notes Payable

As of December 31, 2022 and 2021, notes payable was as follows:

	2022	2021
Tractor loan	$ —	$ 25,013
Insurance financing note payable	772,665	1,771,711
8% Unsecured Convertible Note	541,644	—
Total notes payable	1,314,309	1,796,724
Less: notes payable - current portion	772,665	1,796,724
Notes payable, noncurrent	$ 541,644	$ —

In December 2017, the Company entered into a loan agreement for the purchase of a tractor for $116,661 at a 3.6% interest rate. The loan included annual payments of $25,913 for the next five years starting in December 2018. The tractor loan was paid off in full in November 2022.

On March 27, 2020, President Trump signed into law the CARES Act. In April 2020, the Company entered into a loan agreement (the “PPP Loan”) with First Premier Bank under the Paycheck Protection Program (the “PPP”), which is part of the CARES Act administered by the United States Small Business Administration (“SBA”). As part of the application for these funds, the Company, in good faith, certified that the current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. The certification further requires the Company to take into account its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. Under the PPP, the Company received proceeds of approximately $661,612. In accordance with the requirements of the PPP, the Company utilized the proceeds from the PPP Loan primarily for payroll costs. The PPP Loan has a 1.00% interest rate per annum, matures in April 2022 and is subject to the terms and conditions applicable to loans administered by the SBA under the PPP. Under the terms of PPP, all or certain amounts of the PPP Loan may be forgiven if they are used for qualifying expenses, as described in the CARES Act. The Company recorded the entire amount of the PPP Loan as debt. In February 2021, the Company submitted a forgiveness application related to its PPP Loan. In March 2021, the SBA approved the forgiveness of the PPP Loan, plus accrued interest. The Company recorded a gain on extinguishment of PPP Loan of $665,596 for the forgiveness of the PPP Loan and accrued interest within gain on debt extinguishment of Paycheck Protection Program SBA Loan on the consolidated statement of operations for the year ended December 31, 2021.

8% Unsecured Convertible Note

Additionally, pursuant to the Fourth Amendment to the Company's lease with Sanford Health, the Company and Sanford Health agreed to a period of Abated Rent from October 1, 2022 to September 30, 2023. In exchange for the Abated Rent, effective as of October 1, 2022, the Company issued to Sanford Health an 8% unsecured, convertible promissory note (the "8% Unsecured Convertible Note").

Pursuant to the October Note, the Company shall pay the sum of $541,644 (the “Principal”) plus accrued and unpaid interest thereon on September 31, 2024 (the “Maturity Date”). Simple interest shall accrue on the outstanding Principal from and after the date of the October Note, and shall be payable on the Maturity Date. Sanford Health shall have the right, but not the obligation, to convert all or any part of the outstanding Principal of the October Note, together with any accrued and unpaid interest thereon to the date of such conversion, into such number of fully paid and non-assessable shares of the Company’s common stock, at any time and from time to time, prior to the later of the Maturity Date and the date on which the October Note is paid in full, subject to certain restrictions, at a conversion price per share of Common Stock equal to greater of (x) $1.50 and (y) the price at which the Company sells shares of common stock in any bona fide private or public equity financing prior to the Maturity Date.

The Company evaluated the treatment of the 8% Unsecured Convertible Note under ASC 470 and ASU 2020-06 (early adopted by the Company as of January 1, 2021) and determined the Note in its entirety would be allocated to debt without separating the nonconvertible debt. The Company's consolidated balance sheet as of December 31, 2022 includes accrued interest of approximately $8,000

Insurance Financing

The Company obtained financing for certain Director & Officer liability insurance policy premiums. The agreement assigns First Insurance Funding (Lender) a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies including (a) all returned or unearned premiums, (b) all additional cash contributions or collateral amounts assessed by the insurance companies in relation to the financed policies and financed by Lender, (c) any credits generated by the financed policies, (d) dividend payments, and (e) loss payments which reduce unearned premiums. If any circumstances exist in which premiums related to any Financed Policy could become fully earned in the event of loss, Lender shall be named a loss-payee with respect to such policy.

The total premiums, taxes and fees financed is approximately $1,236,000 with an annual interest rate of 5.47%. In consideration of the premium payment by Lender to the insurance companies or the Agent or Broker, the Company unconditionally promises to pay Lender the amount Financed plus interest and other charges permitted under the Agreement. At December 31, 2022 and 2021 the Company recognized approximately $773,000 and $1,772,000, respectively, as an insurance financing note payable in its consolidated balance sheets. The Company will pay the insurance financing through installment payments with the last payment for the current note being on September 22, 2023.

(12) Preferred Stock

On the Closing Date, pursuant to the Business Combination (as described in Note 5), 17,750,882 outstanding shares of Preferred Stock were automatically converted into 8,259,505 shares of common stock pursuant to the Exchange Ratio.

In addition, upon the closing of the Business Combination, pursuant to the terms of the Second Amended and Restated Certificate of Incorporation, the Company authorized 10,000,000 shares of preferred stock with a par value $0.0001.

Prior to the Business Combination, in August 2019, the Company's Certificate of Incorporation was amended to authorize the Company to issue 50,000,000 shares of preferred stock, of which 6,615,000 shares were designated as Series A preferred stock, 2,525,800 shares were designated as series A-1 preferred stock, 4,039,963 shares were designated as series A-2 preferred stock, 3,333,333 shares were designated as series A-2A preferred stock, and 8,571,429 shares were designated as series B preferred stock. The carrying value of Series A preferred stock was $1 per share, Series A-1 $1.88 per share, Series A-2 & A-2A $3.00 per share, and Series B $3.50 per share.

The preferred stock was entitled to receive noncumulative dividends in preference to any dividend on the common stock when, as, and if declared by the Company's board of directors. The holders of the preferred stock also were entitled to participate pro rata in any dividends paid on the common stock on an as-if-converted basis.

Each holder of preferred stock was entitled to the number of votes equal to the number of shares of common stock that it could be converted into. As long as there were 8,000,000 shares of preferred stock outstanding, the vote or written consent of the holder of the majority of the outstanding preferred stock (all series voting as a single class) was required to approve any amendment of the certificate of incorporation that changes voting, preferences or privileges or restrictions of the preferred stock.

In the event of liquidation or winding up of the Company, the preferred stockholders also were entitled to receive in preference to the holders of the common stock the greater of: a) a per share amount equal to their respective original purchase price plus any declared but unpaid dividends (the "Liquidation Preference"); or b) the amount to be paid on the common stock on an as-if-converted basis. The remaining assets would be distributed to the common stockholders.

The holders of preferred stock had the right to convert the preferred stock into common stock, at any time, utilizing the then- effective conversion rate. The effective conversion rate prior to the Business Combination was 1:1. All preferred shares were automatically converted into common shares utilizing the then effective preferred conversion rate upon: a) the closing of the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, covering the sale of the Company's common stock if gross proceeds are at least $20,000,000 and the Company's shares have been listed on a stock exchange, as defined; or b) the election of the holders of a majority of the outstanding shares of preferred stock.

With any change of control of the Company or financing, the preferred stockholders were to approve through majority vote any such change in control or financing event approved by the board of directors or the majority of the common stockholders. The preferred stock contained certain anti-dilution provisions, as defined.

(13) Stock Option Plans

On August 5, 2014, the Company approved a stock option grant plan (the "2014 Equity Incentive Plan") for employees, directors, and non-employee consultants, which provides for the issuance of options to purchase common stock. The total shares authorized under the plan was originally 8,000,000; however, during 2019, the Plan was amended to increase the total shares authorized under the plan to 16,000,000. As a result of the Business Combination, the 2014 Equity Incentive Plan was amended to reduce the shares authorized to 7,444,800 based upon the impact of the Exchange Ratio.

As a result of the Business Combination, the Company adopted the 2021 Omnibus Equity Incentive Plan (hereinafter collectively with the 2014 Equity Incentive Plan referred to as the "Equity Compensation Plans"), representing 11,000,000 shares of common stock reserved for issuance upon exercise of stock options. As of the beginning of the 2022 calendar year, the shares reserved for future issuance increased by, 869,746, or two percent (2%) of the total number of shares of Common Stock issued and outstanding, to a total of 11,869,746 shares of common stock reserved for issuance under the 2021 Omnibus Equity Incentive Plan

The expected term of the stock options was estimated using the "simplified" method, as defined by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*. The volatility assumption was determined by examining the historical volatilities for industry peer companies, as the Company does not

have sufficient trading history for its common stock. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the options. The dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Therefore, the Company has assumed no dividend yield for purposes of estimating the fair value of the options.

Stock Options

Stock option activity for employees and non-employees under the Equity Compensation Plans for the year ended December 31, 2022:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding options, December 31, 2021	5,107,672	$ 2.44	5.78	$ 28,948,535
Granted	2,934,051	$ 1.54		
Forfeited	(855,007)	$ 3.32		
Exercised	(90,264)	$ 0.85		
Expired	(990)	$ 4.97		
Outstanding options, December 31, 2022	7,095,462	$ 1.99	5.79	$ 109,891
Options vested and exercisable at December 31, 2022	4,269,351	$ 1.84	3.36	$ 109,891

Total unrecognized compensation cost related to non-vested stock options as of December 31, 2022 was approximately $4.2 million and is expected to be recognized within future operating results over a weighted-average period of 3.17 years.

The weighted average grant date fair value of options granted during the year ended December 31, 2022 and 2021, was $0.78 and $5.36 per share, respectively. During the year ended December 31, 2022 and 2021, 634,658 shares with a fair value totaling $3.1 million, and 461,701 shares with a fair value totaling $1.7 million, respectively, vested.

