Table of Contents

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

FORM 10-K

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

For the fiscal year ended December 31, 2020

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: 001-39169

Kiromic BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4762913**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
7707 Fannin Street, Suite 140, Houston, TX	**77054**
(Address of Principal Executive Offices)	Zip Code

(832) 968-4888
(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common Shares, par value $0.001 per share	KRBP	The Nasdaq Stock Market

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 Section 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 232.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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. ☐

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

As of March 31, 2021, there were 7,332,999 of the registrant's ordinary shares outstanding.

Kiromic BioPharma, Inc.

Annual Report on Form 10-K
Year Ended December 31, 2020

TABLE OF CONTENTS

ITEM 1. BUSINESS.

Overview

Revolutionizing Next-Gen Allogenic CAR Therapies for Solid Tumors.

We are a target discovery and gene-editing company utilizing artificial intelligence and our proprietary neural network platform with a therapeutic focus on immuno-oncology.

Our proprietary target discovery engine is called "Diamond."

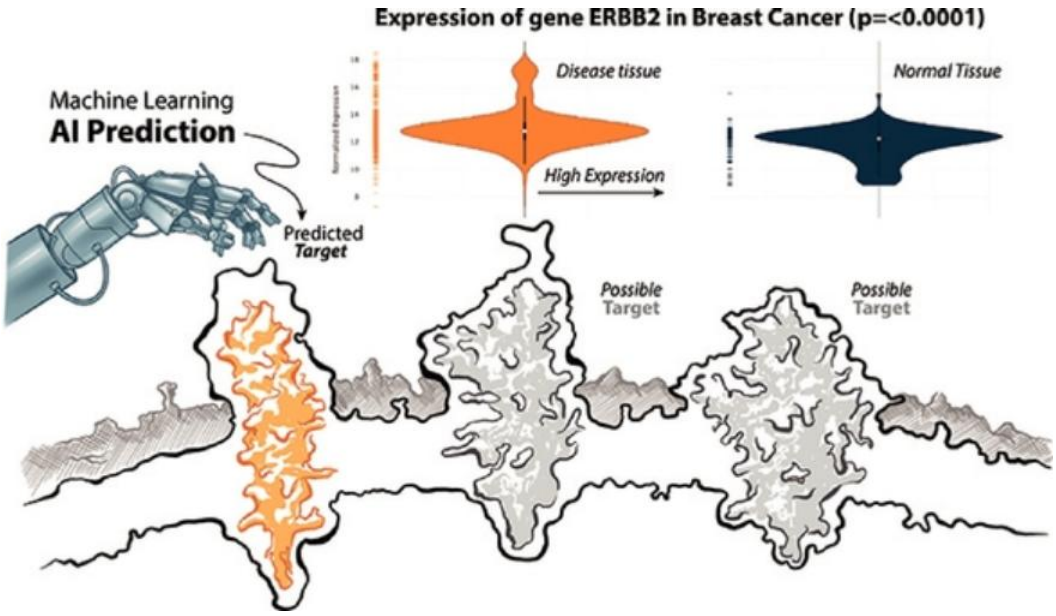
Kiromic's Diamond is big data science meeting target identification, dramatically compressing man-years and billions of drug development dollars to develop a live drug.

Without Kiromic's Diamond, the management of all the data required to solve the Target Identification puzzle is both challenging and inefficient. Normal data required for target identification would require manual analysis of thousands of cancer tissue samples with billions of data points, looking at millions of mutations, and poring over thousands of publications on oncology and targets.

Diamond (Screening, Prioritizing, and Harmonizing)

Diamond is a computational platform and a neural network that can identify new cancer immunological targets for T cells and B cells. Diamond is an artificial intelligence and machine learning approach that can identify novel surface tumor targets. It uses public and proprietary samples and can expand into the tumor target space.

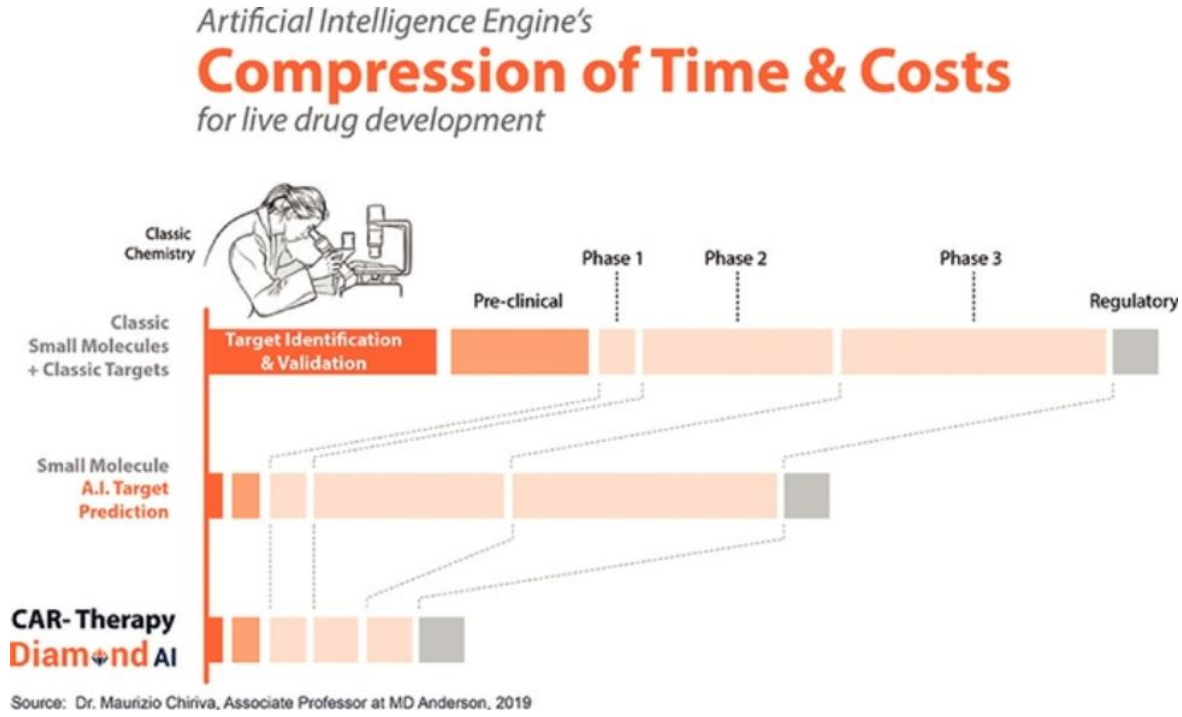
Diamond addresses the main challenges in today's clinical pipeline: *target identification*.



Diamond generates a prioritized list of cancer immunological targets for T cells and B cells. These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR-T cell therapies and vaccine therapies.

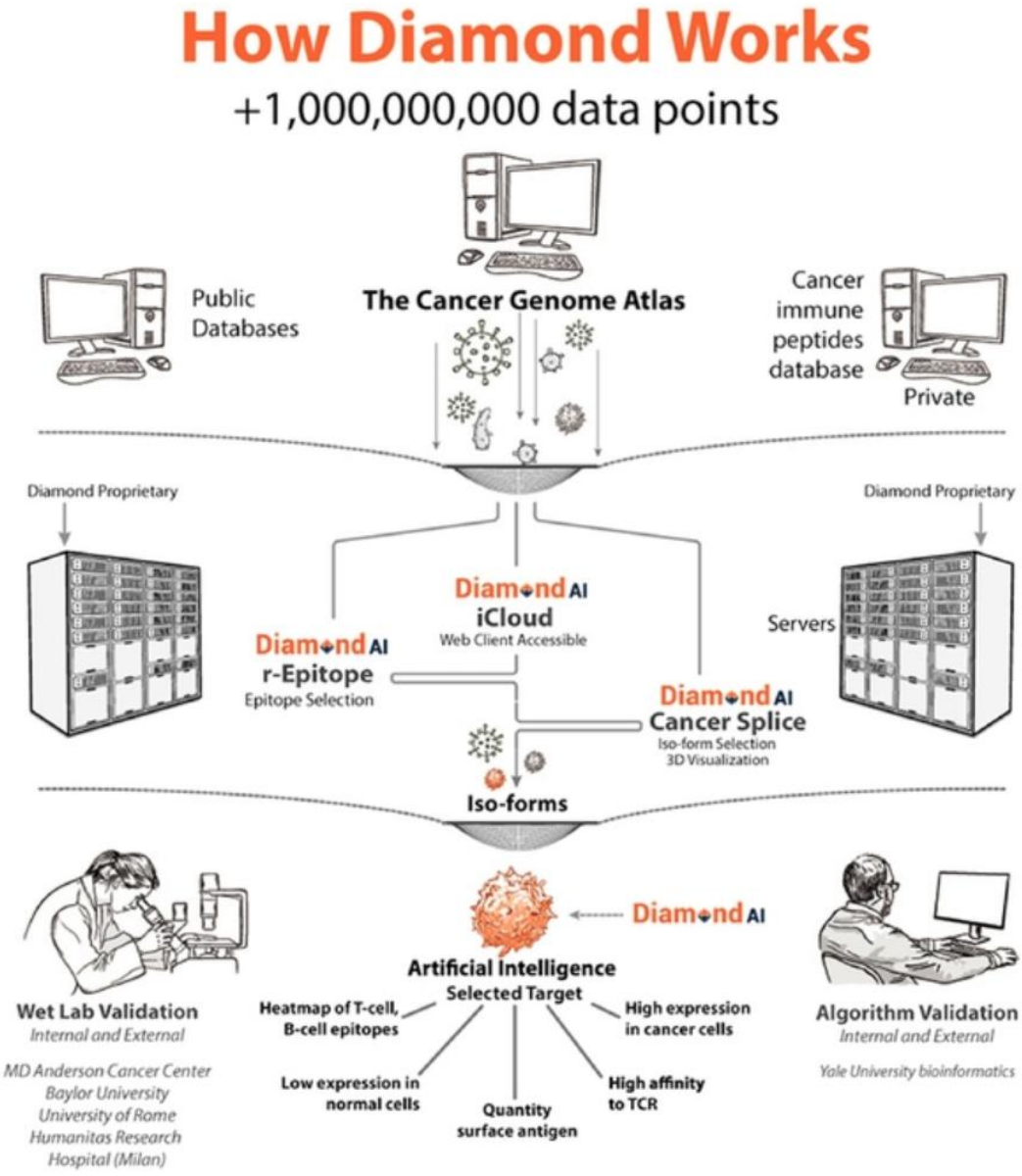
Diamond's cognitive and deep learning capabilities extract information from our extensive digital library consisting of clinical studies, genomic and proteomic datasets. Diamond harmonizes all the raw data and creates datasets, which allows us to screen for cancer targets. Diamond will identify and prioritize lists of genes (biomarkers, wild type, mutant, isoform, neoepitope, etc.) that are highly and specifically expressed in the disease of interest while providing its

distribution and methylation status across the entire patient population. It also maps out the exact portion of the gene that will elicit an immune response.



Diamond performs meta-analysis and convolution studies while standardizing and normalizing data across multiple and variable experimental platforms, then allows for the visualization of consistent and accurate results in a user-friendly fashion.

See our Diagram below which will walk readers through our process of going from antigens and target libraries to finish with target selection by our artificial intelligence engine.


How Diamond Works
+1,000,000,000 data points
Public Databases
The Cancer Genome Atlas
Cancer immune peptides database
Private
Diamond Proprietary
Diamond Proprietary
Diamond AI
iCloud
Web Client Accessible
Servers
Diamond AI
r-Epitope
Epitope Selection
Diamond AI
Cancer Splice
Iso-form Selection
3D Visualization
Iso-forms
Diamond AI
Artificial Intelligence
Selected Target
Heatmap of T-cell, B-cell epitopes
High expression in cancer cells
Low expression in normal cells
Quantity surface antigen
High affinity to TCR
Wet Lab Validation
Internal and External
MD Anderson Cancer Center
Baylor University
University of Rome
Humanitas Research Hospital (Milan)
Algorithm Validation
Internal and External
Yale University bioinformatics

Diamond AI Processes

non-exhaustive list of functions being applied by A.I. Engine

Prioritizing T and B Cell Targets. Diamond generates a prioritized list of immunological targets for T cells and B cells. These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR T cell therapies and vaccine therapies.

Identify Highly Expressed Genes. Diamond's cognitive and deep learning capabilities extract information from our extensive digital library consisting of clinical studies, genomic and proteomic datasets. Diamond harmonizes all the raw data and creates datasets which allows us to screen for cancer targets. Diamond will identify and prioritize lists of genes (biomarkers, wild type, mutant, isoform, neoepitope, etc.) that are highly and specifically expressed in the disease of interest while providing its distribution status across the entire patient population. It also maps out the exact portion of the gene that will elicit an immune response.

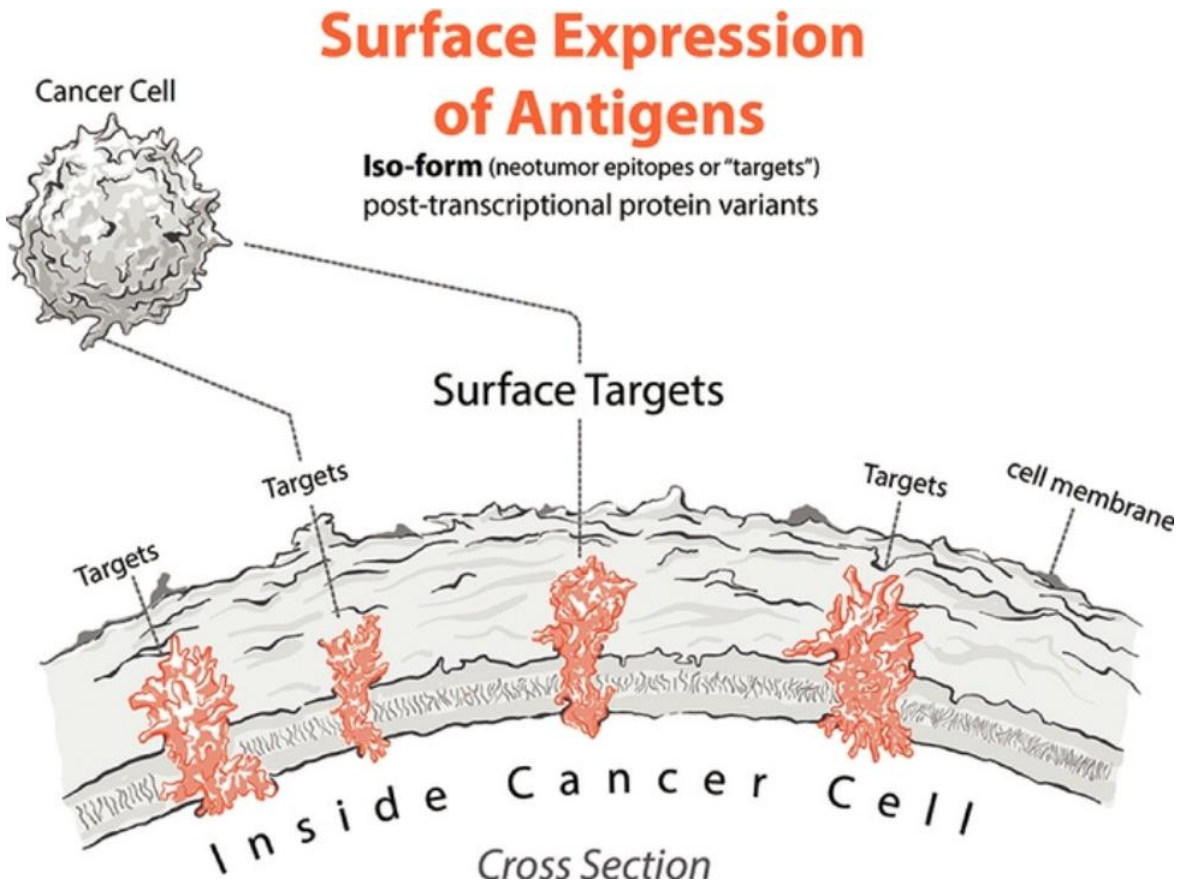
Performs Meta Analysis. Diamond performs meta-analysis and convolution studies while standardizing and normalizing data across multiple and variable experimental platforms, then allows for the visualization of consistent and accurate results in a user-friendly fashion.

Predict Isoform Targets. Cancer cells will down regulate or shed targets in order to avoid detection and destruction by T cells (the immune system). These variations are known as isoforms. CancerSplice also shows a box plot by tissue of expression of the isoform in normal cancer genome atlas tissues and a box plot of the matching isoform in genotype-tissue expression program normal data. The sequence of amino acids that are specific for the selected cancer isoforms are then directly fed to Diamond's artificial neural capsule network for peptide design and prioritization.