The estimated fair value of stock options granted during to employees and consultants for the years ended December 31, 2022 and 2021, were calculated using the Black-Scholes option-pricing model using the following assumptions:

	2022	2021
Expected volatility	78.0 - 97.4%	75.9 - 104.3%
Weighted-average volatility	94.1%	92.8%
Expected dividends	—%	—%
Expected term (in years)	5.50 - 6.08	6.25
Risk-free rate	1.38 - 3.56%	0.14 - 1.38%

Restricted Stock

Restricted stock unit activity for employees and non-employees under the Equity Compensation Plans for the year ended December 31, 2022 was as follows:

	Number of shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2021	—	$ —
Granted	350,000	$ 1.72
Vested	—	$ —
Forfeited	—	$ —
Unvested as of December 31, 2022	350,000	$ 1.72

At December 31, 2022, the Company had an aggregate of $519,000 of unrecognized equity-based compensation related to restricted stock units outstanding. The unrecognized expense for restricted stock units is expected to be recognized over a weighted average period of 3.46 years.

Stock-based compensation expense for the years ended December 31, 2022 and 2021 was as follows:

	2022	2021
Research and development	$ 857,331	$ 964,926
General and administrative	1,816,873	1,349,756
Total	$ 2,674,204	$ 2,314,682

(14) Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The following fair value hierarchy classifies the inputs to valuation techniques that would be used to measure fair value into one of three levels:

Level 1: Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis at December 31, 2022 and 2021, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair values:

	As of December 31, 2022			
	Total	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Liabilities:				
Public Warrant liability	$ 310,500	$ 310,500	$ —	$ —
Private Placement Warrant liability	$ 10,430	—	—	10,430
Total	$ 320,930	$ 310,500	$ —	$ 10,430

	As of December 31, 2021			
	Total	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Liabilities:				
Public Warrant liability	$ 10,292,500	$ 10,292,500	$ —	$ —
Private Placement Warrant liability	$ 427,630	—	—	427,630
Total	$ 10,720,130	$ 10,292,500	$ —	$ 427,630

Public Warrants

Each whole Public Warrant entitles the holder to purchase one share of the Company's common stock at a price of $11.50 per share, subject to adjustment as discussed herein. The Public Warrants became exercisable 30 days after the Closing Date of the Business Combination, and will expire five years after the Closing Date of the Business Combination, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

Once the warrants become exercisable, the Company may call the warrants for redemption:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption (the "30-day redemption period") to each warrant holder; and
- if, and only if, the reported last sale price of the common stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending three business days before the Company sends the notice of redemption to the warrant holders.

If the Company calls the warrants for redemption as described above, the management will have the option to require any holder that wishes to exercise its warrant to do so on a "cashless basis." If the management takes advantage of this option, all holders of warrants would pay the exercise price by surrendering their warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the excess of the "fair market value" (defined below) over the exercise price of the warrants by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of the common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants.

As of December 31, 2022, 5,750,000 Public Warrants classified as liabilities were outstanding.

Private Placement Warrants

The Private Placement Warrants and the common stock issuable upon the exercise of the Private Placement Warrants were not transferable, assignable or saleable until after the completion of the Company's Business Combination. Additionally, the Private Placement Warrants will be exercisable on a cashless basis and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

As of December 31, 2022, 208,600 Private Placement Warrants classified as liabilities were outstanding.

PIPE Private Placement Warrants and PIPE Placement Agent Warrants

In December 2022, the Company entered into a Securities Purchase Agreement with certain institutional and accredited investors for the sale by SAB of 7,363,377 Shares, 7,363,377 Warrants, and in a private placement offering. The combined purchase price per Share and accompanying warrant was $1.08. Three directors of the Company participated in the Private Placement, each paying a $0.125 premium per Share and accompanying warrants, (the "PIPE Private Placement Warrants"). The PIPE Private Placement Warrants, including those purchased by the participating directors of SAB are exercisable beginning six months from the date of issuance at an exercise price equal to $1.08 per Share, and are exercisable for five years from the date of issuance. SAB received gross proceeds of approximately $8.0 million before deducting transaction related fees and expenses. SAB paid Brookline Capital Markets, the placement agent, a cash fee equal to seven percent of the gross proceeds received by SAB in the Private Placement. SAB also issued Brookline Capital Markets a warrant to purchase up to an aggregate of 210,913 shares of Common Stock (the "PIPE Placement Agent Warrants"), equal to seven percent of the number of Shares purchased by Investors introduced to the Company by Brookline Capital Markets. The Placement Agent Warrants have an exercise price equal to $1.35 per share and are exercisable six months from the date of issuance and expires five years from the date of issuance.

As of December 31, 2022, 7,363,377 PIPE Private Placement Warrants and 210,913 PIPE Placement Agent Warrants classified as equity were outstanding.

Presentation and Valuation of the Warrants

Liability Classified Warrants

The Public Warrants and Private Placement Warrants are accounted for as liabilities in accordance with ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* and were presented within warrant liabilities on the consolidated balance sheet as of December 31, 2022 and December 31, 2021. The initial fair value of the warrant liabilities were measured at fair value at the Closing Date, and changes in the fair value of the warrant liabilities were presented within changes in fair value of warrant liabilities in the consolidated statement of operations for the years ended December 31, 2022 and December 31, 2021.

On the Closing Date, the Company established the fair value of the Private Placement Warrants utilizing both the Black-Scholes Merton formula and a MCS analysis. Specifically, the Company considered an MCS to derive the implied volatility in the publicly-listed price of the Public Warrants. The Company then considered this implied volatility in selecting the volatility for the application of a Black-Scholes Merton model for the Private Placement Warrants. The Company determined the fair value of the Public Warrants by reference to the quoted market price.

The Public Warrants were classified as a Level 1 fair value measurement, due to the use of the quoted market price, and the Private Placement Warrants held privately by Big Cypress Holdings LLC, a Delaware limited liability company which acted as the Company's sponsor in connection with the IPO (the "Sponsor"), were classified as a Level 3 fair value measurement, due to the use of unobservable inputs.

Equity Classified Warrants

The Company determined the PIPE Private Placement Warrants and PIPE Placement Agent Warrants met all necessary criteria to be accounted for as equity in accordance with ASC 815- 40, *Derivatives and Hedging— Contracts in Entity' s Own Equity.* As such, they are presented within additional paid-in capital within Company's consolidated statements of changes in stockholders' equity (deficit) and consolidated balance sheets.

Warrants classified as equity are initially measured at fair value. Subsequent changes in fair value are not recognized as long as the warrants continue to be classified as equity.

Warrants classified as equity are initially measured at fair value. Subsequent changes in fair value are not recognized as long as the warrants continue to be classified as equity. The initial fair value of each PIPE Private Placement Warrant and PIPE Placement Agent Warrant issued has been determined using the Black-Scholes option-pricing model. All relevant terms and conditions for the PIPE Private Placement Warrant and PIPE Placement Agent Warrant are identical with the exception of the exercise prices of $1.08 and $1.35, respectively; the key inputs into the valuations as of the initial measurement date were as follows:

	Initial Measurement
Risk-free interest rate	3.62%
Expected term remaining (years)	5.00
Implied volatility	89.0%
Closing common stock price on the measurement date, less discount for lack of marketability (1)	$ 0.66

(1) As the underlying shares are restricted from sale for a period of 180 days from the date of the 2022 Private Placement, the fair value of the warrants were estimated using the Black-Scholes option pricing model that uses several inputs, including market price of the Company's common shares at the end of each reporting period (a level one input), less a discount for lack of marketability (a level two input). The discount for lack of marketability was estimated upon consideration of volatility and the length of the lock-up period.

Upon initial measurement, the fair value of the PIPE Private Placement Warrants and PIPE Placement Agent Warrants were determined to be $0.42 and $0.39, respectively, per warrant for aggregate values of approximately $3,072,000 and $82,000, respectively. In the Private Placement, the Company recognized the PIPE Private Placement Warrants and PIPE Placement Agent Warrants on a relative fair value basis with approximately $2.2 million and $58,000 being allocated to each as a component of additional paid-in capital within the Company's consolidated statements of changes in stockholders' equity (deficit) and consolidated balance sheets.

The following table provides a summary of the changes in the Company's Level 3 fair value measurements:

Initial measurement on the Closing Date	$ 244,062
Change in fair value of Private Placement Warrant liability	183,568
Balance, December 31, 2021	427,630
Change in fair value of Private Placement Warrant liability	(417,200)
Balance, December 31, 2022	$ 10,430

The measurement as of December 31, 2021 for the Public Warrant liability was approximately $428,000 and the change in fair value of the Public Warrant liability was approximately $417,000 for the year ended December 31, 2022.

The key inputs into the valuations as of December 31, 2022 and 2021 were as follows:

	December 31, 2022	December 31, 2021
Risk-free interest rate	4.00%	1.24%
Expected term remaining (years)	3.81	4.81
Implied volatility	82.0%	43.0%
Closing common stock price on the measurement date	$ 0.59	$ 7.81

As of December 31, 2022 and 2021, the Company did not have any other assets or liabilities that are recorded at fair value on a recurring basis.

The Company believes that the carrying amounts of its cash and cash equivalents, accounts receivable, and notes payable approximate their fair values due to their near-term maturities.

(15) Income Taxes

Net deferred tax assets as of December 31, 2022 and 2021 consisted of the following:

	2022	2021
Deferred tax assets:		
Tax Carryforwards	$ 5,576,496	$ 5,078,429
Compensation Accruals	1,781,746	1,255,535
Amortizable R&D Intangibles	7,243,110	—
Other Deferred Tax Assets	1,220,784	2,040,143
Total deferred tax assets	15,822,136	8,374,107
Less valuation allowance	(12,330,481)	(5,300,689)
Total deferred tax assets	$ 3,491,655	$ 3,073,418
Deferred tax liabilities:		
PPE	3,240,489	2,521,871
Other Deferred Tax Liabilities	251,166	551,547
Total deferred tax liabilities	3,491,655	3,073,418
Net deferred tax asset (liability)	$ —	$ —

The reconciliation between the Company's effective tax rate and the statutory tax rate of 21% includes the following significant items: changes in the valuation allowance and permanent items including meals and entertainment. The rate reconciliation was as follows:

	2022		2021	
Rate reconciliation:				
Net (loss) income before tax	$ (18,715,175)		$ (17,144,531)	
Federal income tax at statutory rate	(3,930,187)	21.00%	(3,600,352)	21.00%
Permanent items	(2,207,588)	12.79%	1,029,874	(6.01)%
Valuation allowance	7,029,790	(39.04)%	2,679,238	(15.63)%
Other	(866,386)	5.05%	(108,760)	0.64%
	$ 25,629	(0.20)%	$ —	(0.00)%

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the level of historical losses and the uncertainty of future taxable income over the periods which the Company will realize the benefits of its net deferred tax assets, management believes it is more likely than not that the Company will not fully realize the benefits on the balance of its net deferred tax asset and, accordingly, the Company has established a valuation allowance on its net deferred tax assets. The valuation allowance increased by approximately $7.0 million and approximately $3.0 million, respectively, for the years ended December 31, 2022 and 2021.

As of December 31, 2022, the Company had approximately $22.0 million of federal net operating losses, which were generated after December 31, 2017 and can be carried forward indefinitely under the Tax Act and may generally be used to offset up to 80% of future taxable income. In addition, the Company had federal tax credit carryforwards of approximately $938,000 and approximately $0, respectively for years ended December 31, 2022 and 2021 which are available to reduce future federal income taxes through 2042.

Prior to 2022, taxpayers had the option under Section 174 of the Internal Revenue Code to either deduct their research and development costs or capitalize and amortize such costs over a period of not less than 60 months. As part of the tax law changes in the Tax Act enacted in 2017, starting with tax years beginning after December 31, 2021, Congress requires taxpayers to capitalize expenditures that qualify as Section 174 research and development costs and recover them over 5 years for expenditures attributed to domestic research and 15 years for expenditures attributed to foreign research. The 2022 effective income tax rate was impacted by the Section 174 capitalization requirement combined with the restriction on net operating losses to only reduce taxable income by 80%.

U.S. GAAP provides that the tax effects from uncertain tax positions can be recognized in the consolidated financial statements only if the position is more likely than not of being sustained on audit, based on the technical merits of the position. As of December 31, 2022 and 2021, there were no uncertain tax provisions. There was no interest or penalties related to income taxes for the years ended December 31, 2022 and 2021, and there was no accrued interest or penalties associated with uncertain tax positions as of December 31, 2022 and 2021.

The Company files tax returns as prescribed by the laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company's tax years are still open under the statute from 2019 to present. However, to the extent allowed by law, the taxing authorities may have the right to examine the period from 2016 through 2022 where net operating losses were generated and carried forward and make adjustments to the amount of the net operating loss carryforward amount. The Company is not currently under examination by federal or state jurisdictions.

On August 16, 2022, the President of the United States signed and enacted into law the *Inflation Reduction Act* ("IRA"). Among other provisions, the IRA directs new federal spending toward reducing carbon emissions, lowering healthcare costs, funding the Internal Revenue Service, and improving taxpayer compliance. The IRA did not have a material impact on the Company's tax provision as of December 31, 2022.

(16) Related Party Transactions

For the year-ended December 31, 2022, under the Related Party Transaction Policy the Company adopted in the fourth quarter of 2021, there were no related party transactions with beneficial ownership of 5% or more of any class of the Company's voting securities, immediate family members of any of the foregoing persons, and any entities in which any of the foregoing is an executive officer or is an owner of 5% or more ownership interest.

For the year-ended December 31, 2021, preceding the Company's Merger and adoption of the aforementioned Related Party Transaction Policy, the Company had related party transactions as follows:

- The Company paid consulting fees to a board member, Christine Hamilton, who is also a shareholder, of $25,000.
- The Company made lease and insurance payments to Dakota Ag Properties of approximately $401,000. Dakota Ag Investments (part of Dakota Ag Properties) is a shareholder and owner of the Company.
- The Company made lab supply payments to Sandford Health totaling approximately $108,000. The Company had no related party payables with Sanford Health as of December 31, 2021.

(17) Employee Benefit Plan

The Company sponsors a defined contribution retirement plan. All the Company’s employees are eligible to be enrolled in the employer-sponsored contributory retirement savings plan, which include features under Section 401(k) of the Code, as amended, and provides for Company matching contributions. The Company’s contributions to the plan are determined by its Board of Directors, subject to certain minimum requirements specified in the plan. For the years ended December 31, 2022 and 2021 the Company made matching contributions of 100% on 3% of the employee contributions, with an additional 50% match on the next 2% of employee contributions, resulting in approximately $410,000 and $325,000, respectively, of matching contributions paid by the Company.

(18) Commitments and Contingencies

The Company is not a party to any litigation, and, to its best knowledge, no action, suit or proceeding has been threatened against the Company which are expected to have a material adverse effect on its financial condition, results of operations or liquidity.

(19) Joint Development Agreement

In June 2019, the Company entered into a joint development agreement with the University of South Dakota Research Park, Inc. (“USDRP”) for the construction of a multi-tenant office building and a manufacturing building. Pursuant to the agreement, the Company also entered into a lease agreement for 41,195 square feet of leasable area located in the building. The lease will commence upon completion of the building for an initial term of 12 years at a monthly payment of approximately $118,000. Aurochs, LLC, a wholly owned subsidiary, was founded to manage the construction funds for this project. All pre-construction costs up to a budgeted $2.7 million were paid directly by the Company and reimbursed by USDRP. As of December 31, 2022 and 2021, USDRP has spent approximately $2.12 million in design costs for this facility, with approximately $580,000 of the $2.7 million budget remaining. There were no receivables or payables for this project as of December 31, 2022 and 2021. USDRP and the Company intend to secure outside funding for all expenses incurred after the pre-construction phase. If funding cannot be secured to finance the construction of this facility, the Company will not be required to refund any of the design costs incurred to date. This project is on hold given the Company's choice to engage Emergent to provide contract development and manufacturing (CDMO) services to produce the Company's fully-human polyclonal antibody products.

(20) Supplemental Disclosures

Supplemental cash flow information and non-cash investing and financing activities are as follows for the years ended December 31, 2022 and 2021:

	2022	2021
Supplemental cash flow information:		
Cash paid for interest	$ 293,392	$ 294,459
Cash paid for income taxes	$ 25,629	$ —
Non-cash investing and finance activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 65,088	$ 505,187
Right-of-use assets forfeited due to partial lease terminations	$ 447,810	$ —
Operating lease liabilities eliminated due to partial lease terminations	$ 480,035	$ —
Warrant liabilities assumed related to the Business Combination	$ —	$ 6,569,062
Liabilities assumed related to the Forward Share Purchase Agreement	$ —	$ 6,338,306
Financing fee liabilities assumed related to the Business Combination included in accrued expense and other current liabilities	$ —	$ 3,100,000
Unpaid financing fees included in the accrued expense and other current liabilities	$ —	$ 2,000,000

(21) Quarterly Financial Information (Unaudited)

As further described in Note 2, *Restatement of Financial Statements*, the previously reported balance sheets as of March 31, 2022, and June 30, 2022, as well as, the statement of cash flows for the three months ended March 31, 2022, six months ended June 30, 2022 and nine months ended September 30, 2022, have been restated. Relevant restated financial information for each relevant period is included in this Annual Report on Form 10-K in the tables that follow. As part of the restatement, the Company recorded adjustments to correct the misstatements in the impacted periods. Descriptions of the restatement can be found in Note 2, *Restatement of Financial Statements*. The unaudited interim financial statements reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented.