Diamond AI CancerSplice ™

CancerSplice (Isoform Target Prediction)

Cancer cells will down-regulate or shed targets in order to avoid detection and destruction by T cells (the immune system). One mechanism for this tumor defense is the selection for alternative splice forms of target proteins. These variations are known as isoforms. Target isoforms include variations in their primary amino acid sequence that can change both the final folded form of the target plus their ability to be recognized by pre-existing and modified T cells. Within a heterogeneous cancer cell population, isoforms can preferentially expand to avoid detection and destruction by T cells. These isoforms can make it impossible for T cells to outright bind the targets on cancer cells. No binding to the target means no killing of cancer cells.



To solve the problem of identifying shared, common cancer-specific antigens derived from alternative splicing and cancer-specific isoform formation, we have developed a fully integrated *in silico* methodology to predict cancer-specific isoforms called CancerSplice.

CancerSplice allows for the prediction and prioritization of iso-antigens which could serve as a novel source of tumor targets, highly specific for neoplastic cells but without the drawback of also being highly patient-specific.

CancerSplice allows the user to select a tissue type from the cancer genome atlas along with thresholds for filtering isoforms (minimum and maximum tumor and normal cell transcript parts per million). Based on the tissue selected, CancerSplice displays a sorted list of isoforms that are elevated in high-expressing tumors versus normal tissues which have low expression. Differential analysis is then performed and used to generate two types of lists: (1) isoforms expressed in tumor but not expressed in normal tissues; and (2) isoforms expressed in normal tissues but yet at a much higher level in tumors. CancerSplice then allows the user to click on an isoform in the list to select a specific isoform to display in a detailed panel, which shows the multi-sequence alignment for the isoform, as well as all the other isoforms of that gene.

Finally, CancerSplice also shows a box plot by tissue of expression of the isoform in normal cancer genome atlas tissues and a box plot of the matching isoform in genotype-tissue expression program normal data. The sequence of amino acids that are specific for the selected cancer isoforms are then directly fed to Diamond's artificial neural capsule network for peptide design and prioritization.

Therefore, we believe that we have developed unique tools to address the issue with tumor-specific iso-antigens through CancerSplice and Diamond.

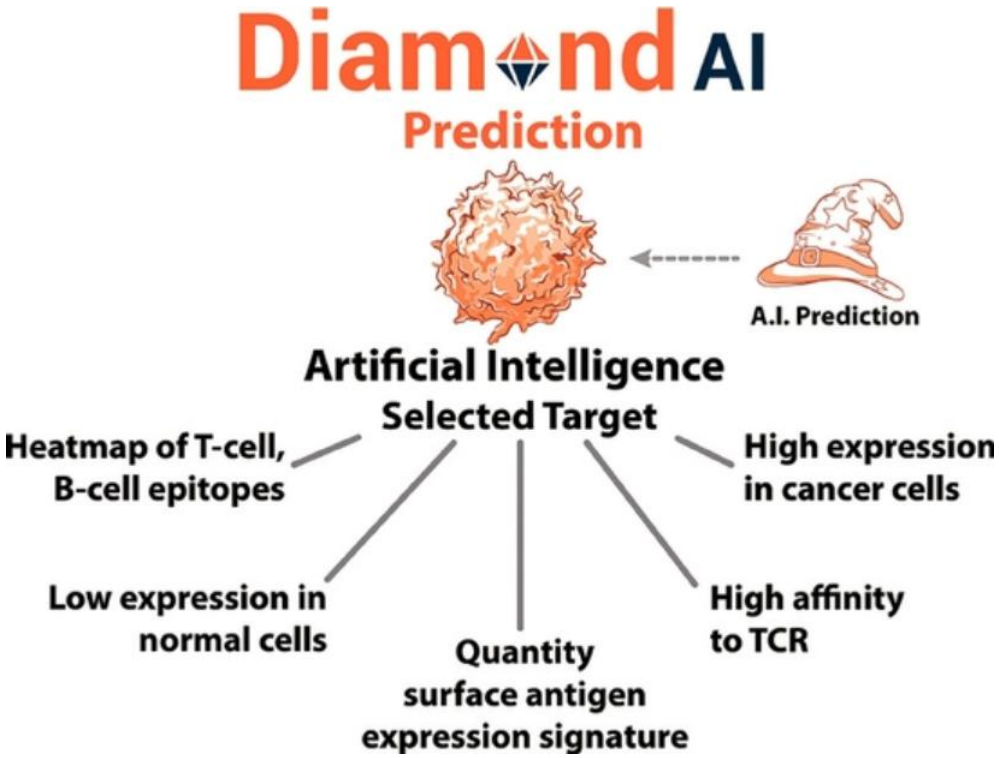
Target isoforms are protein variants of the same targets that occur during the normal processing of immature gene transcripts to the mature form.

Target isoforms include variations in their primary amino acid sequence that can change both the final folded form of the target plus their ability to be recognized by modified T cells (autologous/allogeneic) and other cells, such as NK or invariant NKT cells (often used in the allogeneic setting).

If they are the predominate form on the cell surface, these isoforms can make it impossible for T cells to outright bind the targets on cancer cells.

No binding or insufficient binding to the isoform results in no killing of cancer cells.

Our CancerSplice accurately predicts the most appropriate isoforms for T cells to bind and destroy cancer cells.



Immune Therapies Using Our Artificial Intelligence Selected Targets

With our artificial intelligence (Diamond), we seek to use our targets to train immune cells. The trained immune cells generate a therapeutic immune response in patients. These peptide sequences, known as tumor-specific iso-antigens, generate an immunological response and therefore eradicate cancer cells.

We are developing our brand of CAR cell product candidates known as ALEXIS (Allogenic Lead Exogenous Isoforms). These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. These products are in the pre-IND stage of the FDA clinical trial process. We are currently going through the validation process and expect that IND enabling studies will commence in the second half of 2020.

CAR-T cell therapy, a form of cancer immunotherapy, has recently emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers. In 2017, two autologous anti-CD19 CAR-T cell therapies, Kymriah, developed by Novartis International AG, and Yescarta, developed by Kite Pharma, Inc., (now part of Gilead), were approved by the FDA for the treatment of relapsing/remitting B cell precursor acute lymphoblastic leukemia and relapsing/remitting large B cell lymphoma, respectively. Autologous CAR-T cell therapies are

manufactured individually for the patient's use by modifying the patient's own T cells outside the body, causing the T cells to express CARs. The entire manufacturing process is dependent on the viability of each patient's T cells and takes approximately three to four weeks. Allogenic T cell therapies involve engineering healthy donor T cells, which we believe will allow for the creation of an inventory of off-the-shelf products that can be delivered to a larger portion of eligible patients throughout the world.

We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since we began principal business operations in 2012.

Engineered T Cell Therapy

White blood cells are a component of the immune system and are responsible for defending the body against infectious pathogens and other foreign material. T cells are a type of white blood cell and are involved in both sensing and killing infected or abnormal cells, including cancer cells, as well as coordinating the activation of other cells in an immune response.

T cells can be distinguished from other white blood cells by T cell receptors present on their cell surface. These receptors contribute to tumor surveillance by directing T cells to recognize infected and destroy cancerous cells. When T cells with cancer-specific receptors are absent, present in low numbers, of poor quality or rendered inactive by suppressive mechanisms, cancer may grow and spread. In addition, standard of care treatments, such as chemotherapy regimens, as well as disease specific factors can damage the patient's immune system, thereby inhibiting the ability of T cells to kill cancer.

Engineered T cell therapy is a type of immunotherapy treatment whereby human T cells are removed from the body and engineered to express CARs which, when infused into a patient, may recognize and destroy cancer cells in a more targeted manner.

CARs are engineered molecules that, when present on the surface of a T cell, enable the T cell to recognize specific proteins or antigens that are present on the surface of other cells.

There are two primary approaches to engineered T cell therapy: autologous and allogenic. Autologous therapies use engineered T cells derived from the individual patient, while allogenic therapies use engineered T cells derived from healthy donor T cells.

The autologous approach, pioneered by Novartis, Kite and others, has been highly successful in engineering patients' immune systems to fight cancer, in particular CD19 positive cancers, resulting in significant remission rates. Autologous products are manufactured by first collecting a patient's white blood cells, through a process known as leukapheresis, separating the T cells from the patient's blood sample and proliferating the isolated T cells. After the cells have multiplied, the CAR construct is virally transduced into the T cells and the engineered T cells are then propagated until a sufficient number of cells are available for infusion into the patient. Finally, the engineered T cells are frozen, and then shipped back to the clinical center for administration to the patient. The process from leukapheresis to delivery to the clinical center takes approximately three to four weeks.

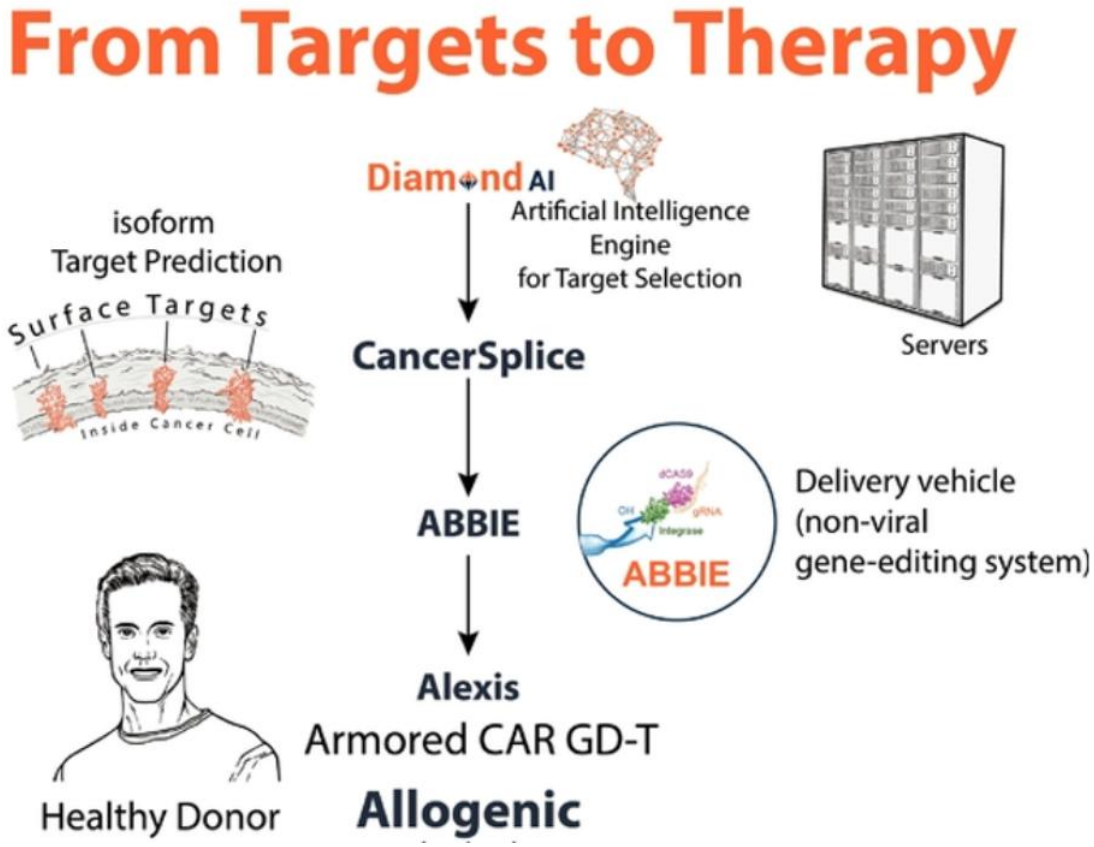
Allogenic engineered T cells are manufactured in a similar manner as autologous, but with two key differences: (1) allogenic T cells are derived from healthy donors, not cancer patients, and (2) allogenic T cells must also be genetically engineered to minimize the risk of graft-versus-host disease, a condition where allogenic T cells can recognize the patient's normal tissue as foreign and cause damage in the patient.

Our Approach

Our operating motto is Better Target, Better Life™.

Our goal is to defeat cancer by developing immunotherapies that rely on improving target discovery and validation. With better targets, we believe our therapies will be more effective than the current crop of immunotherapies using older targets.

We are currently in the process of completing the preclinical work needed to file IND submissions for first in human off the shelf gamma delta chimeric PD1 T cells, and chimeric antigen receptor (isomesothelin) gamma delta T cell therapy products. Our target indications will be metastatic and progressive locally advanced solid malignancies which have no curative options. We validate biomarkers for these product candidates using the technologies and processes discussed in the sections below. The development schema below describes the path forward for developing our novel product candidates.



ABBIE Summary

ABBIE is a novel gene-editing system for inserting therapeutic genes safely into the genome of a host cell that will be incorporated into our off the shelf gamma delta T cell therapy platform, which currently uses a retroviral methodology as noted above.

ABBIE technology comprises two main components, (i) a genome template (extracted from the ALEXIS plasmid), containing the therapeutic genes needed to retrain tumor-killing cells, and (ii) the gene-editing machinery required to safely insert this template into the genome of the therapeutic cells.

The ABBIE protein accompanies the CAR-containing genome template as it passes through the cell membrane into the nucleus and guides the template-flanking sequences (the "glue") safely into the target genome.

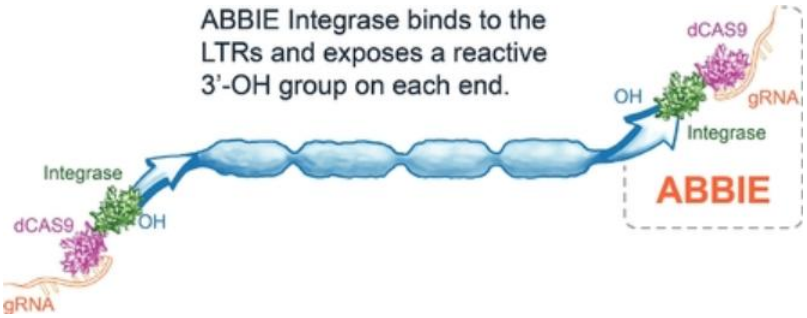
Due to this targeting ability, ABBIE can also be used to remove unwanted, inhibitory genes. CAR expression on the Gamma-Delta T cells allows them to detect and destroy the antigen-expressing targeted cells.

The OFF switch permits fast shutdown in the event of an unexpected toxicity. Additional Anti-tumor factors can help neutralize the toxic tumor microenvironment.

ABBIE: Development

We are currently developing ABBIE (A Binding-Based Integrase Enzyme) for delivering our product candidates. ABBIE is a non-viral gene-editing mechanism to insert the target DNA template information into the T cell genome at a predetermined locus. ABBIE allows for insertion of the genome template into the T cells so that they could express the CAR protein and other accessory proteins while possibly eliminating unwanted inhibitory proteins.

The non-viral vector template is simultaneously physically comingled with the patient's T/NK cells. The non-viral vector transfers the target's genomic information into the T/NK cells, where it is integrated into the T/NK cell's genome. T/NK cells now have been reprogramed with the genomic information for targeting and can successfully identify the targets on the cancer cells. This T/NK cell therapy is infused into the patient. T/NK cells will hunt down cancer cells with the known targets and destroy these cancer cells.



We believe that this gene delivery platform will deliver the DNA template to the T/NK cell genomes at a lower cost and shorter timeframe versus a viral vector. By comparison, a retroviral vector would have a longer development lead time (~12 months) with an increased insertional mutagenesis risk. Insertional mutagenesis means that a random insertion of the DNA could activate uncontrolled cell growth. ABBIE allows for a more consistent expression and will have a shorter development lead time (3-6 months). It avoids unnecessary risks by targeting a single locus and produces more predictable cell-to-cell expressions.

The development of ABBIE involves a multi-step process, which includes preparation of an integration-deficient lentivirus, a sensitive, targeted gene knock-out assay system, optimization of an inducible ABBIE protein expression system, a powerful screen for gene targeting efficiency, and a sensitive screen of additional ABBIE mutants to further improve efficacy. Altogether, the development plan involves construction of dozens of plasmid constructs, which are complete. To date, we have successfully completed the high transduction efficiency lentivirus system for our assays along with the non-integrating lentivirus system. Optimization of the selection schema is over 70% complete and the construction of the inducible expression and knock-out systems are well underway.