Balance sheets

	March 31, 2022 (unaudited)			June 30, 2022 (unaudited)		
	As Previously Reported	Adjustments	Restated	As Previously Reported	Adjustments	Restated
Assets						
Current assets						
Cash and cash equivalents	$ 22,408,409	$ —	$ 22,408,409	$ 16,616,493	$ —	$ 16,616,493
Accounts receivable, net	11,786,420	—	11,786,420	9,612,672	—	9,612,672
Prepaid expenses	1,974,908	1,014,754	2,989,662	1,521,376	253,428	1,774,804
Total current assets	36,169,737	1,014,754	37,184,491	27,750,541	253,428	28,003,969
Long-term prepaid insurance	—	—	—	535,082	—	535,082
Operating lease right-of-use assets	2,351,193	—	2,351,193	2,085,923	—	2,085,923
Financing lease right-of-use assets	3,978,116	—	3,978,116	3,946,306	—	3,946,306
Property, plant and equipment, net	24,973,432	—	24,973,432	24,837,073	—	24,837,073
Total assets	**$ 67,472,478**	**$ 1,014,754**	**$ 68,487,232**	**$ 59,154,925**	**$ 253,428**	**$ 59,408,353**
Liabilities and Stockholders' Equity						
Current liabilities						
Accounts payable	$ 4,981,385	$ —	$ 4,981,385	$ 4,943,581	$ —	$ 4,943,581
Notes payable	25,013	1,014,754	1,039,767	25,013	253,428	278,441
Operating lease liabilities, current portion	1,154,680	—	1,154,680	1,169,139	—	1,169,139
Finance lease liabilities, current portion	145,898	—	145,898	140,767	—	140,767
Income tax payable	92,281	—	92,281	—	—	—
Accrued expenses and other current liabilities	11,856,627	—	11,856,627	9,858,719	—	9,858,719
Total current liabilities	18,255,884	1,014,754	19,270,638	16,137,219	253,428	16,390,647
Operating lease liabilities, noncurrent	1,358,829	—	1,358,829	1,061,122	—	1,061,122
Finance lease liabilities, noncurrent	3,728,941	—	3,728,941	3,694,834	—	3,694,834
Warrant liabilities	2,870,558	—	2,870,558	1,140,478	—	1,140,478
Notes payable, noncurrent	—	—	—	—	—	—
Total liabilities	26,214,212	1,014,754	27,228,966	22,033,653	253,428	22,287,081
Commitments and contingencies (Note 18)						
Stockholders' equity						
Preferred stock; $0.0001 par value; 10,000,000 shares authorized, 10,000,000 shares issued and outstanding at June 30, 2022, and March 31, 2022, respectively	—	—	—	—	—	—
Common stock; $0.0001 par value; 490,000,000 shares authorized at June 30, 2022, and March 31, 2022; 43,501,779 and 43,577543 shares issued, respectively, and 42,955,121 and 43,030,885 outstanding at March 31, 2022 and June 30, 2022, respectively	4,350	—	4,350	4,358	—	4,358
Treasury stock, at cost; 546,658 shares held at March 31, 2022 and June 30, 2022	(5,521,246)	—	(5,521,246)	(5,521,246)	—	(5,521,246)
Additional paid-in capital	74,918,250	—	74,918,250	75,557,244	—	75,557,244
Accumulated deficit	(28,143,088)	—	(28,143,088)	(32,919,084)	—	(32,919,084)
Total stockholders' equity	41,258,266	—	41,258,266	37,121,272	—	37,121,272
Total liabilities and stockholders' equity	**$ 67,472,478**	**$ 1,014,754**	**$ 68,487,232**	**$ 59,154,925**	**$ 253,428**	**$ 59,408,353**

Statements of Cash Flows

	Three Months Ended March 31, 2022 (unaudited)			Six Months Ended June 30, 2022 (unaudited)			Nine Months Ended September 30, 2022 (unaudited)		
	As Previously Reported	Adjustments	Restated	As Previously Reported	Adjustments	Restated	As Previously Reported	Adjustments	Restated
Cash flows from operating activities:									
Net income	$ 985,863	$ —	$ 985,863	$ (3,790,132)	$ —	$ (3,790,132)	$ (10,866,209)	$ —	$ (10,866,209)
Adjustments to reconcile net income to net cash provided by (used in) operating activities:									
Depreciation and amortization	636,235	—	636,235	1,385,427	—	1,385,427	2,270,621	—	2,270,621
Amortization of right-of-use assets	41,207	—	41,207	73,016	—	73,016	97,733	—	97,733
Stock-based compensation expense	897,600	—	897,600	1,467,461	—	1,467,461	2,045,664	—	2,045,664
Gain on sale of equipment	(14,278)	—	(14,278)	(14,278)	—	(14,278)	(15,793)	—	(15,793)
Changes in fair value of warrant liabilities	(7,849,572)	—	(7,849,572)	(9,579,652)	—	(9,579,652)	(10,362,614)	—	(10,362,614)
Changes in operating assets and liabilities									
Accounts receivable	(3,775,713)	—	(3,775,713)	(1,601,964)	—	(1,601,964)	(4,931,330)	—	(4,931,330)
Prepaid expenses	(1,110,395)	755,783	(354,612)	(1,191,944)	1,516,833	324,889	(544,737)	1,771,746	1,227,009
Operating lease right-of-use assets	(18,080)	—	(18,080)	(36,056)	—	(36,056)	(75,276)	—	(75,276)
Accounts payable	522,816	—	522,816	485,058	—	485,058	1,025,751	—	1,025,751
Due to related party	(2,367)	—	(2,367)	(2,367)	—	(2,367)	(2,367)	—	(2,367)
Deferred grant income	(100,000)	—	(100,000)	(100,000)	—	(100,000)	(100,000)	—	(100,000)
Income tax payable	92,281	—	92,281	—	—	—	—	—	—
Accrued expense and other current liabilities	(599,105)	—	(599,105)	(2,597,169)	—	(2,597,169)	(2,217,676)	—	(2,217,676)
Net cash (used in) provided by operating activities	**(10,293,508)**	**755,783**	**(9,537,725)**	**(15,502,600)**	**1,516,833**	**(13,985,767)**	**(23,676,233)**	**1,771,746**	**(21,904,487)**
Cash flows from investing activities:									
Proceeds from the sale of equipment	76,390	—	76,390	76,390	—	76,390	76,390	—	76,390
Purchases of equipment	(1,357,324)	—	(1,357,324)	(1,970,156)	—	(1,970,156)	(2,048,660)	—	(2,048,660)
Net cash used in investing activities	**(1,280,934)**	**—**	**(1,280,934)**	**(1,893,766)**	**—**	**(1,893,766)**	**(1,972,270)**	**—**	**(1,972,270)**
Cash flows from financing activities:									
Payments of notes payable	—	(755,783)	(755,783)	—	(1,516,833)	(1,516,833)	—	(1,771,746)	(1,771,746)
Payments related to the Forward Share Purchase Agreement	(5,521,246)	—	(5,521,246)	(5,521,246)	—	(5,521,246)	(5,521,246)	—	(5,521,246)
Principal payments on finance leases	(48,751)	—	(48,751)	(87,884)	—	(87,884)	(120,053)	—	(120,053)
Proceeds from exercise of stock options	7,830	—	7,830	76,971	—	76,971	76,972	—	76,972
Net cash used in financing activities	**(5,562,167)**	**(755,783)**	**(6,317,950)**	**(5,532,159)**	**(1,516,833)**	**(7,048,992)**	**(5,564,327)**	**(1,771,746)**	**(7,336,073)**
Net (decrease) increase in cash, cash equivalents, and restricted cash	(17,136,609)	—	(17,136,609)	(22,928,525)	—	(22,928,525)	(31,212,830)	—	(31,212,830)
Cash, cash equivalents, and restricted cash									
Beginning of year	39,545,018	—	39,545,018	39,545,018	—	39,545,018	39,545,018	—	39,545,018
End of period	$ 22,408,409	$ —	$ 22,408,409	$ 16,616,493	$ —	$ 16,616,493	$ 8,332,188	$ —	$ 8,332,188

(22) Subsequent Events

On March 21, 2023, the Company entered into a settlement agreement with Ladenburg (the "2023 Ladenburg Agreement", and the action brought by Ladenburg, the "Ladenburg Action"), effective March 23, 2023. In connection with the Ladenburg Agreement, on March 24, 2023, the Company (i) issued to Ladenburg a warrant to purchase up to 300,000 shares of common stock, exercisable for three years from the date of issuance at $0.5424 per share; and (ii) furnished to Ladenburg a one-time cash payment of $500,000. Pursuant to the terms and subject to the conditions set forth in the 2023 Ladenburg Agreement, the Company will (i) no later than June 30, 2023, pay $1.5 million to Ladenburg in cash or shares of common stock, at the Company's option; and (ii) no later than December 31, 2023, pay $1.1 million to Ladenburg in cash or shares of common stock, at the Company's option. Following the completion of the Company's obligations under the Ladenburg Agreement, Ladenburg has agreed to dismiss the Ladenburg Action with prejudice and extinguish any and all obligations of the Company in connection therewith. Any issuance of securities under the Ladenburg Agreement has been made or shall be made pursuant to exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering, and Rule 506 of Regulation D promulgated under the Securities Act.

The Company notes the consideration due to Ladenburg under the 2023 Ladenburg Agreement, excluding the warrants issuable thereunder, are contained within the 2021 and 2022 consolidated balance sheets within accrued expenses and other current liabilities.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

SAB Biotherapeutics, Inc. ("we," "our," "us" or the "Company") has the following two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) its common stock, $0.0001 par value per share ("Common Stock"), and (ii) its warrants, with each whole warrant exercisable for one share of common stock for $11.50 per share (the "Warrants").

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities. The descriptions below are qualified by reference to the actual text of our amended and restated certificate of incorporation (the "Certificate of Incorporation") and amended and restated bylaws (the "Bylaws"). We urge you to read our Certificate of Incorporation in its entirety for a complete description of the rights and preferences of our securities.

Our authorized capital stock consists of 490,000,000 shares of common stock $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. As of March 28, 2023, there were 50,944,420 shares of our Common Stock issued and 50,397,762 shares of our Common Stock outstanding, and no shares of preferred stock issued and outstanding. As of March 28, 2023, the Company has not designated any series of preferred stock.

Common Stock

Voting Power

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of our directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share on matters to be voted on by stockholders.

Dividends

Holders of Common Stock will be entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. In no event will any stock dividends or stock splits or combinations of stock be declared or made on common stock unless the shares of common stock at the time outstanding are treated equally and identically.

Liquidation, Dissolution and Winding Up

In the event of our voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the common stock will be entitled to receive an equal amount per share of all of our assets of whatever kind available for distribution to stockholders, after the rights of the holders of the preferred stock have been satisfied.

Preemptive or Other Rights

Our stockholders have no preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to common stock.

Election of Directors

Our board of directors is divided into three classes, Class I, Class II and Class III, with only one class of directors being elected in each year and each class serving a three-year term, except with respect to the election of directors at the special meeting held in connection with the Business Combination, Class I directors are elected to an initial one-year term (and three-year terms subsequently), the Class II directors are elected to an initial two-year term (and three-year terms subsequently) and the Class III directors are elected to an initial three-year term (and three-year terms subsequently). There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors.