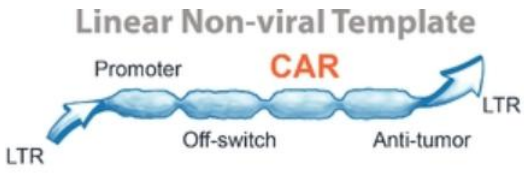


Figure 1. Our ABBIE gene-editing technology begins with the transgene template plasmid. Plasmid DNA is cut with restriction enzyme, ScaI, liberating the transgene template along with the retroviral-derived long-terminal repeats (LTRs), which is purified away from the plasmid DNA and ScaI protein.

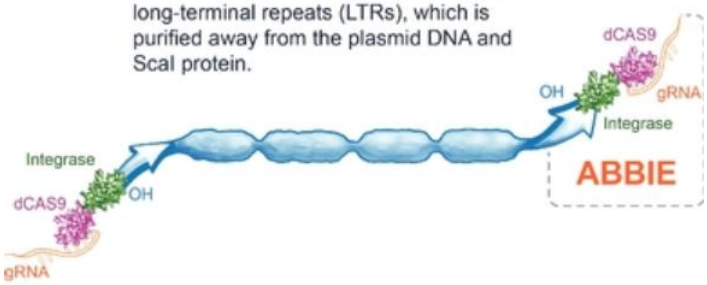


Figure 2. The ABBIE integrase, derived from HIV, is added, which binds to the LTRs and exposes a reactive 3'-OH group on each end.

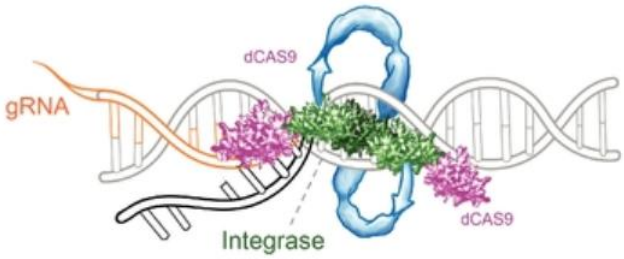


Figure 3. The guide RNA (gRNA) tethers ABBIE-bound template to the target site via DCas9, and Integrase helps to attach the exposed 3'OH groups to the target site on both strands without causing a dsDNA break.

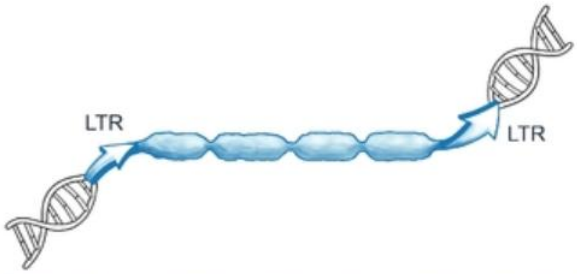
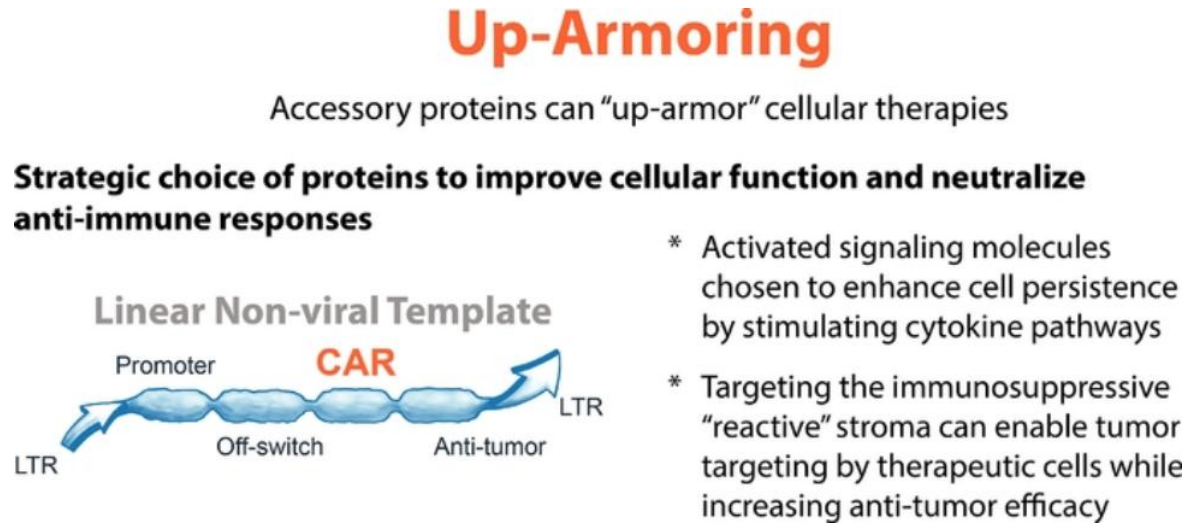


Figure 4. Following stable integration of the template into the target DNA locus, a short DNA duplication is present on each end.



Up-Armoring is another promising technology that is under development at Kiromic which will further enhance future versions of our off the shelf gamma delta T cell delivery platform.

SWITCHES

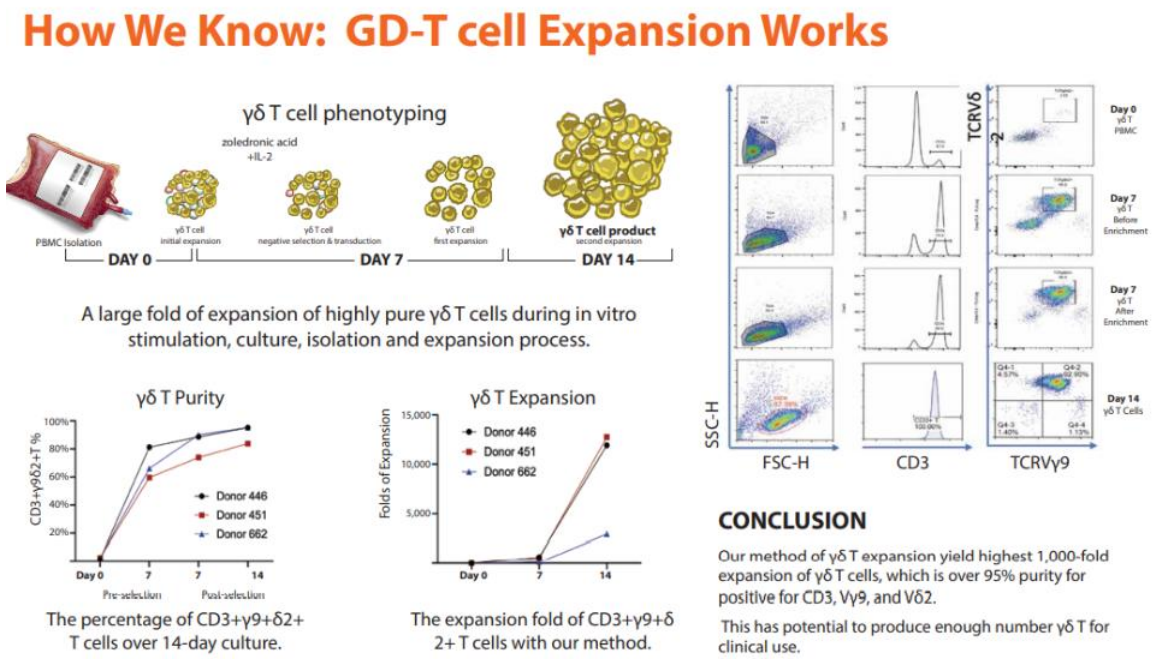
ACTIVATION Switch. A rapidly deployed activation switch can provide a survival and proliferation signal to the therapeutic cells to enhance their efficacy and persistence in vivo.

ATTENUATION Switch. A rapidly deployed attenuation switch can intercept activation signals transiently to minimize toxicity following successful anti-tumor interactions. Choice of two non-mutually exclusive Attenuation Switch approaches: (a) a protein-based switch that rapidly triggers attenuation of target cells in a dose-dependent fashion. (b) a small molecule-based approach to rapidly and reversibly attenuate cell signaling.

SAFETY Switch. A rapidly deployed, protein-based safety switch can eliminate therapeutic cells in case of acute toxicity. The safety switch is designed to eliminate either: (a) essentially all active therapeutic cells. (b) only the most active cells, preserving a cohort of backup therapeutic cells for long-term control of residual relapsing tumor cells. The Safety Switch will be co-expressed along with the bioactive chimeric activation receptor (CAR), the Activation Switch, and the Attenuation Switch.

Manufacturing Allogeneic Effector Cells

The three primary steps to creating our engineered effector cells are: (1) collection, (2) gene editing, and (3) purification, formulation, and storage.



Manufacturing

Step 1. Collection

The starting material for our engineered gamma delta T cell products are white blood cells. For our allogenic products, the cells are collected from a healthy donor. The collected cells are then sent to the Kiromic central processing facility, where the peripheral blood mononuclear cells, including gamma delta T cells, are isolated from the other sample components.

Step 2. Gene Editing

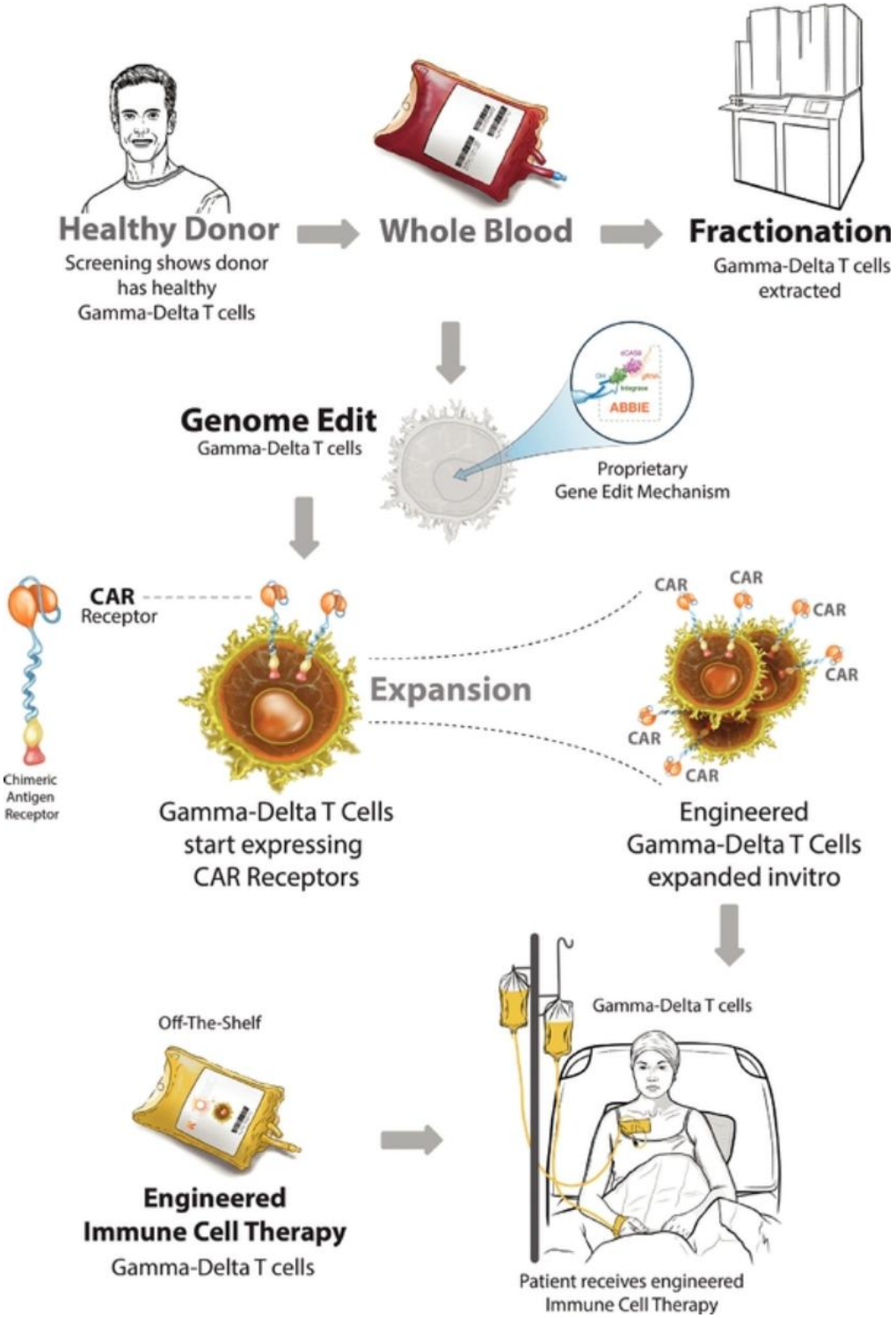
These cells are stimulated to proliferate, then transduced with a non-replicating retroviral vector.

We are also developing ABBIE, which is a non-viral gene-editing mechanism to insert the target DNA template information into the gamma delta T cell genome. The genomic sequence will direct the expression of proteins on the cell surface that allows the transduced gamma delta T cells to recognize and bind to a target molecule that is present on cancer cells.

Step 3. Purification, Formulation, and Storage

These engineered cells are then propagated in cell culture bags until sufficient cells are available. The engineered gamma delta T cells are then washed and frozen at the cell processing site.

For our allogenic products, the engineered cells are frozen and sent to long-term storage in the vapor phase of liquid nitrogen. This inventory will be securely stored and then shipped to oncology centers as needed.

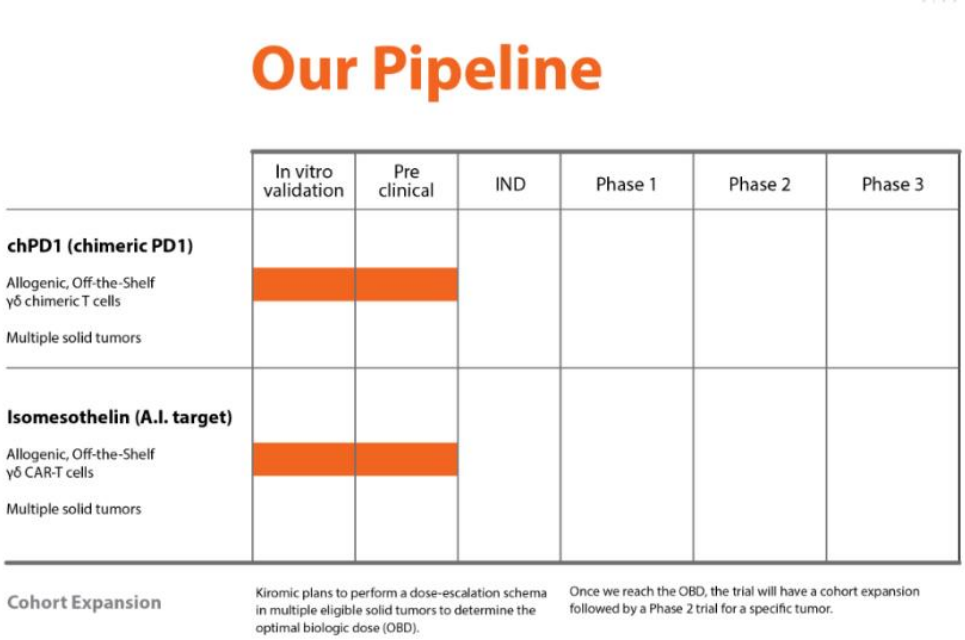


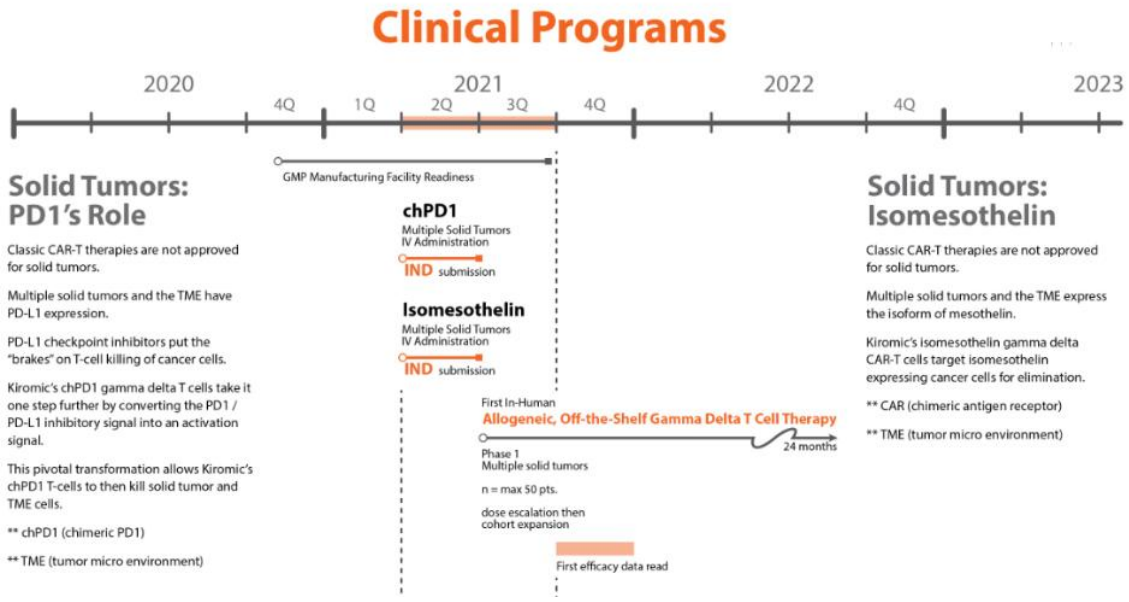
As noted previously, the gene editing is currently being done with an industry standard retroviral vector, however, in future versions we expect to utilize our non-viral ABBIE gene editing platform.

Our Product Pipeline and Development

Using our proprietary technologies, we are researching and developing multiple product candidates for the treatment of blood cancers and solid tumors. Our product candidates are allogenic engineered cells to be used for specific patients as off-the-shelf treatments for patients with metastatic or progressive locally advanced solid malignancies, including ovarian carcinoma and malignant pleural mesothelioma.

Our product pipeline and clinical program projected timelines (*clinical timelines and final patient accrual numbers are predicated upon FDA review and will be modified in accordance to FDA requirements)* are represented in the diagrams below:





Clinical Program

Not only is cancer the second leading cause of mortality worldwide, but 90% of cancer deaths are due to metastatic disease, with the remainder due primarily to locally advanced disease. Current treatments for locally advanced disease include systemic chemotherapy, radiation, and surgery, but offer only limited benefit for many subjects with locally advanced disease that is not amendable to curative surgical resection.

What makes this challenging is that solid tumors develop in complex and dynamic microenvironments that influence their growth, invasion, and metastasis. Therefore, effective novel therapies are needed for subjects with advanced solid tumors.

The field of immunotherapy is currently expanding with a variety of approaches and Kiromic Biopharma's suite of gamma delta T cell therapies is uniquely positioned to make an impact in this setting based upon our promising preclinical in vitro and in vivo studies which have revealed strong and specific tumor cytotoxicity with minimal adverse effects.

Clinical Program

The ALEXIS platform of products has been designed to incorporate our Diamond target discovery platform into an off the shelf (allogeneic) gamma delta T cell therapy that will be able to address the challenging patient population of metastatic and progressive locally advanced solid malignancies (including ovarian, malignant pleural mesothelioma, and multiple other indications as well).

Multiple solid malignancies express one or both of these biomarkers, and we anticipate that they will eventually be combined into a single powerful CAR-T cell for solid malignancies, or as a synergistic dual therapy that will achieve an impact in this devastating disease.

ALEXIS-ISO-1

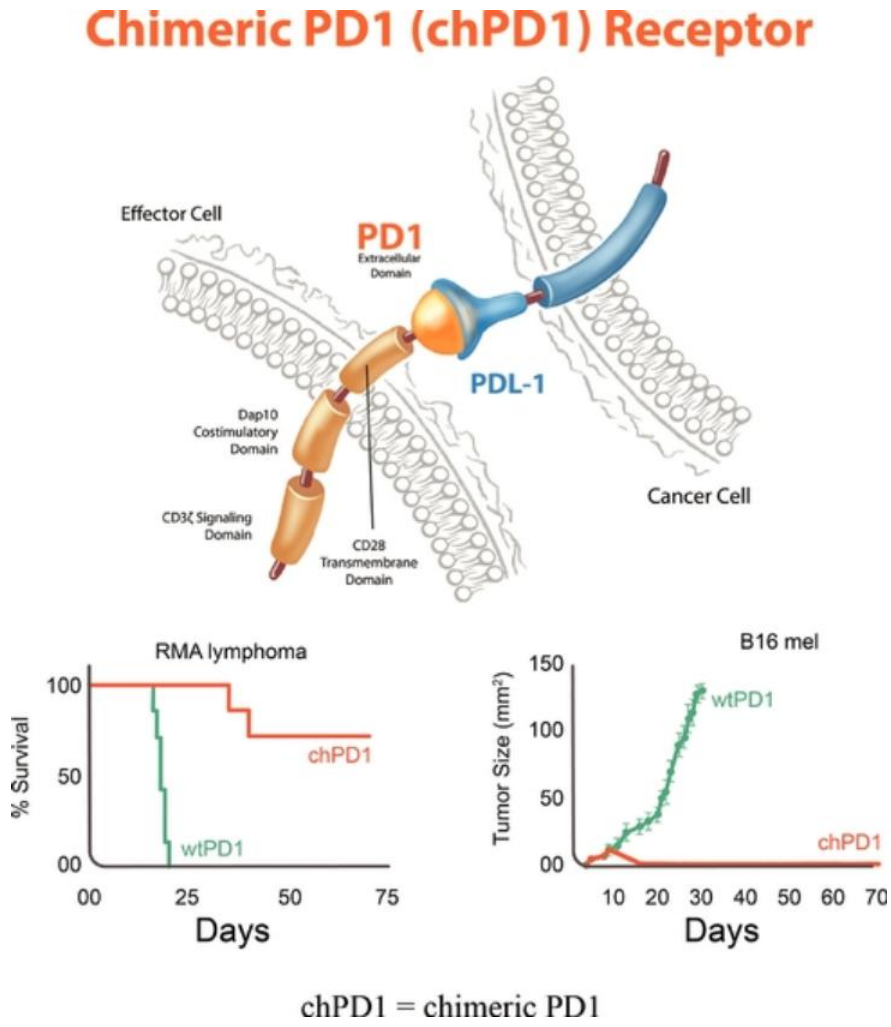
Our allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin).

ALEXIS-PRO-1

Our allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1

PD-1: Avoiding Antigen Escape

To further boost the potency of our effector cells, we have developed an off the shelf chimeric gamma delta PD1 T cell switch receptor therapy that interferes with the inhibitory "checkpoint" protein, PD-L1, found on most tumor cells and cells of the tumor microenvironment (TME). By converting what is normally an inhibitory signal into an activating signal, we predict that this will overcome the resistance of the TME and mitigate the issue of antigen loss typically seen with solid malignancies in particular.



chPD1 = chimeric PD1

The chPD1 Receptor is activated by engagement with PD-L1+ (or even PD-L2+) tumors.

Typical checkpoint inhibitors block PD-1 and PD-L1, although they have limitations since they do nothing to actually activate/energize the T cell into action, and since typically the subject's T cells are not working properly, the results are not as optimized as they would otherwise be.

Our chPD-1 (chimeric PD-1) thus takes it one step further by converting PD-1 and PD-L1 from an inhibitory signal to an activation signal. This pivotal transformation allows our chimeric T-cells to then kill solid tumor cells and the cells of the TME.

Although this chimeric PD1 gamma delta T cell can effectively lyse both hematologic and solid tumors expressing PD-L1, the focus of the first related Investigational New Drug (IND) submission will focus on solid malignancies that

express PD-L1 as this represents one of the greatest need in oncology at this time. This IND submission is supported by strong in vitro and in vivo tumor cytotoxicity data, and thus far no significant adverse effects have been noted in the animal models tested, which has included the testing of multiple types of solid malignancies.

Development Plan

ALEXIS-ISO-1 will be studied in "A Phase 1, First-in-Human, Open-label, Dose Escalation Study of an Allogeneic Gamma Delta CAR-T Cell Therapy (KB-ISM) in Subjects with Isomesothelin positive Metastatic or Progressive Locally Advanced Solid Malignancies.

The primary goal will be to assess safety, tolerability, and efficacy at increasing dose levels in order to estimate the optimal biologic dose (OBD) which will serve as the dose for an additional 20 patient cohort expansion.

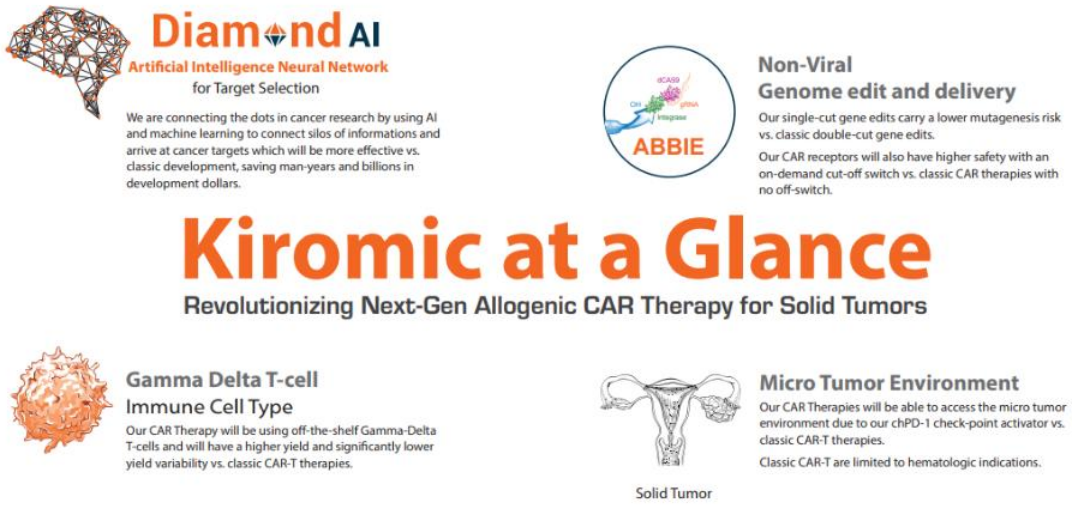
Prior to treatment, all patients are expected to undergo selected screening process to assure that they meet all the corresponding inclusion and exclusion criteria, and are expressing the intended target (Iso Mesothelin).

ALEXIS-PRO-1 will be studied in "A Phase 1, First-in-Human, Open-label, Dose Escalation Study of an Allogeneic Gamma Delta PD1 T Cell Switch Receptor Therapy (KB-PD1) in Subjects with PD-L1 positive Metastatic or Progressive Locally Advanced Solid Malignancies".

The primary goal will be to assess safety, tolerability, and efficacy at increasing dose levels in order to estimate the optimal biologic dose (OBD) which will serve as the dose for an additional 20 patient cohort expansion.

Prior to treatment, all patients are expected to undergo selected screening process to assure that they meet all the corresponding inclusion and exclusion criteria, and are expressing the intended target (PD-L1).

We plan to file a Phase 1 IND submission for both ALEXIS-PRO-1 and ALEXIS-ISO-1 in Q2 2021 with the first patients projected for enrollment in Q3 2021, and with first results projected in Q4 2021.



Our Manufacturing Operations

We have invested resources to optimize our manufacturing process, including the development of improved analytical methods. We plan to continue to invest in process science, product characterization and manufacturing to continuously improve our production and supply chain capabilities over time.

Our product candidates are designed and manufactured via a platform comprised of defined unit operations and technologies. The process is gradually developed from small to larger scales, incorporating compliant procedures to

create current cGMP conditions. Although we have a platform-based manufacturing model, each product is unique and for each new product candidate, a developmental phase is necessary to individually customize each engineering step and to create a robust procedure that can later be implemented in a cGMP environment to ensure the production of clinical batches. This work is performed in our research and development environment to evaluate and assess variability in each step of the process in order to define the most reliable production conditions.

We will engage third-party CMOs to manufacture the retroviral vector that delivers the applicable CAR gene into the T cells under cGMP. We believe all materials and components utilized in the production of the cell line, retroviral vector and final T cell product are readily available from qualified suppliers.

We believe the use of contract manufacturing and testing for the first clinical product candidates is cost-efficient and has allowed us to rapidly prepare for clinical trials in accordance with our development plans. We expect third-party CMOs will be capable of providing and processing sufficient quantities of product candidates to meet anticipated clinical trial demands.

In addition, we believe we have sufficient space at our headquarters in Houston, Texas, which is being adapted to manufacture clinical grade products.

If any of our product candidates are approved, to meet projected needs for commercial sale quantities, we anticipate that we will need to obtain additional manufacturing capacity through CMOs to be able to supply and process products on a patient-by-patient basis.

We intend to screen multiple manufacturers, including both current and alternate suppliers, to secure sufficient capacity for commercial purposes prior to the filing of a Biological License Application. We believe that commercial requirements can be met, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs.

Our Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, as well as novel discoveries, product development technologies, and know-how.

Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and applications related to our technology, inventions, and improvements that are important to the development and implementation of our business.

We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position. The confidentiality agreements are designed to protect our proprietary information and the invention assignment agreements are designed to grant us ownership of technologies that are developed for us by our employees, consultants, or other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of using and manufacturing the same.

Patents

We are actively building an intellectual property portfolio around our product candidates and our discovery programs, based on intellectual property we own as well as licensed intellectual property. We are the owners of, co-owners of, or the licensee of multiple patents and patent applications in the United States and worldwide. Our patent portfolio includes patent applications having claims directed to aspects of our lead product candidates, ALEXIS-PRO-1 and ALEXIS-ISO-1, as well as other research-stage candidates. Our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward: (1) antigen binding domains directed to the targets of our product candidates; (2) CAR constructs used in our product candidates; (3) methods of treatment for therapeutic indications; (4) manufacturing processes; and (5) and methods for genetically engineering immune cells suitable for autologous and allogenic use.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier- filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

As of December 31, 2020, our patent estate includes three issued U.S. patents and 22 pending patent applications (13 of which are in the U.S.), each of which we either own, jointly own, or for which we have an exclusive commercial license (either in its entirety or within our field of use), as is more fully described below. Our patent families related to our product candidates are described below.

Diamond (Screening, Prioritizing, and Harmonizing) and CancerSplice (Isoform Target Prediction), Therapeutic Targets and Vaccine Therapeutics

Our tumor targets patent estate includes portfolio families directed to target identification processes, therapeutics and treatments we co-developed or developed internally (1-9) and one portfolio family (10) directed to therapeutics and treatments related to a vaccine therapeutic under development.

1. The application titled "Platform for Identification of Tumor-Associated Cancer/Testis Antigens" is a United States utility patent application that is expected to expire on April 25, 2037, absent any patent term adjustment (PTA) or patent term extension (PTE). The claims in this patent application include composition of matter, use and process for a method of identifying cancer/testes antigens (CTAs) useful as cancer treatment targets, the method comprising: identifying human sperm proteins to which patients diagnosed with solid or hematological malignancies have established a humoral immune response.

2. The application entitled "Methods for Identifying and Using Diseases-Associated Antigens" is an international Patent Cooperation Treaty (PCT) patent application from which national/regional applications, if filed, are expected to expire on May 29, 2040. The claims in this patent application are directed in part to methods for identifying proteins encoded by genes having tumor-associated hot-spot mutations and/or tumor-associated mRNA splice variants, methods for identifying immunogenic portions of such proteins, and uses thereof.

3. The application titled, "Anti-Human/Mouse Sperm Protein 17 (SP17) Antibody and Derivatives Thereof" is a United States utility patent application that is expected to expire on March 22, 2037, absent any patent term adjustment or patent term extension. The claims in this patent application include composition of matter, use, and method for a novel monoclonal antibody, designated as GD6, and various derivatives thereof, which target an epitope of human and murine Sperm Protein 17 (SP17) which possesses broad expression on cells derived from numerous solid malignancies.

4. The family titled "Compositions and Methods for Treating Cancers" contains one utility patent application that has been filed in the United States and has entered the national phase in Europe, Mexico, and China that are expected to expire on March 13, 2037, absent any patent term adjustment or patent term extension. The claims in these patent applications include composition of matter, uses and methods related to administering to a subject having a cancer a therapeutically effective amount of the pharmaceutical composition of combinations of Galectins, which are S-type lectins that bind ß-galactose-containing glycoconjugates.

5. The family titled, "CdS Quantum Dot-Chitosan-Anti-SP17 Nanohybrid as a Potential Cancer Biomarker" contains one utility patent filed in the United States that is expected to expire on February 23, 2038, absent any patent term adjustment or patent term extension. The claims in this patent application include composition of matter of a nanoconjugate consisting of a quantum dot nanoparticle conjugated to an anti-SP17 antibody, wherein the conjugating molecule is chitosan. The claims in this patent application also include methods for detecting cancer cells in biological systems consisting in administering the anti-SP17 nanoconjugate and performing imaging analysis using the quantum-dot fluorescence emission.