Warrants

Public Stockholders' Warrants

Pursuant to the Warrant Agreement, each whole warrant entitles the registered holder to purchase one share of Common Stock at a price of $11.50 per share, subject to adjustment as discussed below, at any time commencing 30 days after the completion of the merger. Pursuant to the Warrant Agreement, a warrant holder may exercise its Warrants only for a whole number of shares of Common Stock. This means only a whole warrant may be exercised at a given time by a warrant holder. The Warrants will expire five years after the completion of the merger, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

The Company is not obligated to deliver any shares of Common Stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), covering the issuance of the shares of Common Stock issuable upon exercise of the Warrants is then effective and a current prospectus relating to those shares of Common Stock is available, subject to the Company satisfying its obligations described below with respect to registration. No Warrant will be exercisable for cash or on a cashless basis, and the Company will not be obligated to issue any shares to holders seeking to exercise their Warrants, unless the issuance of the shares upon such exercise is registered or qualified under the securities laws of the state of the exercising holder, or an exemption from registration is available. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. If the Common Stock is at the time of any exercise of a Warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, the Company may, at its option, require holders of public Warrants who exercise their Warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event the Company so elects, it will not be required to file or maintain in effect a registration statement, but will use its reasonable best efforts to qualify the shares under applicable blue sky laws to the extent an exemption is not available.

Redemption of Warrants.

Redemption of Warrants when the price per share of our common stock equals or exceeds $18.00.

Once the warrants become exercisable, the Company may call the Warrants for redemption.

Warrants will not be exercisable for cash unless the Company has an effective and current registration statement covering the shares of Common Stock issuable upon exercise of the Warrants and a current prospectus relating to such shares of Common Stock.

The Company may call the Warrants for redemption, in whole and not in part, at a price of $0.01 per warrant, (i) at any time after the Warrants become exercisable, (ii) upon not less than 30 days' prior written notice of redemption to each holder of Warrants after the Warrants become exercisable, and (iii) if, and only if, the reported last sale price of the shares of Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations), for any 20 trading days within a 30 trading day period commencing after the Warrants become exercisable and ending on the third trading day prior to the notice of redemption to holders of Warrants.

The right to exercise will be forfeited unless the Warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of a Warrant will have no further rights except to receive the redemption price for such holder's Warrant upon surrender of such warrant.

If the Company calls the Warrants for redemption as described above, the Company's management will have the option to require all holders that wish to exercise Warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the Warrants for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the Warrants, multiplied by the difference between the exercise price of the Warrants and the "fair market value" (as defined below) by (y) the fair market value. The "fair market value" for this purpose means the average reported last sale price of the shares of Common Stock for the ten trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of Warrants.

The exercise price and number of shares of Common Stock issuable on exercise of the Warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary dividend or our recapitalization, reorganization, merger or consolidation. However, except as described below, the Warrants will not be adjusted for issuances of shares of Common Stock at a price below their respective exercise prices.

No fractional shares will be issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would be entitled to receive a fractional interest in a share, the Company will, upon exercise, round up to the nearest whole number the number of shares of Common Stock to be issued to the warrant holder.

Certain Anti-Takeover Provisions of Delaware Law

Our Amended and Restated Bylaws provide that special meetings of our stockholders may be called only by a majority vote of the board of directors, by the Chairperson of the board of directors, or by the chief executive officer.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Amended and Restated Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely under our current bylaws and the Amended and Restated Bylaws, a stockholder's notice will need to be received by the company secretary at our principal executive offices not later than the close of business on the 90th day nor earlier than the open of business on the 120th day prior to the first anniversary of the preceding year's annual meeting. Pursuant to Rule 14a-8 of the Exchange Act, proposals seeking inclusion in our annual proxy statement must comply with the notice periods contained therein. Our Amended and Restated Bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but Unissued Shares

Our authorized but unissued common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum Selection

The Certificate of Incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (subject to certain limited exceptions) shall be the sole and exclusive forum for any of the following claims (i) any derivative claim or cause of action brought on our behalf, (ii) any claim or cause of action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or to the Company's stockholders, (iii) any claim or cause of action against us, our directors, officers or employees arising pursuant to any provision of the DGCL, the Certificate of Incorporation or the Amended and Restated Bylaws, (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the Amended and Restated Bylaws, (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against the Company or any current or former director, officer or other employee of the Company governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Any person or entity holding, owning or otherwise acquiring any interest in shares of capital stock of the Company shall be deemed to have notice of and to have consented to such provisions.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law in the types of lawsuits to which they apply, a court may determine that these provisions are unenforceable, and to the extent they are enforceable, the provisions may have the effect of discouraging lawsuits against our directors and officers, although our stockholders will not be deemed to have waived our compliance with federal

securities laws and the rules and regulations thereunder. Additionally, we cannot be certain that a court will decide that these provisions are either applicable or enforceable, and if a court were to find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Our Certificate of Incorporation provides that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the Proposed Charter provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Anti-Takeover Provisions

We are subject to provisions of Section 203 of the DGCL regulating corporate takeovers under our Certificate of Incorporation. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

• a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");

• an affiliated of an interested stockholder; or

• an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

• "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

• our board of directors approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;

• after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock;

• on or subsequent to the date of the transaction, our initial business combination is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Exhibit 10.5

EMPLOYMENT AGREEMENT

This Employment Agreement (the "***Agreement***") is dated May 20, 2022 and effective as of June 6, 2022 (the "***Effective Date***"), by and between **SAB BIOTHERAPEUTICS, INC.**, a Delaware corporation (the "***Company***"), and **ALEXANDRA KROPOTOVA** (the "***Employee***").

WHEREAS, the Company desires that the Employee joins the Company to serve in the capacity of Executive Vice President-Chief Medical Officer of the Company, and the Employee has agreed to serve in such position in accordance with the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, and for other valuable consideration, the Company and the Employee hereby agree as follows:

1. Certain Definitions. The following terms, as used herein, have the following meanings:

(a) "***Cause***" means one or more of the following: (i) the Employee's willful failure to perform her duties hereunder or the lawful directives of the Company's Board of Directors or nominees thereof (other than as a result of illness or injury), (ii) the conviction of, or plea of *nolo contendere* by, the Employee to, a felony or a crime involving moral turpitude, (iii) the Employee's commission of any willful acts of personal dishonesty in connection with her responsibilities as an employee of the Company that could reasonably be expected to materially impair or damage the property, goodwill, reputation, business or finances of the Company, (iv) the Employee's willful and material violation of the Company's policies regarding ethics or conduct (including sexual harassment and other similar policies) that could reasonably be expected to impair or damage the property, goodwill, reputation, business or finances of the Company or its affiliates or (v) the Employee's breach of her obligations under the Confidentiality Agreement.

(b) "***Change of Control***" means the occurrence of any of the following events: (i) a change in the ownership of the Company which occurs on the date that any one person or entity, or more than one person or entity acting as a group (collectively, a "***Person***" for purposes of this definition), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; (ii) a change in the effective control of the Company which occurs on the date that a majority of members of the Company's Board of Directors is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Company's Board of Directors prior to the date of the appointment or election; or (iii) change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such Person or Persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, or (2) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company. For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets. For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company. Notwithstanding the foregoing, a transaction will not be deemed a Change of Control unless the transaction qualifies as a change in control event within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time. Further and for the avoidance of doubt, a transaction will not constitute a Change of Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(c) "***Change of Control Period***" means the twelve (12) month period following a Change of Control.

(d) "***Date of Termination***" means the date specified in a written notice of termination delivered pursuant to Section 6, or the Employee's last date as an active employee of the Company before a termination of employment due to her death or Non-Renewal.

(e) "***Designated Location***" means an office to be established by the Company in the greater Philadelphia area at a location reasonably acceptable to the Company and the Executive.

(f) "***Disabled***" or "***Disability***" means a mental or physical condition that renders the Employee substantially incapable of performing her duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for four (4) or more consecutive months or for a total of four (4) months during any twelve (12) consecutive months.

(g) "***Good Reason***" means, unless the Employee has consented in writing thereto, the occurrence of any of the following: (i) the assignment to the Employee of any duties materially inconsistent with the Employee's position, including any change in status, title, authority, duties, non-temporary change in reporting line to anyone other than the Chief Executive Officer of the Company, or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities, (ii) a material reduction in the Employee's Base Salary by the Company or (iii) the relocation of the Employee's office to a location more than fifty (50) miles from the Designated Location.

2. Term of Employment. The Employee will start her employment with the Company, upon the terms and conditions set forth in this Agreement for the period commencing on the Effective Date and ending on the earlier of: (a) December 31, 2023 (subject to extension as provided in the following sentence) and (b) the Employee's Date of Termination (such period, including any extension as provided below, shall be referred to as the "***Term of Employment***"). This Agreement and the Term of Employment shall be automatically extended for successive additional one (1)-year terms, unless either party provides written notice of non- renewal at least ninety (90) days before the end of then-current Term of Employment. The Employee agrees to sign all documentation evidencing the foregoing as may be presented to the Employee for signature by the Company.

3. Employee's Duties and Obligations.

(a) Duties. The Employee shall serve as the Company's Executive Vice President-Chief Medical Officer. The Employee shall be responsible for all duties customarily associated with the Chief Medical Officer of a publicly-traded company. The Employee shall report to the Chief Executive Officer of the Company and shall be subject to reasonable policies established by the Chief Executive Officer and the Company's board of directors.

(b) Location of Employment. The Employee's principal place of business shall be at the Designated Location. In addition, the Employee acknowledges and agrees that the performance by the Employee of the Employee's duties shall require travel including, without limitation, overseas travel from time to time. It is understood that Employee will be working predominantly out of the Designated Location unless the Employee and the Company agree to an alternative arrangement.