6. The family includes a United States Provisional Application entitled, "OroVAX: AI Prediction of SARS-CoV-2 Immune Epitope Peptides for the Development of an Oral Vaccine" and a United States Provisional Application entitled "Peptide Compositions for the Treatment of Pathogenic Infections," the first of which is expected to expire on May 9, 2021. No claims were filed in the earlier-filed provisional application. We plan to file at least an international PCT patent application claiming priority to these two provisional applications on or before May 8, 2021.

7. The family titled, "Hydrogen Peroxide-Containing Oral Care Composition for Mitigation, Prevention, or Treatment of Human Coronavirus-Associated Infections." It is a United States Provisional Application that is expected to expire on May 14, 2021. No claims were filed with the provisional application. We plan to file a United States utility patent application claiming priority to the provisional application before the provisional application expires.

8. The family containing one application filed in Europe entitled, "Novel Nanoparticle—Based Vaccine Targeting Cancer/Testis Antigens (CTA) and its' Use in Solid and Hematological Malignancies," that is expected to expire on November 19, 2035, absent any extension of the patent right by a supplementary protection certificate (SPC). The claims in this patent application are directed to an oral vaccine composition and use thereof.

9. The application entitled "Disease-Associated Isoform Identifier" is a United States Provisional Application expected to expire on November 19, 2020. We plan to file at least an international PCT patent application claiming priority to this provisional application on or before November 18, 2021.

10. The family has been exclusively in-licensed from Mercer University. It is titled, "Nanospheres Encapsulating Bioactive Material and Method for Formulation of Nanospheres" and contains three issued United States Patents and one pending application. One of the issued patents is expected to expire on September 29, 2029 supplemented by 540 days of patent term adjustment, the remaining two issued patents and the pending application are expected to expire on September 29, 2029. The claims in this patent family include composition of matter and methods for a method for forming microspheres containing bioactive material, comprising dissolving a polymer matrix, such as albumin or betacyclodextrin, in an aqueous medium in a first vessel.

Chimeric PD1 Receptor

Chimeric PD1 Receptor is the additional targeting element that interferes with the inhibitory "checkpoint" protein, PD1 found on most activated T cells and other effector cells.

The Chimeric PD1 Receptor patent family includes patent applications titled, "PD1-Specific Chimeric Antigen Receptor as an Immunotherapy" that have been exclusively in-licensed from Longwood University. The patent family contains patent applications filed in the United States and in other jurisdictions that are expected to expire on September 26, 2038, absent any patent term adjustment or patent term extension. The claims in the patent application are directed to chimeric antigen receptor (CAR) polypeptide; a vector comprising the CAR polypeptide; and a T lymphocyte genetically modified to express the CAR polypeptide. The claims in the patent application also are directed to a method of treating cancer using T lymphocytes genetically modified to express the CAR polypeptide.

Gamma-Delta T-cell Expansion

We have developed binding molecules directed to an iso-mesothelin isoform expressed in tumors at a higher level than in non-tumor tissues, including chimeric antigen receptor (CAR) binding molecules. We also have developed a chimeric PD1 molecule and effector cell expansion processes, e.g., Gamma-Delta T-cell expansion processes and Invariant Natural Killer T (iNKT) cell manufacturing processes, for manufacturing allogeneic effector cells.

The family includes a United States Provisional Application entitled "Mesothelin Isoform Binding Molecules and Uses Thereof" and a United States Provisional Application entitled "Mesothelin Isoform Binding Molecules and Chimeric PD1 Binding Molecules, Cells Containing the Same and Uses Thereof," the first of which is expected to expire on July 8, 2021. We plan to file at least an international PCT patent application claiming priority to these two provisional applications on or before July 7, 2021.

Switch Technology

The Activation Switch can provide a survival and proliferation signal to the therapeutic cells to enhance their efficacy and persistence in vivo. The Attenuation Switch can intercept activation signals transiently to minimize toxicity following successful anti-tumor interactions. The Safety Switch can eliminate therapeutic cells in case of acute toxicity.

The Switch Technology patent family titled "Tri Switch Technology for Multi-Dimensional Control of Cell Therapy" is a United States Provisional Application that is expected to expire on June 15, 2021. No claims were filed on the provisional application. We plan to file a United States utility patent application claiming priority to the provisional application before the provisional application expires.

ABBIE (Genetic Delivery Vehicle)

ABBIE is the delivery vehicle for our lead product candidates, ALEXIS-PRO-1 and ALEXIS-ISO-1, as well as our other research-stage candidates.

The ABBIE patent family has been exclusively in-licensed from CGA 369, Inc. It is entitled, "CAS 9 Retroviral Integrase and CAS 9 Recombinase Systems for Targeted Incorporation of a DNA Sequence into a Genome of a Cell or Organism." The patent family contains patent applications that were filed in Europe, China, Japan, Korea, and the United States and patents granted are expected to expire on March 31, 2036, absent any patent term adjustment or patent term extension. The claims in this patent family are directed to recombinant proteins, compositions that include such proteins and guide RNA, vectors encoding such proteins, and methods of use. Two patent applications in the family are not currently pending and we have made submissions for reinstatement.

License Agreements

Mercer University

On December 1, 2016, we entered into a license agreement with Mercer University, or Mercer, pursuant to which Mercer granted to us an exclusive license for certain inventions and technologies related to nanoparticles useful as vaccines. As compensation for this license, we paid Mercer a license fee and agreed to pay royalties of the net selling price of all licensed products sold once we start selling the products developed with the licensed intellectual property. Finally, we also agreed to make the following milestone payments: (i) upon initiation of an FDA Phase II clinical trial; (ii) upon the first dosing in the FDA Phase III clinical trial, and (iii) upon Biologic License Application (“BLA”) approval. The potential milestone payments total $325,000 in the aggregate. The royalty range for the license agreement is between 1% and 5%. The term of this license agreement continues until all licensed patents expire. The Mercer patents associated with the license agreement contain three issued United States Patents and one pending application, the last of which is expected to expire on September 29, 2029 (with 540 days of patent term adjustment). We may terminate this agreement at any time upon sixty (60) days written notice. Mercer may terminate this agreement upon the occurrence of a material breach of the agreement that is not cured by us within sixty (60) days of notice of such breach.

CGA 369

On September 14, 2018, we entered into a license agreement with CGA 369 Intellectual Holdings, Inc., or CGA, which was amended on October 16, 2019. Pursuant to this license agreement, CGA granted to us an exclusive license for certain inventions and technologies related to the use of engineered DNA binding proteins exhibiting genome specificity such as Cas9, TALE, and Zing finger proteins attached by a linker with viral integrases or a recombinase in older to deliver DNA sequence of interest (or gene of interest) to a targeted site in a genome of a cell or organism. As compensation for this license, we agreed to pay CGA a license fee, which payment is conditioned upon a sublicense and our receipt of upfront fee in connection with such sublicense of at least $5 million. We also agreed to pay royalties based on a percentage of the net selling price of all licensed products sold once we start selling the products developed with the licensed intellectual property. The net selling price is equal, subject to certain exceptions, to the gross selling price less (i) sales and excise taxes, value added taxes, and duties which fall due and are paid by the purchaser as a direct consequence of such sales and any other governmental charges imposed upon the importation, use or sale of such product, but only to the extent that such taxes and duties are actually included and itemized in the gross amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of such product, customarily included and itemized in the gross amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of all comparable products in the relevant market and are not recovered or recoverable; (ii) trade, quantity and cash discounts that are customary in the pharmaceutical industry and that are actually allowed on such product; (iii) allowances or credits to customers on account of rejection, withdrawal, recall, or return of such product or on account of retroactive price reductions or price protection charges or reprocurement/failure to supply charges affecting such product, to the extent that such allowances, credits or charges are customary in the pharmaceutical industry; and (iv) discounts, rebates and chargebacks specifically related to such product on an accrual basis, which shall be trued up and reconciled in the ordinary course of business, including, but not limited to, those granted to government agencies. Finally, we also agreed to make the following milestone payments: (i) upon completion of a positive Phase III clinical trial; (ii) upon FDA approval; (iii) upon our aggregate net sales of licensed products reaching $100 million in a single calendar year; (iv) upon our aggregate net sales of licensed products reaching $250 million in a single calendar year, and

(v) upon our aggregate net sales of licensed products reaching $500 million in a single calendar year. The potential milestone payments total to $9.5 million in the aggregate. The royalty range for the CGA 369 license is between 1% and 5%. The CGA 369 patents associated with the license agreement contains five utility applications in Europe, China, Japan, Korea, and the United States, the last of which is expected to expire on March 31, 2036. The term of this license agreement continues until all licensed patents expire. We may terminate this agreement at any time upon sixty (60) days written notice. CGA may terminate this agreement upon the occurrence of a material breach of the agreement that is not cured by us within ninety (90) days of notice of such breach.

Longwood University

Effective March 25, 2020, we entered into a license agreement with Longwood University, or Longwood. Pursuant to this license agreement, Longwood granted to us the exclusive right to negotiate a worldwide, exclusive license for certain patent rights. The patent rights pertain to "T-cells expressing a chimeric-PD l- CD3zeta receptor reduce tumor burden in multiple murine syngeneic models of solid cancer." As compensation for this right, we agreed to pay Longwood an upfront fee of $15,000. We also agreed to reimburse Longwood for fees and expenses incurred for the preparation, filing, prosecution and maintenance of such patent rights.

Our Research and Development Collaborations

MDACC Grant

We provided a grant to the University of Texas, MD Anderson Cancer Center ("MDACC"). The arrangement provides for MDACC to test the efficacy of: 1) AIDT-1 isoform targeting (and/or other isoforms for hematological diseases: 2) ALEXIS Isoform Mesothelin Targeting: The anti-mesothelin isoform CAR we plan to test in these pre-clinical studies could be potentially developed for more effective and safer target expression expressing solid malignancies and/or alternative targets for solid tumor. As compensation for this collaboration, we agreed to pay MDACC a fee. The agreement's commencement date was April 1, 2020 and terminates on March 31, 2021.

Molipharma Agreement

On April 3, 2020, we entered into a joint venture agreement ("Joint Venture") with Molipharma, S.R.L. ("Molipharma") to collaborate in (1) a clinical trial program in oncology development ("Oncology") and (2) a clinical trial program in COVID-19 Vaccine ("COVID-19 Vaccine").

With respect to Oncology, we will grant a low single digit royalty to Molipharma for turnover of the marketing of ovarian cancer research in Europe. With respect to COVID-19 Vaccine, economic rights in Europe will transfer to Molipharma, and economic rights in the United States will transfer to us. Molipharma agreed to undertake to financially support the research program for COVID-19 and we agreed to financially support the research program in oncology. The Joint Venture has a duration of five years, extendable for a further five years, unless notice of non-renewal is sent one year before the expiration date. The parties may withdraw from the Joint Venture only for serious and justified reasons or by mutual consent.

Leon Office (H.K.) Agreement

On January 28, 2021, we executed a strategic alliance agreement with Leon Office (H.K.) (“Leon”) a company established under existing laws of Hong Kong. It is intended that Leon acts as an independent business development advisor on our behalf. Leon will seek to introduce organizations and individuals that will create business development opportunities for us, to expand our reach to international markets with a focus on certain Asian markets and to increase brand recognition and exposure through developing liaisons, collaborations, branches and subsidiaries. The cost of the agreement is $360,000 annually, payable in four quarterly installments.

Our Competition

Our products will compete with novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to standard of care treatments.

In 2017, two autologous anti-CD19 CAR T cell therapies, Kymriah, developed by Novartis International AG, and Yescarta, developed by Kite Pharma, Inc., were approved by the FDA for the treatment of relapsing/remitting B-cell precursor acute lymphoblastic leukemia and relapsing/remitting large B cell lymphoma, respectively.

Due to the promising therapeutic effect of T cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies, as well as in the development of allogenic T cell therapies.

Potential cell therapy competitors include:

• *Autologous T cell therapy competition:* Adaptimmune Therapeutics PLC, Amgen Inc., Autolus Therapeutics plc, bluebird, Gilead (acquired Kite), Novartis International AG, Celgene (acquired Juno), Tmunity Therapeutics, Inc. and Unum Therapeutics Inc.

• *Allogenic T cell therapy competition:* Atara Biotherapeutics, Inc., Celyad S.A., CRISPR Therapeutics AG, Fate Therapeutics Inc., Intellia Therapeutics, Inc., Gilead (acquired Kite), Allogene Therapeutics, Inc., Poseida Therapeutics, Inc., Precision Biosciences, Inc., Sangamo Therapeutics, Inc., and Cytomed Therapeutics Pte, Ltd.

Competition will also arise from non-cell based immune and other pursued by small-cap biotechnology and large-cap pharmaceutical companies including Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Incyte Corporation, Merck & Co., Inc., and F. Hoffmann-La Roche AG. For instance, we may experience competition from companies, such as Amgen Inc., Regeneron Pharmaceuticals, Inc., Xencor Inc., MacroGenics, Inc., GlaxoSmithKline plc and F. Hoffmann-La Roche AG, that are pursuing bispecific antibodies, which target both the cancer antigen and T cell receptor, thus bringing both cancer cells and T cells in close proximity to maximize the likelihood of an immune response to the cancer cells. Additionally, companies, such as Amgen Inc., GlaxoSmithKline plc and Seattle Genetics, Inc., are pursuing antibody drug conjugates, which utilize the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, pre-clinical testing, clinical trials, manufacturing, and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, and convenience.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, as well as for technologies complementary to, or necessary for, our programs.

Corporate Information

Our principal executive office is 7707 Fannin, Suite 140, Houston, TX 77054. Our telephone number is (832) 968-4888. Our website is www.kiromic.com. The information contained on our website is not a part of this annual filing, nor is such content incorporated by reference herein, and should not be relied upon in determining whether to make an investment in our common stock.

GreenPlanet Pharma

Our wholly-owned subsidiary, GreenPlanet Pharma, Inc., operates an oral healthcare business. It has developed a mouthwash using a high quality, safe, and natural ingredient formulation to provide effective symptomatic relief for a wide range of oral irritations and health concerns.

This business has not generated any revenues.

Government Regulation

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a Biologic License Application, or BLA, for marketing authorization. Our products are considered more than minimally

manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. 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 time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's GCPs, and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

• FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. 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 patients 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. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the 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 completed. Certain clinical trials involving human gene transfer research also must be overseen by an Institutional Biosafety Committee, or IBC, a standing committee to provide peer review of the safety of research plans, procedures, personnel training and environmental risks of work involving recombinant DNA molecules. IBCs are typically assigned certain review responsibilities relating to the use of recombinant DNA molecules, including reviewing potential environmental risks, assessing containment levels, and evaluating the adequacy of facilities, personnel training, and compliance with the National Institutes of Health Guidelines. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

• *Phase 1.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

•*Phase 2.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the 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 to benefit ratio of the product and provide an adequate basis for product labeling.

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 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 patients, 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 or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. 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 biological product has been associated with unexpected serious harm to patients.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for 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.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, 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, or the PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for biological products. 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. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe,

potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult 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 Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product.

A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will 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 cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP 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.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness 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 FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any product for an indication for which orphan designation has been granted.

However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

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 generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and 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 product 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 user 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.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product, submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the 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 that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy, or RMAT, designation was established by FDA in 2017 to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any

combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review.

Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of 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 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.

Fast Track designation, priority review, RMAT and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although a physician may prescribe a legally available product for an off-label use, if the physicians deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved 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 cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement,

warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The Biologics Price Competition and Innovation Act, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits 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 product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and 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 trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the CMS, other divisions of the HHS (e.g., the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments). For example, our business practices, including any future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, transparency requirements, and similar state, local and foreign laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti- Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law 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 federal civil False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, 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. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is

available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

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 penalties, including without limitation, civil, criminal and 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, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In

addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time.

Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- created an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;

- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;

- 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 manufacturers' outpatient drugs to be covered under Medicare Part D;

- 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 by, among other things, allowing states to offer Medicaid coverage to additional individuals and added new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expanded of the list of entities eligible for discounts under the 340B Drug Discount Program;

- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- expanded healthcare fraud and abuse laws, including the Foreign Corrupt Practices Act, or the FCPA, and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- created 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;

- required reporting of certain financial arrangements with physicians and teaching hospitals;

- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to physicians;

- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and

- created a licensure framework for follow on biologic products.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the current U.S. President has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act.

On January 22, 2018, the current U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices.

The Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

Congress is continuing to consider legislation that would alter other aspects of the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for

fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further 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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the U.S. President's administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing 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.