(c) Confidential Information, Assignment of Rights, Non-Solicitation and Non-Competition Agreement. In consideration of the covenants contained herein, the Employee has executed and agrees to be bound by the Confidential Information, Assignment of Rights, Non-Solicitation and Non-Competition Agreement (the "***Confidentiality Agreement***") attached to this Agreement as **Exhibit A**. The Employee shall comply at all times with the covenants (including covenants not to compete or solicit employees, consultants and independent contractors) and other terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information. The Employee's obligations under the Confidentiality Agreement shall survive the Term of Employment.

4. Devotion of Time to the Company's Business. During the Term of Employment, the Employee shall devote substantially all of her business time, attention and effort to the affairs of the Company, excluding any periods of disability, vacation, or sick leave to which the Employee is entitled, and shall use her reasonable best efforts to perform the duties properly assigned to her hereunder and to promote the interests of the Company. Notwithstanding the foregoing, during the Term of Employment, the Employee may (a) engage in charitable, educational, religious, civic and other types of activities, and (b) serve as a member of the board of directors or other similar governing body of one (1) company which does not engage in any business which is competitive with the business of the Company (such activities the "***Permitted Activities***") to the extent that such Permitted Activities do not interfere with the performance of Employee's duties hereunder or conflict with the business of the Company, its subsidiaries or affiliates.

5. Compensation and Benefits.

(a) Base Salary. The Company shall pay to the Employee in accordance with its normal payroll practices (but not less frequently than monthly) an annual salary at a rate of five hundred and twenty-five thousand dollars ($525,000) per annum ("***Base Salary***"). The Employee's Base Salary shall be reviewed annually for the purpose of determining increases, if any, based on the Employee's performance, the performance of the Company, then prevailing salary scales for comparable positions, inflation and other relevant factors. Effective as of the date of any increase in the Employee's Base Salary, Base Salary as so increased shall be considered the new Base Salary for all purposes of this Agreement and may not thereafter be reduced. Any increase in Base Salary shall not limit or reduce any other obligation of the Company to the Employee under this Agreement.

(b) Annual Bonus. During the Term of Employment, the Employee shall be eligible to receive an annual cash incentive award ("***Annual Bonus***") pursuant to the bonus plan then in effect for Employee employees of the Company (the "***Bonus Plan***"). All Annual Bonuses are subject to the terms and conditions of then-current Bonus Plan adopted by the Company. If the Employee achieves her target performance goals for a calendar year, which goals shall be determined by the Compensation Committee of the Company's Board of Directors on an annual or more frequent basis, the Annual Bonus shall be targeted at forty-five percent (45%) of the Employee's Base Salary. Based on achievement of agreed upon Company and personal goals, the Annual Bonus may be less than or exceed this target. To be eligible to receive an Annual Bonus, or any portion thereof, the Employee must be actively employed by the Company at the time the Annual Bonus, if any, is paid, except as otherwise provided below. The Annual Bonus for the year ending December 31, 2022 will not be prorated. Any future Annual Bonus that covers less than a full calendar year may be subject to proration.

(c) Equity Awards. As soon as practicable following the Effective Date, and subject to approval of the Compensation Committee of the Company's Board of Directors (the "***Compensation Committee***"), the Employee shall receive a grant of 300,000 restricted stock units (the "***RSU Award***") under the SAB Biotherapeutics, Inc. 2021 Omnibus Equity Incentive Plan (the "***Equity Plan***"). The terms and conditions of the RSU Award shall be documented in a corresponding restricted stock unit award agreement between the Company and the Employee. The RSU Award will vest over four years with 25% of the RSU Award vesting on the one year anniversary of the Effective Date and the remaining 75% of the RSU Award vesting on a monthly basis in thirty-six equal installments. From time to time, the Employee may receive additional equity incentive awards under the Equity Plan (or under any other equity incentive plan adopted by the Company to supplement or succeed the Equity Plan with the RSU Award, "***Equity Awards***") subject to such terms and conditions as the Compensation Committee, in its sole discretion, may determine.

(d) Benefits. During the Term of Employment, the Employee shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior employees or to other full-time employees on substantially the same basis that such benefits are provided to such senior Employees of a similar level or to other full-time employees.

(e) Vacations. During the Term of Employment, the Employee shall be entitled to twenty (20) days paid vacation per year, or such greater amount as may be earned under the Company's standard vacation policy.

(f) Reimbursement of Expenses. During the Term of Employment, the Employee shall be entitled to receive prompt reimbursement for all reasonable business-related or employment-related expenses incurred by the Employee upon the receipt by the Company of reasonable documentation in accordance with standard practices, policies and procedures applicable to other senior Employees of the Company.

6. Termination of Employment. The Term of Employment shall be automatically terminated upon the first to occur of the following:

(a) Death. The Employee's employment shall terminate immediately upon the Employee's death.

(b) Disability. If the Employee is Disabled, either party may terminate the Employee's employment due to such Disability upon delivery of written notice to the other party. The effective date of such termination of employment will be the Date of Termination set forth in such written notice or immediately upon delivery of such written notice if no effective date is specified in the written notice. For avoidance of doubt, if the Employee's employment is terminated pursuant to this Section 6(b), her employment will not constitute a termination of employment by the Company without Cause or by the Employee for Good Reason.

(c) Termination by the Employee Without Good Reason. The Employee may terminate her employment for any reason other than Good Reason upon her delivery of written notice to the Company at least thirty (30) days prior to her Date of Termination.

(d) Termination by the Employee for Good Reason. The Employee may terminate her employment for Good Reason if (i) not later than ninety (90) days after the occurrence of any act or omission that constitutes Good Reason, the Employee provides the Company with a written notice setting forth in reasonable detail the acts or omissions that constitute Good Reason, (ii) the Company fails to correct or cure the acts or omissions within thirty (30) days after it receives such written notice, and (iii) the Employee terminates her employment with the Company after the expiration of such cure period but not later than thirty (30) days after the expiration of such cure period.

(e) Termination by the Company Without Cause. The Company may terminate the Employee's employment without Cause upon delivery of written notice to the Employee at least thirty (30) days prior to her Date of Termination.

(f) Termination Upon Non-Renewal. Unless otherwise agreed to by the parties, the Employee's employment shall terminate on the last day of then-current Term of Employment if either the Company or the Employee provides the other party with a written notice of non-renewal of this Agreement in accordance with Section 2 and the parties do not enter into a new employment agreement prior to the expiration of this Agreement ("***Non-Renewal***").

(g) Termination by the Company for Cause. Upon the occurrence of any act or omission that constitutes Cause, the Company may terminate the Employee's employment upon delivery of written notice to the Employee at least fifteen (15) days prior to her Date of Termination, unless the Employee cures, if curable, such acts or omissions constituting Cause to the satisfaction of the Company prior to the expiration of such period.

7. Compensation and Benefits Payable Upon of Termination of Employment Unrelated to a Change of Control.

(a) Payment of Accrued But Unpaid Compensation and Benefits. Upon the Employee's termination of employment for any reason outside of the Change of Control Period, the Employee (or her Beneficiary following the Employee's death) shall receive (i) a lump sum payment on the Date of Termination in an amount equal to the sum of the Employee's earned but unpaid Base Salary through her Date of Termination plus her accrued but unused vacation days at the Employee's Base Salary in effect as of her Date of Termination;

plus (ii) any other benefits or rights the Employee has accrued or earned through her Date of Termination in accordance with the terms of the applicable fringe or employee benefit plans and programs of the Company. Except as provided in Section 7(b) or Section 7(c) below or as expressly provided pursuant to the terms of any employee benefit plan, the Employee will not be entitled to earn or accrue any additional compensation or benefits for any period following her Date of Termination.

(b) Termination of Employment Due to Death or Disability. In addition to the compensation and benefits payable under Section 7(a) above, if the Employee's employment is terminated due to her death or Disability outside of the Change of Control Period, the Employee (or her Beneficiary following the Employee's death) shall receive:

(i) the Employee's accrued but unpaid Annual Bonus, if any, for the calendar year ended prior to her Date of Termination payable at the same time annual bonuses for such calendar year are paid to other key Employees of the Company pursuant to the terms of the Bonus Plan; and

(ii) reimbursement of the COBRA premiums, if any, paid by the Employee's spouse and dependents for continuation coverage for the Employee's spouse and dependents under the Company's group health, dental and vision plans for a six (6) month period from the Date of Termination.

(c) Termination of Employment by the Company Without Cause, by the Employee for Good Reason or Upon Non-Renewal by the Company. In addition to the compensation and benefits payable under Section 7(a) above, if the Employee's employment is terminated by the Company without Cause, by the Employee for Good Reason or upon Non- Renewal where it is the Company that provided written notice of non-renewal of this Agreement in accordance with Section 2, and such termination occurs outside of the Change of Control Period, and the Employee returns an executed Release to the Company, which becomes final, binding and irrevocable within sixty (60) days following the Employee's Date of Termination in accordance with Section 10, the Employee (or her Beneficiary following the Employee's death) shall receive:

(i) the Employee's accrued but unpaid Annual Bonus, if any, for the calendar year ended prior to her Date of Termination payable at the same time annual bonuses for such calendar year are paid to other key Employees of the Company pursuant to the terms of the Bonus Plan;

(ii) one hundred percent (100%) of the Employee's outstanding unvested Equity Awards as of the Date of Termination will be fully vested and exercisable;

(iii) a severance payment payable in a single lump sum within five (5) business days after the Employee's Release becomes final, binding and irrevocable in accordance with Section 10, in an amount equal to twelve (12) months of Base Salary; and

(iv) reimbursement of the COBRA premiums, if any, paid by the Employee for continuation coverage for the Employee, her spouse and dependents under the Company's group health, dental and vision plans for a six (6) month period from the Date of Termination.