The Foreign Corrupt Practices Act

The FCPA prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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, The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in

relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

California Consumer Privacy Act

California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or the CPPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. As of January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Human Capital

Our Employees. As of December 31, 2020, we had a total of 19 employees. Of the 19 employees, 18 employees were employed in the United States of America with one employee employed in Italy. Our highly qualified and experienced team includes scientists, physicians, laboratory technicians, finance professionals, and administrative professionals. We also utilize a number of consultants for financial reporting, clinical, regulatory, and Securities and Exchange Commission (“SEC”) compliance.

We believe that we maintain a satisfactory working relationship with our employees, and we have not experienced any significant labor disputes or any difficulty in recruiting staff for our operations. None of our employees is represented by a labor union.

Employee Engagement, Talent Development & Benefits. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, and opportunities for equity ownership.

Diversity, Inclusion, and Culture. Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

Overseas Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials 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 trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU 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 EU, with the exception of, among other things, country-specific document requirements.

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

If we or our potential collaborators 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.

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation, or the GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors", together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

- We have never been profitable and may never achieve or maintain profitability.
- If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.
- We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.
- Our business is dependent on the successful development, regulatory approval and commercialization of our personalized immunotherapy product candidates, which are in the early stages of development and have not been tested in humans.
- Our tumor-specific cancer immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.
- We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our immunotherapy candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.
- The genome editing field is relatively new and evolving rapidly, and other existing or future technologies may provide significant advantages over our Diamond, CancerSplice and ABBIE technologies, which could materially harm our business.
- If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.
- Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators. We plan to enter into significant arrangements with collaborators and expect to depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.
- We plan to enter into significant arrangements with collaborators and expect to depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.
- We expect to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

- We may rely on third parties for the manufacturing process of product candidates, and failure by those parties to adequately perform their obligations could harm our business.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.
- Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.
- The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.
- Our ability to compete effectively in our markets may decline if we do not adequately protect our patents and proprietary rights, and our patents and proprietary rights do not necessarily address all potential threats to our competitive advantage.

ITEM 1A. RISK FACTORS.

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10-K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Our Business and Industry

We have never been profitable and may never achieve or maintain profitability.

We have not commercialized any products and have yet to generate any revenue from product sales. The amount of our future net losses will depend, in part, on our expenses and our ability to generate revenues. Our current and future product candidates will require substantial additional development time and resources before we may realize revenue from product sales, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our current research and development programs, including conducting laboratory, preclinical and greenhouse studies for product candidates;
- initiate clinical or field trials for product candidates;
- seek to identify, assess, acquire or develop additional research programs or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for any product candidates that may successfully complete development;
- establish a sales, marketing and distribution infrastructure to commercialize any products that may obtain marketing approval;
- further develop and refine the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers of biological materials or product candidates;
- validate a commercial-scale manufacturing facility compliant with current good manufacturing practices, or cGMP;
- further develop our genome editing technology;
- acquire or in-license other technologies;
- seek to attract and retain new and existing personnel; and
- expand our facilities.

No clinical studies have begun on any of our new therapeutic product candidates, and it will be several years, if ever, before we obtain regulatory approval for a therapeutic product candidate, at which time any revenues for such product candidate will depend upon many factors, including, market conditions, costs and effectiveness of manufacturing, sales, marketing and distribution operations related to such product candidate, and the terms of any collaboration or other strategic arrangement we may have with respect to such product candidate and levels of reimbursement from third-party payors.

If we are unable to develop and commercialize one or more product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval or is commercialized are insufficient, we may not achieve profitability or sustain profitability, which would have an adverse effect on the value of our common stock will be materially adversely affected.

If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.

The process of identifying product candidates and conducting preclinical and clinical trials is time consuming, expensive, uncertain and takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate clinical or field trials of, and seek marketing approval for, product candidates. In addition, if any therapeutic product candidate that we develop alone or with collaborators obtains marketing approval, we may incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution efforts. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise sufficient capital when needed, we may be forced to delay, reduce or eliminate current or future research programs, product development activities and/or commercialization efforts.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain sufficient funding on a timely basis or on favorable terms, we may be required to significantly delay, reduce or eliminate one or more of our research or product development programs and/or commercialization efforts. We may also be unable to expand our operations or otherwise capitalize on business opportunities as desired. Any of these events could materially adversely affect our financial condition and business prospects.

We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.

We are a genome editing company with a limited operating history. We began principal business operations in 2012 and spent the first three years of our company's history developing and refining our core technology, and only since then have we focused our efforts on advancing the development of product candidates.

Investment in biopharmaceutical product development is a highly speculative endeavor and entails substantial upfront capital expenditures. There is significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain any required regulatory approvals or become commercially viable. Our platforms and the technologies we are using are new and unproven. We have not yet commenced human clinical trials for any of our product candidates, nor have we demonstrated an ability to initiate or successfully complete any clinical trials, obtain any required marketing approvals, manufacture products, conduct sales, marketing and distribution activities, or arrange for a third party to do any of the foregoing on our behalf.

Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing products. Our limited operating history, particularly in light of the rapidly evolving nature of the biopharmaceutical industries and the genome editing field, may make it difficult to evaluate our technology and business prospects or to predict our future performance.

We may expend our limited resources pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates.

Research programs to identify new product candidates and product development platforms require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs, product candidates or product development platforms that ultimately prove to be unsuccessful. Clinical trials of any of our product candidates is not assured despite the expenditure of significant resources in pursuit of their development, and our spending on

current and future research and development programs, product candidates and product development platforms may not yield any commercially viable products.

Additionally, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our financial situation creates doubt whether we will continue as a going concern.

The Company has not generated any revenues to date. For the years ended December 31, 2020 and 2019, the Company had a net loss of $19,200,200 and $3,727,900, respectively. There can be no assurances that we will be able to achieve a level of revenues adequate to generate sufficient cash flow from operations or obtain funding from additional financing through private placements, public offerings and/or bank financing necessary to support our working capital requirements. No assurance can be given that additional financing will be available, or if available, will be on acceptable terms. These conditions raise substantial doubt about our ability to continue as a going concern.

Our business may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel Coronavirus (‘‘COVID-19’’) has evolved into a global pandemic. COVID-19 has spread to many regions of the world. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

Should COVID-19 continue to spread, our business operations could be delayed or interrupted. For instance, our research and development may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If COVID-19 continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our research activities, including clinical trials.

Infections and deaths related to the pandemic may disrupt the United States’ healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

In the event of a shelter-in-place order or other mandated local travel restrictions, our employees conducting research and development or manufacturing activities may not be able to access their laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole.

However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

We will incur increased costs as a result of becoming a public company and in the administration of our organizational structure.

As a public company, we will incur significant legal, accounting, insurance, and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with the Sarbanes-Oxley Act and related rules implemented by SEC. We will incur ongoing periodic expenses in connection with the administration of our organizational structure. The expenses incurred by public companies for reporting and corporate governance purposes have generally been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any significant degree of certainty. In estimating these costs however, we took into account expenses related to insurance, legal, accounting, and compliance activities, as well as other expenses not currently incurred. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

We identified material weaknesses in our internal control over financial reporting at December 31, 2020, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. Though we disclose changes made in our internal controls and procedures on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following this annual report. As an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following this annual report, or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event our internal control over financial reporting is not effective.

Notwithstanding the foregoing, in connection with the audit of our financial statements for the year ended December 31, 2020, we and our auditors identified certain control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses resulted from (i) lack of internal control processes and procedures regarding the financial close and reporting process, procure to pay process, and human resources and payroll process; (2) those controls being designed without the appropriate segregation of duties; and (3) lack of full time accounting and finance personnel, including, but not limited to, personnel focused upon enhanced scrutiny of accounting entries in the areas where we have observed material weaknesses in our internal control over financial reporting. In order to remediate this material weakness, we have hired and plan to continue to hire additional accounting, finance, system engineers, and data analysts. We have implemented, and plan to continue to implement, new controls, new processes and technologies to implement formalized internal controls framework and procedures. We cannot assure you that the measures that we have taken to

remediate, and that will be taken to remediate, these material weaknesses will be sufficient to prevent future material weaknesses from occurring. We also cannot assure you that we have identified all of our existing material weaknesses.

In light of the control deficiencies and the resulting material weaknesses that were identified, we believe that it is possible that, had we and our registered public accounting firm performed an assessment or audit, respectively, of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified.

When evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we are unable to remediate our existing material weaknesses or identify additional material weaknesses and are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

Risks Related to our Product Candidates

Our business is dependent on the successful development, regulatory approval and commercialization of our personalized immunotherapy product candidates, which are in the early stages of development and has not been tested in humans.

We have no products approved for sale. 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 ALEXIS-PRO-1 and ALEXIS-ISO-1, as well as other product candidates derived from our tumor-specific immunotherapy approach, which may never occur.

In the future, we may also become dependent on other product candidates that we may develop or acquire; however, no product candidates based on our tumor-specific immunotherapy approach have been tested in humans and given our early stage of development, it may be many years, if at all, before we have demonstrated the safety and efficacy of a personalized immunotherapy treatment sufficient to warrant approval for commercialization.

We have not previously submitted a biologics license application, or BLA, to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The clinical and commercial success of our current and any future product candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;

- our ability to complete IND-enabling studies and successfully submit an IND;
- timely completion of our preclinical studies and clinical trials, which may be slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to consistently manufacture our product candidates on a timely basis;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk-benefit profile of our product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our cancer immunotherapy approach;
- our ability to successfully develop a commercial strategy and thereafter commercialize our current product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our product candidates that may be approved;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our current or future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide

assurances that we will be able to generate sufficient revenue through the sale of our product candidate or any future product candidates to continue our business or achieve profitability.

Our tumor-specific cancer immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

We are using our proprietary technologies to develop tumor-specific immunotherapy product candidates to treat cancer. Our foundational science and product development approach are based on our ability to predict the presence of a patient's tumor-specific iso-antigens, or TSIAs, and develop a

TSIA-directed therapy that will elicit a meaningful specific immune-system cell response (T or NK cells). We believe that this approach may offer an improved therapeutic effect by driving an intense, focused attack selectively upon a patient's tumor. However, this approach to treating cancer is novel and the scientific research that forms the basis of our efforts to predict the presence of TSIA and to develop a CAR that targets TSIA-directed cancer immunotherapy candidates is both preliminary and limited.

Our tumor-specific immunotherapy product candidates have experienced limited testing in humans. We are currently in the process of validating different tumor-specific immunotherapy product candidates. When we validate adequate biomarkers for these product candidates, we will commence preclinical animal studies, and the results of our preclinical animal studies may not translate into humans. For example, our prediction model may fail to accurately predict the presence of TSIAs, resulting in little or no T cell activity, or our therapy may fail to elicit a significant or durable enough T or NK cell response to effectively destroy a tumor.

As such, we cannot assure you that even if we are able to develop cancer immunotherapy candidates capable of recognizing TSIA and eliciting a T cell response, that such therapy would safely and effectively treat cancers. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic.

Furthermore, no regulatory authority has granted approval for a cancer immunotherapy based on a heterologous prime-boost approach. As such, we believe the FDA has limited experience with evaluating our approach, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our immunotherapy candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Diamond, CancerSplice and ABBIE are novel technologies, making it difficult to predict the time, cost and potential success of product candidate development. We have not yet been able to assess the safety and efficacy of any product candidates in humans. Our success depends on our ability to develop and commercialize product candidates using our novel genome editing technology ABBIE. The novel nature of our technology makes it difficult to accurately predict the developmental challenges we may face for product candidates as they proceed through research, preclinical or greenhouse studies and clinical or field trials.

There have been a limited number of clinical trials of products created with genome editing technologies, none of which has utilized our technology, and no therapeutic product candidates created with other genome editing technologies have received marketing approval in the United States or Europe. Because our therapeutic research programs are all in research or preclinical stages, we have not yet been able to assess the safety or efficacy of any product candidates in humans.

Current or future product candidates may not meet safety and efficacy requirements for continued development or ultimate approval in humans and may cause significant adverse events or toxicities. All of our product candidates are designed to act at the level of DNA, and because animal DNA differs from human DNA, it will be difficult for us to test our therapeutic product candidates in animal

models for either safety or efficacy, and any testing that we conduct may not translate to their effects in humans. Moreover, animal models may not exist for some of the targets, diseases or indications that we intend to pursue.

Our product candidates may not be able to properly implement desired genetic edits with sufficient accuracy to be viable therapeutic products, and there may be long-term effects associated with them that we cannot predict at this time. Any problems we experience related to the development of our genome editing technology or any of our or our collaborators' research programs or product candidates may cause significant delays or unanticipated costs, and we may not be able to satisfactorily solve such problems. These factors may prevent us or our collaborators from completing our preclinical studies or any clinical trials that we or our collaborators may initiate, or profitably commercializing any product candidates on a timely basis, or at all.

The genome editing field is relatively new and evolving rapidly, and other existing or future technologies may provide significant advantages over our Diamond, CancerSplice and ABBIE technologies, which could materially harm our business.

To date, we have focused our efforts on optimizing our proprietary genome editing technology and exploring its potential applications. Other companies have previously undertaken research and development of genome editing technologies using sequence-specific DNA-cutting enzymes, or nucleases, that are designed to perform modifications in the DNA of living cells and organisms, or using zinc finger nucleases, transcription activator- like effector nucleases, or TALENs, and clustered regularly interspaced short palindromic repeats associated protein-9 nuclease, or CRISPR/Cas9, although none has obtained marketing approval for a product candidate developed using such technologies. Other genome editing technologies, or other existing or future technologies, may lead to the development of treatments or products that may be considered better suited for use in human therapeutics, which could reduce or eliminate our commercial opportunity.

We are heavily dependent on the successful development and translation of our technologies, and due to the early stages of our product development operations, we cannot give any assurance that any product candidates will be successfully developed and commercialized. To date, we have invested substantially all of our efforts and financial resources to develop our technologies and advance our current product development programs, including conducting preclinical studies and other early research and development activities, and providing general and administrative support for these operations.

Our future success is dependent on our ability to successfully develop and, where applicable, obtain regulatory approval for, including marketing approval for, and then successfully commercialize, product candidates, either alone or with collaborators. We have not yet developed and commercialized any product candidates, and we may not be able to do so, alone or with collaborators. Our research and development programs may not lead to the successful identification, development or commercialization of any products.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators.

We face an inherent risk of product liability and professional indemnity exposure related to the testing in clinical trials of our product candidates. We will face an even greater liability risk if we commercially sell any products that we or our collaborators may develop for human use.

Manufacturing defects, errors in product distribution or storage processes, improper administration or application and known or unknown side effects of product usage may result in liability claims against us or third parties with which we have relationships. These actions could include claims resulting from acts by our collaborators, licensees and subcontractors over which we have little or no control. For example, our liability could be sought by patients

participating in clinical trials for potential therapeutic product candidates as a result of unexpected side effects, improper product administration or the deterioration of a patient's condition, patient injury or even death.

Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing any product candidates or products that we develop alone or with collaborators. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that product candidates or products we develop alone or with collaborators caused harm, we could incur substantial liabilities.

Clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, 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.

Product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if our collaborators or ourselves successfully commercialize any products.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers 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 market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities 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 a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered 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 annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law, certain other healthcare providers starting in 2022 and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our

business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.Risks Related to Our Reliance on Third Parties.

We expect to depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.

Working with collaborators poses several significant risks, including the following:

- limited availability of resource allocation and other developmental decisions made by our collaborators about the product candidates or technologies that we seek to develop with them may result in the delay or termination of research programs, studies or trials, repetition of or initiation of new studies or trials or provision of insufficient funding or resources for the completion of studies or trials or the successful marketing and distribution of any product candidates that may receive approval;

- collaborators could independently develop, or develop with third parties, product candidates or technologies that compete directly or indirectly with our product candidates or technologies if the collaborators believe that competitive products or technologies are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and

- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization activities or that result in costly litigation or arbitration that diverts management attention and resources.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. If our collaborations do not result in the successful development and commercialization of product candidates or technologies, or if one of our collaborators terminates its agreement with us, we may not receive any future funding or milestone or royalty payments under the collaboration.

If we do not receive the funding we expect under these agreements, our development of product candidates or technologies could be delayed, and we may need additional resources to develop such product candidates or technologies. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators and may need to raise additional capital to pursue further development or commercialization of the applicable product candidates or technologies.

These events could delay development programs and negatively impact the perception of our company in business and financial communities. Failure to develop or maintain relationships with any current collaborators could result in the loss of opportunity to work with that collaborator or reputational damage that could impact our relationships with other collaborators in the relatively small industry communities in which we operate.