Notwithstanding the foregoing, if the Employee materially breaches this Agreement or the Employee's Confidentiality Agreement, then the Company's continuing obligations under this Section 7(c) shall cease as of the date of the breach and the Employee shall be entitled to no further payments hereunder.

8. Termination of Employment by the Company Without Cause, by the Employee for Good Reason or Upon Non-Renewal by the Company in Connection with a Change of Control. In addition to the compensation and benefits payable under Section 7(a) above, if the Employee's employment is terminated by the Company without Cause, by the Employee for Good Reason or upon Non-Renewal where it is the Company that provided written notice of non-renewal of this Agreement in accordance with Section 2, and such termination occurs during the Change of Control Period, and the Employee returns an executed Release to the Company, which becomes final, binding and irrevocable within sixty (60) days following the Employee's Date of Termination in accordance with Section 10, the Employee (or her Beneficiary following the Employee's death) shall receive:

(a) a single lump sum within five (5) business days after the Employee's Release becomes final, binding and irrevocable in accordance with Section 10, equal to the Employee's accrued but unpaid Annual Bonus, if any, for the calendar year ended prior to her Date of Termination;

(b) a single lump sum within five (5) business days after the Employee's Release becomes final, binding and irrevocable in accordance with Section 10, equal to one hundred percent (100%) of Employee's target bonus as in effect for the calendar year in which Employee's termination of employment occurs; provided that the amount paid to Employee pursuant to this Section 8(b) will be prorated based on the actual amount of time Employee is employed by the Company during the calendar year (or the relevant performance period if something different than a calendar year) during which the termination occurs;

(c) one hundred percent (100%) of the Employee's outstanding unvested Equity Awards as of the Date of Termination will be fully vested and exercisable;

(d) a severance payment payable in a single lump sum within five (5) business days after the Employee's Release becomes final, binding and irrevocable in accordance with Section 10, in an amount equal to twelve (12) months of Base Salary; and

(e) reimbursement of the COBRA premiums, if any, paid by the Employee for continuation coverage for the Employee, her spouse and dependents under the Company's group health, dental and vision plans for a twelve (12) month period from the Date of Termination.

9. Terminations Within Sixty (60) Days Prior to a Change of Control. If (a) the Employee incurred a termination prior to a Change of Control that qualifies Employee for severance payments under Section 7(c) and (b) a Change of Control occurs within sixty (60) days following Employee's termination of employment, then upon the Change of Control, the Employee shall be entitled to a lump-sum payment of the amount calculated under this Section 8, less amounts already paid under Section 7(c), subject to compliance with Section 10.

10. Release. As a condition of receiving the compensation and benefits described in Section 7(c) or Section 8, the Employee must execute a release of any and all claims arising out of the Employee's employment with the Company or the Employee's separation from such employment (including, without limitation, claims relating to age, disability, sex or race discrimination to the extent permitted by law), excepting (i) claims for benefits under any employee benefit plan in accordance with the terms of such employee benefit plan, (ii) any right to exercise Equity Awards that are vested on the Date of Termination pursuant to the terms of such Equity Awards (as modified by the Employment Agreement), (iii) claims based on breach of the Company's obligations to pay the compensation and benefits described in Section 5 and Section 7(a), Section 7(c) or Section 8 of this Employment Agreement, (iv) claims arising under the Age Discrimination in Employment Act after the date the Employee signs such release, and (v) any right to indemnification by the Company or to coverage under directors and officers liability insurance to which the Employee is otherwise entitled in accordance with this Agreement and the Company's articles of incorporation or by laws or other agreement between the Employee and the Company (the "***Release***"). Such Release shall be in a form tendered to the Employee by the Company within five (5) business days following the termination of the Employee's employment by the Company without Cause or by the Employee for Good Reason, which shall comply with any applicable legislation or judicial requirements, including, but not limited to, the Older Workers Benefit Protection Act, and shall be substantially in the form of release attached as **Exhibit B**. The compensation and benefits described in Section 7(c) or Section 8 will not be paid to the Employee if the Employee fails to execute the Release within the time frame specified in such Release, if the Employee revokes the Release within the applicable revocation period set forth in such Release or if the revocation period expires more than sixty (60) days following the Employee's Date of Termination.

11. Excess Parachute Excise Tax.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Internal Revenue Code of 1986, as amended and the regulations promulgated thereunder (the "***Code***") to or for the benefit of the Employee (whether pursuant to the terms of this Agreement or otherwise, but determined before application of any reductions required pursuant to this Section 11) (a "***Payment***") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by the Employee (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "***Excise Tax***"), the Company will automatically reduce such Payments to the extent, but only to the extent, necessary so that no portion of the remaining Payments will be subject to the Excise Tax, unless the amount of such Payments that the Employee would retain after payment of the Excise Tax and all applicable Federal, state and local income taxes without such reduction would exceed the amount of such Payments that the Employee would retain after payment of all applicable Federal, state and local taxes after applying such reduction. Unless otherwise elected by the Employee, to the extent permitted under Code Section 409A, such reduction shall first be applied to any severance payments payable to the Employee under this Agreement, then to the accelerated vesting on any Equity Awards.

(b) All determinations required to be made under this Section 11, including the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to the Employee as may be designated by the Company (the "***Accounting Firm***") which shall provide detailed supporting calculations both to the Company and the Employee within fifteen (15) business days of the receipt of notice from the Employee that there has been a Payment, or such earlier time as is requested by either the Company or the Employee. All fees and expenses of the Accounting Firm shall be borne solely by the Company. If the Accounting Firm determines that no Excise Tax is payable by the Employee, it shall furnish the Employee with a written opinion to such effect. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

12. Legal Fees. Each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

13. Beneficiary. If the Employee dies prior to receiving all of the amounts payable to her in accordance with the terms of this Agreement, such amounts shall be paid to one or more beneficiaries (each, a "***Beneficiary***") designated by the Employee in writing to the Company during her lifetime, or

if no such Beneficiary is designated, to the Employee's estate. Such payments shall be made in accordance with the terms of this Agreement. The Employee, without the consent of any prior Beneficiary, may change her designation of Beneficiary or Beneficiaries at any time or from time to time by a submitting to the Company a new designation in writing.

14. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand, email or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Company:

SAB Biotherapeutics, Inc. 2100 East 54th Street North Sioux Falls, South Dakota Attn: Chief Executive Officer
Email: esullivan@sabbiotherapeutics.com If to the Employee:
To the address on file with the records of the Company.

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

15. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

16. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this agreement or any dispute or claim between the Employee and the Company or its officers, directors, agents, or employees (a "***Dispute***"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand." Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 16. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm or to enforce the terms of the Confidentiality Agreement.

(b) The Dispute shall be resolved by a single arbitrator in an arbitration administered by the American Arbitration Association in accordance with its Employment Arbitration Rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The decision of the arbitrator shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrator may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 16 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("***AAA***") located in South Dakota or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Employment Arbitration Rules of the AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a sixty (60)-day period. In addition, the following rules and procedures shall apply to the arbitration:

(e) The arbitrator shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 16.

(f) The decision of the arbitrator, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrator hereunder.

(g) The arbitrator shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory and punitive damages if authorized by applicable law.

(h) Except as otherwise provided in Section 12 or by law, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 16, and the costs of the arbitrator(s) shall be equally divided between the parties.

(i) Except as provided in the last sentence of Section 16(a), the provisions of this Section 16 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 16 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

17. Recoupment.

(a) Policy. Any incentive-based compensation received by the Employee including Annual Bonus and Equity Awards, whether pursuant to this Agreement or otherwise, that is granted, earned or vested based in any part on attainment of a financial reporting measure, shall be subject to the terms and conditions of the Company's Claw Back Compensation Policy, if any (the "***Recoupment Policy***"), and any other policy of recoupment of compensation as shall be adopted from time to time by the Company's Board of Directors or its Compensation Committee as it deems necessary or appropriate to comply with the requirements of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Section 304 of the Sarbanes-Oxley Act of 2002, and any implementing rules and regulations of the U.S. Securities and Exchange Commission and applicable listing standards of a national securities exchange adopted in accordance with any of the foregoing. The terms and conditions of the Recoupment Policy, including any changes to the Recoupment Policy adopted from time to time by the Company, are hereby incorporated by reference into this Agreement.

(b) Non-Indemnification and Advancement for Recoupment. The Company shall not be obligated to indemnify or advance funds to the Employee for any payment or reimbursement by the Employee to the Company of any bonus or other incentive- based or equity-based compensation previously received by the Employee or payment of any profits realized by the Employee from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934 or under the rules of the stock exchange on which the common stock of the Company is listed (including any such payments or reimbursements under Section 304 and 306 of the Sarbanes-Oxley Act of 2002, or pursuant to Section 954 of the Dodd-Frank Wall

Street Reform and Consumer Protection Act and any implementing rules and regulations of the U.S. Securities and Exchange Commission and applicable listing standards of a national securities exchange adopted in accordance with any of the foregoing).

18. Miscellaneous

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes any and all other prior agreements, promises, understandings and representations regarding the Employee's employment, compensation, severance or other payments contingent upon the Employee's termination of employment, whether written or otherwise.

(c) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(d) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(e) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of the Employee (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to the Employee, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(f) Successors and Assigns; Non-alienation of Benefits. Except as provided in Section 18(e) in the case of the Company, or to the Beneficiary in the case of the death of the Employee, this Agreement is not assignable by any party. Compensation and benefits payable to the Employee under this Agreement shall not be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance, charge, garnishment, execution or levy of any kind, either voluntary or involuntary, prior to actually being received by the Employee or a Beneficiary, as applicable, and any such attempt to dispose of any right to benefits payable hereunder shall be void and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(g) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(h) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the Date of Termination shall survive termination of this Agreement.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

19. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of the Employee to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge the Employee with or without Cause.