Moreover, all of the risks relating to product development, regulatory approval and commercialization described in this prospectus apply to the activities of our collaborators. If our existing collaboration agreements or any collaborative or strategic relationships we may establish in the future are not effective and successful, it may damage our reputation and business prospects, delay or prevent the development and commercialization of product candidates and inhibit or preclude our ability to realize any revenues.

We expect to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain

regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We expect to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations, or CROs, to conduct preclinical studies and future clinical trials for our product candidates. Nevertheless, we will be responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on such third parties will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulations, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Although we intend to design the trials for our product candidates either alone or with collaborators, third parties may conduct all of the trials. As a result, many important aspects of our research and development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future studies and trials will also result in less direct control over the management of data developed through studies and trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Such third parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities, become financially distressed or form relationships with other entities, some of which may be our competitors.

We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs or other third parties, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. For any violations of laws and regulations during the conduct of our preclinical studies and future clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

If we, our collaborators, our CROs or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We also are required to register certain ongoing clinical trials and post the results of such completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If our CROs or other third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, trials for product candidates may be extended, delayed or terminated, and we or our collaborators may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. If we are required to repeat, extend the duration of or increase the size of any trials we conduct, it could significantly delay commercialization and require significantly greater expenditures.

As a result of any of these factors, our financial results and the commercial prospects for any product candidate that we or our collaborators may develop would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If we are unable to obtain sufficient quantities of raw materials and supplies, at acceptable prices and on a timely basis, it could harm our business.

We are dependent on third parties for the supply of various biological materials, such as cells, cytokines and antibodies, and the manufacture of product supplies, such as media, plasmids, mRNA and viral vectors, that are necessary to produce our product candidates. The supply of these materials could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all.

Changing suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we or our collaborators may not be able to develop, manufacture and market product candidates in a timely and competitive manner, or at all. If any of our product candidates receives approval, we will likely need to seek alternative sources of supply of raw materials or manufactured product supplies and there can be no assurance that we will be able to establish such relationships to provide such supplies on commercially reasonable terms or at acceptable quality levels, if at all.

If we are unable to identify and procure additional sources of supply that fit our required needs, we could face substantial delays or incur additional costs in procuring such materials.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of allogenic T cell therapies for cancer. We may also request regulatory approval of future CAR-based product candidates by target, regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations.

Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective 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;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;

- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities 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, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. The FDA's review of our data of our ongoing clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as ''interchangeable'' based on its similarity to an approved biologic. Under the Biologics Price Competition and Innovation Act, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the Biologics Price Competition and Innovation Act may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could

result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Because we are developing novel CAR T cell immunotherapy product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies, formerly known as the Office of Cellular, Tissue and Gene Therapies, within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise the Center for Biologics Evaluation and Research on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the EU a special committee called the Committee for Advanced Therapies was established within the European Medicines Agency in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products to assess the quality, safety and efficacy of advanced-therapy medicinal products, and to follow scientific developments in the field. Advanced-therapy medicinal products include gene therapy products as well as somatic cell therapy products and tissue engineered products.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our

CAR T cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products.

Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

If and when our planned Phase 1 clinical trials for ALEXIS-PRO-1 and ALEXIS-ISO-1 and our other initial product candidates are completed and, assuming positive data, we expect to advance to potential registrational trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. If the results from our clinical trials are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development

plans will be sufficient for submission of a BLA. For example, the FDA may require that we conduct a comparative trial against an approved therapy including potentially an approved autologous T cell therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

The FDA may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. We believe an accelerated approval strategy is warranted given the limited alternatives for patients that our initial product candidates target, but the FDA may ultimately require a Phase 3 clinical trial prior to approval, particularly since our product candidates represent a novel treatment. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

- Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the 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 clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;

- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;

- 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 the 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;

- the FDA or comparable foreign regulatory authorities will review our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; 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.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) 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 or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

We may seek orphan drug designation for at least one of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations.

Regenerative Medicine Advanced Therapy designation, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Regenerative Medicine Advanced Therapy, or RMAT, designation for one or more of our product candidates. In 2017, the FDA established the RMAT designation to expedite review of a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review.

Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. There is no assurance that we will be able to obtain RMAT designation for any of our product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that

the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Negative public opinion and increased regulatory scrutiny of genetic research and therapies involving gene editing may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The gene editing technologies that we use are novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates. Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians in the large bone marrow transplant centers to be particularly influential and we may not be able to convince them to use our product candidates for many reasons. For example, certain of the product candidates that we will be developing target a cell surface marker that may be present on cancer cells as well as non-cancerous cells. It is possible that our product candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete

Risks Related to Intellectual Property

Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our business position.

The patent positions of biopharmaceutical and biotechnology companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office (the USPTO) and its foreign counterparts are sometimes uncertain and could change in the future.

Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or designed around. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to reexamination, post-grant review and/ or inter parties review proceedings in the USPTO.

International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, inter parties review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Furthermore, even if not challenged, our patents and patent applications may not adequately protect our technology and any product candidates or products that we develop alone or with collaborators or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications that we hold with respect to our product candidates or potential products is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, such product candidates or potential products.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and product candidates or products without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We rely on our outside counsel and employ an outside firm to pay these fees due to USPTO and non-US patent agencies. The USPTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market which would have a material adverse effect on our business.

If the patent applications we hold or have in-licensed with respect to our current and future research and development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our technology or any products and product candidates that we or our collaborators may develop, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our or our collaborators' ability to commercialize future product candidates. Any such outcome could have a material adverse effect on our business.

Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantages.

We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect Diamond, CancerSplice, ABBIE, and ALEXIS and other product candidates. Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to Diamond, CancerSplice, ABBIE, and ALEXIS and other product candidates, as well as successfully defending these rights against third- party challenges and successfully enforcing these rights to prevent third-party infringement. We will only be able to protect Diamond, CancerSplice, ABBIE, and ALEXIS and other product candidates from unauthorized use by third parties to the extent that valid and enforceable patents or effectively protected trade secrets cover them.

Our ability to obtain and maintain patent protection for Diamond, CancerSplice, ABBIE, and ALEXIS and other product candidates is uncertain due to a number of factors, including the following factors:

- we may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we may not be the first to file patent applications covering product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our compositions and methods may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions, or methods of use thereof;
- others may design around our patent claims to produce competitive technologies or products that fall outside of the scope of our patents;
- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;
- we may not seek or obtain patent protection in countries and jurisdictions that may eventually provide us a significant business opportunity;
- we may decide not to maintain or pursue patents and patent applications that, at some point in time, may cover our products, potential products, or product candidates;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- others may identify prior art or other bases upon which to challenge and ultimately invalidate our patents or otherwise render them unenforceable;
- the growing scientific and patent literature relating to engineered endonucleases and modified CAR-T/NK cells, including our own patents and publications, may make it increasingly difficult or impossible to patent new engineered nucleases and modified CAR-T/NK cells in the future;
- our representatives or their agents may fail to apply for patents in a timely fashion; and
- despite our efforts to enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in patents and patent applications, an inventorship or ownership dispute could arise

that may permit one or more third parties to practice our technologies or enforce our patent rights, including possible efforts to enforce patent rights against.

Even if we have or obtain patents covering Diamond, CancerSplice, ABBIE, and ALEXIS or any other product candidates or compositions, others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop any product candidates or to successfully commercialize any approved products alone or with collaborators. In addition, because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that may cover Diamond, CancerSplice, ABBIE, and ALEXIS or any other product candidates or compositions. These patent applications may have priority over patent applications filed by us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited.

Without patent protection for current or future product candidates, we may be open to competition from generic versions of such potential products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to those we or our collaborators may develop.

In addition, we also try to protect our trade secrets, know-how and other proprietary information through non-disclosure and confidentiality provisions in our agreements with parties who have access to them, such as our employees, consultants and research partners. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets, know-how and/or other proprietary information in the event of unauthorized uses or disclosure or other breaches of the provisions, and we may not be able to prevent such unauthorized uses or disclosure. Moreover, if a party having an agreement with us has an overlapping or conflicting obligation to a third party, our rights in and to certain intellectual property could be undermined. Monitoring unauthorized and inadvertent disclosure and uses is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. In addition, monitoring unauthorized disclosure and uses of our trade secrets is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside the United States may be less willing to protect trade secrets.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Because we may rely on third parties to manufacture our potential product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our current and potential product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third

parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, are used inappropriately to create new inventions or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. Additionally, we may need to outsource and rely on third parties for many aspects of the development, sales and marketing of any products covered under our current and future license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with our licensors. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If such licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing products using such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

If we are unable to do so, we or our collaborators may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. In other cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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 would be prohibitively expensive, and 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, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may 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 have patent protection, but 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 them from competing.

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 biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs 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 our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, 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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may now and in the future employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to the Market for Our Common Stock

Our common stock may be volatile or may decline regardless of our operating performance, and you may not be able to resell your shares at or above the purchase price.

The market price for our common stock is likely to be volatile. In addition, the market price of our common stock may fluctuate significantly in response to several factors, most of which we cannot control, including:

- quarterly variations in our operating results compared to market expectations;
- adverse publicity about us, the industries we participate in or individual scandals;
- announcements of new offerings or significant price reductions by us or our competitors;
- stock price performance of our competitors;

- fluctuations in stock market prices and volumes;
- changes in senior management or key personnel;
- changes in financial estimates by securities analysts;
- the market's reaction to our reduced disclosure as a result of being an ''emerging growth company'' under the JOBS Act;
- negative earnings or other announcements by us or our competitors;
- defaults on indebtedness, incurrence of additional indebtedness, or issuances of additional capital stock;
- global economic, legal and regulatory factors unrelated to our performance; and
- the other factors listed in this ''Risk Factors'' section.

In addition, the recent outbreak of COVID-19 has caused broad stock market and industry fluctuations. We may incur rapid and substantial decreases in our stock price in the future that are unrelated to our operating performance or prospects. Additionally, recently, securities of certain companies have experienced significant and extreme volatility in stock price due short sellers of shares of common stock, known as a "short squeeze." Volatility in the market price of our common stock may prevent investors from being able to sell their shares at or above the purchase price. As a result, you may suffer a loss on your investment.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the market price for the shares and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our common stock or publishes inaccurate or unfavorable research about our business, the market price for our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our common stock to decline.

We do not expect to pay dividends in the foreseeable future, and you must rely on price appreciation of your shares for return on your investment.

We have paid no cash dividends on any class of our stock to date and we do not anticipate paying cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Accordingly, investors must be prepared to rely on sales of their shares after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our shares. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

We may issue additional debt and equity securities, which are senior to our common stock as to distributions and in liquidation, which could materially adversely affect the market price of our common stock.

In the future, we may attempt to increase our capital resources by entering into additional debt or debt-like financing that is secured by all or up to all of our assets, or issuing debt or equity securities, which could include issuances of commercial paper, medium-term notes, senior notes, subordinated notes or shares. In the event of our liquidation, our

lenders and holders of our debt securities would receive a distribution of our available assets before distributions to our stockholders. In addition, any additional preferred stock, if issued by our company, may have a preference with respect to distributions and upon liquidation, which could further limit our ability to make distributions to our stockholders. Because our decision to incur debt and issue securities in our future offerings will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings and debt financing.

Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future. Thus, you will bear the risk of our future offerings reducing the value of your common stock and diluting your interest in our company.

General Risk Factors

Our future success depends on our ability to retain our Chief Executive Officer, and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development experience, technical skills, leadership and continued service of certain members of our management and scientific teams, including Maurizio Chiriva Internati, our Chief Executive Officer, Scott Dahlbeck, our Chief Medical Officer, Gianluca Rotino, our Chief Strategy and Innovation Officer, and Tony Tontat, our Chief Financial Officer and Chief Operating Officer.

Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. We maintain a $10 million ‘‘key man’’ life insurance policy for Dr. Chiriva Internati, our Chief Executive Officer, but not for any of our other team members. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and, if we retain commercialization responsibility for any product candidate we develop alone or with collaborators, sales and marketing personnel, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms or at all given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

The inability to recruit, integrate, motivate and retain additional skilled and qualified personnel, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We will need to significantly expand our organization, and our future financial performance, ability to develop and commercialize product candidates alone or with collaborators and ability to compete effectively will depend in part on our ability to effectively manage any future growth. We may have difficulty identifying, hiring and integrating new personnel.

Many of the biotechnology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can identify and develop product candidates, enter into collaborative arrangements and otherwise operate our business will be limited.

Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel.

Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources from other projects, such as the development of product candidates. If we are not able to effectively manage the expansion of our operations, it may result in weaknesses in our infrastructure, increase our expenses more than expected, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity.

We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.

We are subject to income and non-income taxes in the United States. Income tax accounting often involves complex issues, and judgment is required in determining our provision for income taxes and other tax liabilities. We could become subject to income and non-income taxes in non-US jurisdictions as well. In addition, many operating foreign jurisdictions have detailed transfer pricing rules, which require that all transactions with non-resident related parties be priced using arm's length pricing principles within the meaning of such rules. The application of withholding tax, goods and services tax, sales taxes and other non-income taxes is not always clear and we may be subject to tax audits relating to such withholding or non-income taxes. We believe that our tax positions are reasonable, and our tax reserves are adequate to cover any potential liability. We are currently not subject to any tax audits.

However, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

We or third parties with whom we have relationships may be adversely affected by natural or manmade disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural or manmade disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged our infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time, and our research and development activities could be setback or delayed.

The disaster recovery and business continuity plan(s) we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our or third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

Our Company's governing documents designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of state law actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Fourth Amended and Restated Certificate of Incorporation dictates that the Delaware Court of Chancery is the sole and exclusive forum for certain state law based actions including certain derivative actions or proceedings brought on behalf of us; an action asserting a breach of fiduciary duty owed by an officer, a director, employee or to our shareholders; any claim arising under Delaware corporate law; and any action asserting a claim governed by the internal affairs doctrine.

This exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or other federal securities laws for which there is exclusive federal or concurrent federal and state jurisdiction.

This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES.

We lease our corporate headquarters at 7707 Fannin Street, Suite 140 in Houston, Texas under a noncancelable operating lease expiring in May 2021. The lease contains approximately 13,500 square feet. On November 19, 2020, the Company's board of directors approved the lease renewal of its premises in Houston, Texas. Once the current lease expires in May, 2021, the renewed lease agreement will commence under an operating lease agreement that is noncancelable from commencement until May 1, 2024.

We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS.

From time to time in the future, we may become involved in litigation or other legal proceedings that arise in the ordinary course of business. A complaint was filed on March 22, 2021 in the Court of Chancery of the State of Delaware against us by a former consultant and director. The complaint alleges, among other things, that the plaintiff is entitled to additional stock options and he is seeking declaratory judgment and specific performance. We believe that all of the claims in the complaint are without merit and we intend to defend vigorously against them.

We are not currently party to any other legal proceedings, and we are not aware of any other pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results or financial condition. To the extent that we are subject to a legal proceeding, it could have a material adverse impact on us because of litigation costs and diversion of management resources.

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 is traded on the Nasdaq Capital Market under the symbol "KRBP."

Stockholders

As of March 31, 2021, there were 115 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

Use of Proceeds from Initial Public Offering

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-238153) that was declared effective by the SEC on October 15, 2020. We issued and sold 1,250,000 shares of common stock at an initial public offering price of $12.00 per share for aggregate gross offering proceeds of $15 million. ThinkEquity, a division of Fordham Financial Management, Inc. acted as the book-running manager for the offering. The offering terminated following the closing of the initial public offering.

The net proceeds to the Company from the initial public offering, after deducting the underwriting discount and the underwriters' fees and expenses and all offering expenses were approximately $12.7 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

No material changes in our planned uses of the net proceeds from those described in the prospectus dated October 15, 2020 have occurred.

Sales of Unregistered Sales of Securities

On January 24, 2020, we issued 4,782,608 shares of Series B Preferred Stock for $2,200,000. On January 29, 2020, we filed a certificate of correction to its amended and restated its certificate of incorporation to authorize the issuance of up to 16,500,000 shares of Series B Preferred Stock. On January 31, 2020, the Company issued an additional 1,739,130 shares of Series B Preferred Stock for $800,000.

We also issued each investor a warrant to purchase 0.0859 shares of common stock for each Series B Preferred Share purchased, or warrants for an aggregate of 1,399,921 shares of common stock (the "Pre-Funded Warrants"). The Pre-Funded warrants had an exercise price of $0.003494 per share and expired ten years after the date of issuance. On June 8, 2020 and June 10, 2020, the holders of all the outstanding Pre-Funded Warrants exercised the warrants for cash and received 1,399,921 shares of common stock upon exercise.