20. Section 409A of the Code.

(a) The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be construed and interpreted in accordance with such intent. The Employee's termination of employment (or words to similar effect) shall not be deemed to have occurred for purposes of this Agreement unless such termination of employment constitutes a "separation from service" within the meaning of Code Section 409A and the regulations and other guidance promulgated thereunder.

(b) Notwithstanding any provision in this Agreement to the contrary, if the Employee is deemed on the date of the Employee's separation from service to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B) and using the identification methodology selected by the Company from time to time, or if none, the default methodology set forth in Code Section 409A, then with regard to any payment or the providing of any benefit that constitutes "non-qualified deferred compensation" pursuant to Code Section 409A and the regulations issued thereunder that is payable due to the Employee's separation from service, to the extent required to be delayed in compliance with Code Section 409A(a)(2)(B), such payment or benefit shall not be made or provided to the Employee prior to the earlier of (i) the expiration of the six (6)-month period measured from the date of the Employee's separation from service, and (ii) the date of the Employee's death. On the first day of the seventh (7th) month following the date of the Employee's separation from service or, if earlier, on the date of the Employee's death, all payments delayed pursuant to this Section 20 shall be paid or reimbursed to the Employee in a lump sum, and any remaining payments and benefits due to the Employee under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(c) To the extent any reimbursement of costs and expenses (including reimbursement of COBRA premiums pursuant to Section 7(c)(iv)) provided for under this Agreement constitutes taxable income to the Employee for Federal income tax purposes, such reimbursements shall be made as soon as practicable after the Employee provides proper documentation supporting reimbursement but in no event later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, and (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year.

(d) If under this Agreement, any amount is to be paid in two (2) or more installments, each such installment shall be treated as a separate payment for purposes of Section 409A.

21. Employee Acknowledgement. The Employee hereby acknowledges that the Employee has read and understands the provisions of this Agreement, that the Employee has been given the opportunity for the Employee's legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that the Employee has received a copy of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this Employment Agreement to be executed as of the 20th day of May 2022.

SAB BIOTHERAPEUTICS, INC.

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

EMPLOYEE

By: */s/ Alexandra Kropotova*
Name: Alexandra Kropotova

EXHIBIT A

CONFIDENTIAL INFORMATION, ASSIGNMENT OF RIGHTS, NON-SOLICITATION AND NON-COMPETITION AGREEMENT

[SEE ATTACHED]

EXHIBIT B

WAIVER AND RELEASE

This is a Waiver and Release ("***Release***") between Alexandra Kropotova ("***Employee***") and SAB Biotherapeutics, Inc. (the "***Company***"). The Company and the Employee agree that they have entered into this Release voluntarily, and that it is intended to be a legally binding commitment between them.

In consideration for and contingent upon the Employee's right to receive the benefits described in the Employment Agreement between the Company and the Employee (the "***Employment Agreement***") and this Release, the Employee hereby agrees as follows:

(a) General Waiver and Release. Except as provided in Paragraph (e) below, the Employee and any person acting through or under the Employee hereby release, waive and forever discharge the Company, its past and present subsidiaries and affiliates, and their respective successors and assigns, and their respective past and present officers, trustees, directors, shareholders, Employees and agents of each of them, from any and all claims, demands, actions, liabilities and other claims for relief and remuneration whatsoever (including without limitation attorneys' fees and expenses), whether known or unknown, absolute, contingent or otherwise (each, a "***Claim***"), arising or which could have arisen up to and including the date of her execution of this Release, including without limitation those arising out of or relating to the Employee's employment or cessation and termination of employment, or any other written or oral agreement, any change in the Employee's employment status, any benefits or compensation, any tortious injury, breach of contract, wrongful discharge (including any Claim for constructive discharge), infliction of emotional distress, slander, libel or defamation of character, and any Claims arising under Title VII of the Civil Rights Act of 1964 (as amended by the Civil Rights Act of 1991), the Americans With Disabilities Act, the Rehabilitation Act of 1973, the Equal Pay Act, the Older Workers Benefits Protection Act, the Age Discrimination in Employment Act, the Employee Retirement Income Security Act of 1974, or any other federal, state or local statute, law, ordinance, regulation, rule or Employee order, any tort or contract claims, and any of the claims, matters and issues which could have been asserted by the Employee against the Company or its subsidiaries and affiliates in any legal, administrative or other proceeding. the Employee agrees that if any action is brought in her name before any court or administrative body, the Employee will not accept any payment of monies in connection therewith.

(b) Miscellaneous. the Employee agrees that Section 7(c) of the Employment Agreement (which is specifically incorporated herein by reference) specifies payments from the Company to himself, the total of which meets or exceeds any and all funds due her by the Company, and that she will not seek to obtain any additional funds from the Company with the exception of non-reimbursed business expenses. (This covenant does not preclude the Employee from seeking workers' compensation, unemployment compensation, or benefit payments from the Company's insurance carriers that could be due her.)

(c) Non-Solicitation, Confidentiality and Non-Solicitation Covenants. the Employee warrants that the Employee has, and will comply fully with Section 3(c) of the Employment Agreement and the provisions of the Confidential Information, Assignment of Rights, Non-Solicitation and Non-Competition Agreement by and between the Company and the Employee.

(d) THE COMPANY AND THE EMPLOYEE AGREE THAT THE BENEFITS DESCRIBED IN SECTION 7(C) OF THE EMPLOYMENT AGREEMENT AS SUBJECT TO EMPLOYEE'S COMPLIANCE WITH SECTION 9 THEREOF ARE CONTINGENT UPON THE EMPLOYEE SIGNING THIS RELEASE. THE EMPLOYEE FURTHER UNDERSTANDS AND AGREES THAT IN SIGNING THIS RELEASE, EMPLOYEE IS RELEASING POTENTIAL LEGAL CLAIMS AGAINST THE COMPANY. THE EMPLOYEE UNDERSTANDS AND AGREES THAT IF SHE DECIDES NOT TO SIGN THIS RELEASE, OR IF SHE REVOKES THIS RELEASE, THAT SHE WILL IMMEDIATELY REFUND TO THE COMPANY ANY AND ALL SEVERANCE PAYMENTS AND OTHER BENEFITS SHE MAY HAVE ALREADY RECEIVED.

(e) The waiver contained in Paragraph (a) and (b) above does not apply to:

(i) Any claims for benefits under employee benefit plans in accordance with the terms of the applicable employee benefit plan, including the Employee's right to elect continuation coverage under the Company's group health, dental and/or visions plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (COBRA),

(ii) Any right to exercise stock options or stock appreciation rights that were vested and exercisable on the Date of Termination in accordance with the terms thereof (as modified by the Employment Agreement);

(iii) Any Claim under or based on a breach of the Company's obligations to pay the compensation and benefits described in Sections 5 or 7(a) or (c) of the Employment Agreement,

(iv) Rights or Claims that may arise under the Age Discrimination in Employment Act after the date that the Employee signs this Release, and

(v) Any right to indemnification by the Company or to coverage under directors and officers liability insurance to which the Employee is otherwise entitled in accordance with the Employment Agreement or the Company's articles of incorporation or by-laws or other agreement between the Employee and the Company.

(f) EMPLOYEE ACKNOWLEDGES THAT SHE HAS READ AND IS VOLUNTARILY SIGNING THIS RELEASE. EMPLOYEE ALSO ACKNOWLEDGES THAT SHE IS HEREBY ADVISED TO CONSULT WITH AN ATTORNEY, SHE HAS BEEN GIVEN AT LEAST ***[21][45]*** DAYS TO CONSIDER THIS RELEASE BEFORE THE DEADLINE FOR SIGNING IT; ***[SHE HAS RECEIVED A RECEIVED A WRITTEN DESCRIPTION OF THE JOB TITLES AND AGES ALL INDIVIDUALS SELECTED FOR THIS JOB ELIMINATION PROGRAM AND THE AGES OF ANY INDIVIDUALS IN THE SAME JOB CLASSIFICATIONS WHO ARE NOT SELECTED FOR THIS JOB ELIMINATION PROGRAM AS PROVIDED BY THE ADEA (SUCH DESCRIPTION ATTACHED AS EXHIBIT A HERETO)]***; AND SHE UNDERSTANDS THAT SHE MAY REVOKE THE RELEASE WITHIN SEVEN (7) DAYS AFTER SIGNING IT. IF NOT REVOKED WITHIN SUCH PERIOD, THIS RELEASE WILL BECOME EFFECTIVE ON THE EIGHTH (8) DAY AFTER IT IS SIGNED BY EMPLOYEE.

BY SIGNING BELOW, BOTH THE COMPANY AND EMPLOYEE AGREE THAT THEY UNDERSTAND AND ACCEPT EACH PART OF THIS RELEASE.

_____
Alexandra Kropotova

_____
Date Signed

ACCEPTED AND DATED AS OF: _____

SAB BIOTHERAPEUTICS, INC.

By: _____
Name:
Title:

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-262452 on Form S-8 of our report dated April 14, 2023, relating to the consolidated financial statements of SAB Biotherapeutics, Inc. and Subsidiaries as of December 31, 2022 and 2021 and for each of the two years in the period ended December 31, 2022, included in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
April 14, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eddie J. Sullivan, certify that:

1. I have reviewed this Annual Report on Form 10-K of SAB Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 14, 2023

By: **

Eddie J. Sullivan
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Russell Beyer, certify that:

1. I have reviewed this Annual Report on Form 10-K of SAB Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 14, 2023

By: **

Russell Beyer
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of SAB Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 14, 2023

By: */s/ Eddie J. Sullivan*

Eddie J. Sullivan
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of SAB Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 14, 2023

By: */s/ Russell Beyer*

Russell Beyer
Chief Financial Officer
(Principal Financial and Accounting Officer)