On June 19, 2020, we issued an aggregate of 722,000 shares of common stock to out Chief Financial Officer and Chief Scientific Officer for prior services rendered.

No underwriters were involved in these issuances. We believe that each of the above issuances was exempt from registration under the Securities Act in reliance on Regulation S under the Securities Act or pursuant to Section 4(2) of the Securities Act regarding transactions not involving a public offering.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 11. of Part III of this Annual Report.

Issuer Purchases of Equity Securities

There have been no repurchases of our shares of common stock either on the open market or by private transaction during the year ended December 31, 2020.

ITEM 6. SELECTED FINANCIAL DATA.

The following table presents our selected financial data and certain other financial data. The balance sheet data as of December 31, 2020 and 2019, and the results of operations data for the years then ended were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

The financial data and other financial data presented below should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K and with Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our financial statements and the related notes. Our historical results are not indicative of our future results.

For the Years Ended December 31,	2020	2019
Operating expenses:		
Research and development	$ 5,052,900	$ 1,201,700
General and administrative	14,144,000	2,503,700
Total operating expenses	19,196,900	3,705,400
Loss from operations	(19,196,900)	(3,705,400)
Other expense		
Interest expense	(3,300)	(22,500)
Total other expense	(3,300)	(22,500)
Net loss	$ (19,200,200)	$ (3,727,900)
Net loss per share, basic and diluted	$ (4.41)	$ (1.39)
Weighted average common shares outstanding, basic and diluted	4,505,867	2,862,809

As of December 31,	2020	2019
Balance sheet data		
Cash and cash equivalents	$ 10,150,500	$ 1,929,100
Working capital	9,271,700	1,366,700
Total assets	12,829,700	2,652,700
Total stockholders' equity	$ 11,362,100	$ 1,979,000

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis of financial condition and results of operations provides information that management believes is relevant to an assessment and understanding of our plans and financial condition. The following financial information is derived from our financial statements and should be read in conjunction with such financial statements and notes thereto set forth elsewhere herein.

Overview

Kiromic BioPharma, Inc. (together with its subsidiary, "we," "us," "our" or the "Company") is a target discovery and gene-editing company utilizing artificial intelligence and our proprietary neural network platform with a therapeutic focus on immuno-oncology. We are focused on extending the benefits of immunotherapy by leveraging our proprietary technologies. Our approach seeks to generate a therapeutic immune response in patients by unleashing the demonstrated natural power of a patient's own immune system to recognize tumor-specific peptide sequences presented on cancer cells, known as tumor specific iso-antigens, capable of generating an immunological response and therefore eradicate cancer cells. We are developing our brand of chimeric antigen receptor ("CAR") T cell product candidates known as ALEXIS. These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. These products are in the pre-initial new drug ("IND") stages of the US Food and Drug Administration (the "FDA") clinical trial process. We are currently going through the IND enabling trials process and we expect that first in human dosing in Phase I of clinical trials will commence in the third quarter of 2021.

CAR T cell therapy, a form of cancer immunotherapy, has recently emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers. In 2017, two autologous anti-CD19 CAR T cell therapies, Kymriah, developed by Novartis International AG, and Yescarta, developed by Kite Pharma, Inc., were approved by the FDA for the treatment of relapsing/remitting B-cell precursor acute lymphoblastic leukemia and relapsing/remitting large B cell lymphoma, respectively. Autologous CAR T cell therapies are manufactured individually for the patient's use by modifying the patient's own T cells outside the body, causing the T cells to express CARs. The entire manufacturing process is dependent on the viability of each patient's T cells and takes approximately two to four weeks. Allogenic T cell therapies involve engineering healthy donor T cells, which we believe will allow for the creation of an inventory of off-the-shelf products that can be delivered to a larger portion of eligible patients throughout the world.

We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since we began principal business operations in 2012.

Trends and Uncertainties—COVID-19

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict, as the responses that we, other businesses and governments are taking continue to evolve. Furthermore, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that it could cause a local and/or global economic recession. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remain uncertain.

The severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company's service providers, suppliers, contract research organizations and our clinical trials, all of which are uncertain and cannot be predicted. As of the date of this report, the extent to which the COVID-19 pandemic may in the future materially impact our financial condition, liquidity or results of operations is uncertain.

Recent Developments

After considering the Form 10-K filing date of March 31, 2021, management extended its consideration of the going concern assumption through March 31, 2022. Management's plans were updated to further finance operations through additional equity or debt financing arrangements, and/or third party collaboration funding; however, if the Company is unable to raise additional funding to meet its working capital needs, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations. The negative cash flows and lack of financial resources of the Company raise substantial doubt as to the Company's ability to continue as a going concern, and that substantial doubt has not been alleviated.

New Investigational Drug Application Resubmission Announcement

On December 17, 2020 we filed two investigational new drug applications with the U.S. Food and Drug Administration (“FDA”). The first application was for a Phase 1 clinical trial of intravenously administered allogenic CAR-T for epithelial ovarian carcinoma (“EOC”) and malignant pleural mesothelioma (“MPM”). The second application was for a Phase 1 clinical trial of an intrapleural/intraperitoneal administered allogenic CAR-T for EOC and MPM.

Since filing the original applications in December 2020, we have had communications with the FDA, and numerous consults with scientific board and clinical advisors regarding resubmission. On March 9, 2021, we announced that we planned to resubmit the two investigational new drug applications. The revised applications will be for first in-human dosing of our Off-the-Shelf, Allogenic Gamma-Delta T cell therapy for metastatic and progressive locally advanced solid malignancies.

Principal Factors Affecting Our Financial Performance

Our operating results are primarily affected by the following factors:

- slow or delayed IND applications;
- slow or delayed clinical trial enrollment;
- patent reinforcement and prosecution; and
- changes in laws or the regulatory environment affecting our company.

Emerging Growth Company

We qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As a result, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

- have an auditor report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., Critical Audit Matters);
- submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency;" and
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will remain an emerging growth company for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our total annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. We will record revenue from collaboration agreements, including amounts related to upfront payments, annual fees for licenses of our intellectual property and research and development funding. However, none of those agreements have been executed as of the issuance date of this report.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates. These include the following:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including contract research organizations and other third parties that conduct preclinical research and development activities and clinical trials on our behalf;
- costs of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and future clinical trials, including the costs of contract manufacturing organizations, that will manufacture our clinical trial material for use in our preclinical studies and potential future clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- license payments made for intellectual property used in research and development activities; and
- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically, identifiable to research activities.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we initiate a Phase 1/2a clinical trial for our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates and continue to discover and develop additional product candidates.

We cannot determine with certainty the duration and costs of future clinical trials of our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates and any other our product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development, operations and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs that are not specifically attributable to research activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities and development of product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table sets forth key components of our results of operations for the years ended December 31, 2020 and 2019.

	Three Months Ended December 31,		Increase (Decrease)	
	2020	2019	$	%
Operating expenses:				
Research and development	$ 5,052,900	$ 1,201,700	$ 3,851,200	320.48 %
General and administrative	14,144,000	2,503,700	11,640,300	464.92 %
Total operating expenses	19,196,900	3,705,400	15,491,500	418.08 %
Loss from operations	(19,196,900)	(3,705,400)	15,491,500	418.08 %
Other expense				
Interest expense	(3,300)	(22,500)	19,200	(85.33)%
Total other expense	(3,300)	(22,500)	19,200	(85.33)%
Net loss	$ (19,200,200)	$ (3,727,900)	$ 15,510,700	(416.07)%

Research and development expenses. Our research and development expenses increased by $3,851,200, or 320.48%, to $5,052,900 for the year December 31, 2020 from $1,201,700 for the year ended December 31, 2019. The following table summarizes our research and development expenses by product candidate or development program:

	Year Ended December 31,		Increase (Decrease)	
	2020	2019	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 89,900	$ —	$ 89,900	100.00 %
ALEXIS-ISO-1	331,600	15,900	315,700	1,985.53 %
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	2,821,700	574,300	2,247,400	391.33 %
Laboratory supplies and services	385,500	218,600	166,900	76.35 %
Outsourced research and development	800,400	321,700	478,700	148.80 %
Laboratory equipment and maintenance	57,500	17,100	40,400	236.26 %
Facility-related costs	344,700	40,700	304,000	746.93 %
Intellectual property	217,800	12,100	205,700	1,700.00 %
Other research and development costs	3,800	1,300	2,500	192.31 %
Total research and development expenses	$ 5,052,900	$ 1,201,700	$ 3,851,200	320.48 %

As illustrated above, the increase in research and development expenses resulted from (i) a $2,247,400 increase in employee related costs, which primarily included a $1,020,900 increase in wages, benefits and payroll taxes and a $1,183,800 increase in stock compensation expenses attributable to research and development employees; (ii) a $166,900 increase in laboratory supplies in services, which primarily included a $109,800 increase in spending on disposables and consumables for in-vitro testing and validation of pipeline candidates, with the remaining balance driven by supplies spending; (iii) a $304,000 increase in facility-related costs, primarily driven by a $181,200 increase in allocated rent net of granting agency reimbursements, and a $113,200 increase in allocated depreciation expenses with the remaining amount attributed to repairs, maintenance, and utilities; (iv) a $205,700 increase in intellectual property expenses, which was driven by legal expenses and intellectual property filings for new patents; (v) a $40,400 increase in laboratory equipment and maintenance, driven entirely by new non-capitalizable equipment purchases and maintenance to support in-vitro testing and validation by our research and development scientists; and (vi) a $478,700 increase in

outsourced research and development costs driven by a $197,400 increase in research studies and other consulting fees with the remaining balance driven by increased stock based compensation expenses attributed to non-employees.

These cost increases were primarily incurred to support in-vitro testing and validation of our product candidates. This required increases to our headcount, square footage at our Houston Facility, experimentation costs, and intellectual property families to protect our findings. In addition, we incurred costs related to the following:

1. Augmented our research and development team: In the years ended December 31, 2020 and 2019, our average headcount increased to 9 employees from 2 employees allocable to research and development and clinical trials preparation.

2. Amended lease agreements: We amended our Houston facility lease agreement to expand the leased property by 4,100 square feet.

3. In-vitro experimentation costs: $584,000 in disposable and consumable spending during the year ended December 31, 2020 for validation experiments and other services related to our ALEXIS-ISO-1 and ALEXIS-PRO-1 candidates, and ABBIE.

4. Intellectual property augmentation: Longwood University (“Longwood”), granted us the exclusive right to negotiate a worldwide, exclusive license for certain patent rights. The patent rights pertain to "T-cells expressing a chimeric -PD l-CD3zeta receptor reduce tumor burden in multiple murine syngeneic models of solid cancer." As compensation for this right, we agreed to pay Longwood an upfront fee of $15,000. We also agreed to reimburse Longwood for fees and expenses incurred for the preparation, filing, prosecution and maintenance of such patent rights. We also filed two utility patent applications and four provisional patent applications to protect intellectual property associated with our other value drivers.

The cost increases were also partially due to the difference in grant reimbursements in the years ended December 31, 2020 and 2019. In August 2018, the National Institute of Health (NIH), the primary agency of the United States government responsible for biomedical and public health research, awarded a Phase I/II grant in the amount of $2,235,000 for the development and non-clinical testing of a new anti-arteriosclerosis gene therapy delivered by engineered adeno-associated viral vectors. Phase I of the grant approved amounts of $851,000 and which covers the period September 2018 through August 2019, entitles us to reimbursement for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees. The Company did not complete Phase I by August 2019, but was granted an extension to complete Phase I by the NIH through August 2021. Starting after Phase I completion in 2021, Phase II of the grant covers reimbursements for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees of $1,384,000. During the years ended December 31, 2020 and 2019, we recognized $142,400 and $298,000, respectively, as reductions to research and development expense within the statements of operations pursuant to the grant from the NIH.

General and administrative expenses. Our general and administrative expenses increased by $11,640,300, or 464.92%, to $14,144,000 for the year ended December 31, 2020 from $2,503,700 for the year ended December 31, 2019.

During the year ended December 31, 2020, the increase primarily resulted from an increase in stock compensation expenses of $11,257,900, an increase in wages and salaries totaling $606,800, offset by reduced professional services expenses of $411,500.

The increase in stock compensation expense was primarily driven by common stock issuances of 725,536 shares to our Chief Financial Officer and Chief Operating Officer (“CFO and COO”), Chief Strategy and Innovation Officer (“CSIO”), Chief Medical Officer (“CMO”), and another employee in exchange for services rendered totaling $9,432,000. In addition, stock option grant modification allocated to general and administrative expense increased stock compensation expense by $1,791,200.

Wages and salaries were impacted by increases to headcount, and employee salary rates. During the years ended December 31, 2020 and 2019, the headcount for employees allocated to general and administrative purposes increased to

4.5 employees from three employees, respectively. In addition, the Chief Executive Officer's salary increased to an annual rate of $504,000 from $280,000 as of December 31, 2020 and 2019, respectively. Furthermore, the CSIO and CFO and COO transitioned from consulting agreements to employment agreements after the IPO was completed. The salary rates for each of those executives is $300,000 annually.

Interest expense. Interest expense decreased by $19,200, to $3,300 for the year ended December 31, 2020 from $22,500 for the year ended December 31, 2019. The decrease is driven by the variance in the balance of convertible promissory notes during the year ended December 31, 2019.

Total interest expense accrued on the notes in the year ended December 31, 2019 totaled $22,500. On August 15, 2019, each holder of convertible promissory notes issued during 2019 agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of Series A-1 Preferred Stock.

Total interest expense accrued in the year ended December 31, 2020 was primarily driven by $3,100 of cash paid for interest on the Note payable. The Note payable is attributed to the Director and Officer’s insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased to $19,200,200 during the year ended December 31, 2020 compared to $3,727,900 during the year ended December 31, 2019.

Liquidity and Capital Resources

As of December 31, 2020, we had cash and cash equivalents of $10,150,500. As of December 31, 2019 we had cash and cash equivalents of $1,929,100. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sale of our convertible promissory notes, preferred stock, and common stock.

Following our recent offering of Series B Preferred Stock discussed below and increased expenditures related to our ongoing research and development efforts as well as the completion of an initial public offering on October 15, 2020, we determined that our current levels of cash will not be sufficient to meet our anticipated cash needs for our operations through March 31, 2022. We have incurred significant operating losses since inception, and we expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase, including in connection with conducting preclinical studies and clinical trials for our product candidates, contracting with contract manufacturing organizations and building out internal capacity to have product manufactured to support preclinical studies and clinical trials, expanding our intellectual property portfolio and providing general and administrative support for our operations. As a result, these conditions raise substantial doubt about the Company’s ability to continue as a going concern.

We are seeking significant additional capital funding to develop our platform, additional hiring of scientific professionals, hiring other general and administrative employees, and clinical trials. However, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. In consideration of our plans, substantial doubt cannot be alleviated with respect to our continued operations through March 31, 2022. Management's plans, of which the raising additional capital is not within management's control and cannot be assured, do not alleviate such substantial doubt through March 31, 2022.

Summary of Cash Flow

The following table sets forth a summary of our cash flows for the periods presented:

	Year Ended December 31,	
	2020	2019
Net cash used in operating activities	$ (6,126,600)	$ (2,913,900)
Net cash used in investing activities	(1,457,600)	(302,700)
Net cash provided by financing activities	15,805,600	4,761,400
Net increase in cash and cash equivalents	8,221,400	1,544,800
Cash and cash equivalents at beginning of the year	1,929,100	384,300
Cash and cash equivalents at end of the year	10,150,500	1,929,100

Cash flows from operating activities

Net cash used in operating activities was $6,126,600 for the year ended December 31, 2020, as compared to $2,913,900 for year ended December 31, 2019. In the year ended December 31, 2020, net loss of $19,200,200 and outflows from prepaid expenses and other current assets in the amount of $499,700 were the cash drivers. These cash outflows were offset by non-cash stock compensation expenses from common stock issuances in the amount of $9,432,000, stock compensation expenses from stock options and restricted stock units of $3,813,700, and accrued expenses in the amount of $112,900.

Net cash used in operating activities increased by a total of $3,212,700 year-over-year. The main driver for the increase is the $15,428,100 increase in net loss offset by non-cash inflows from increased stock compensation expenses in the amount of $12,722,800. We primarily used cash to augment our research and development team, expand our leased property, expand our intellectual property portfolio, and pay for corporate development costs related to obtaining additional financing. See "Results of Operations" above for further details.

Cash flows from investing activities

Net cash used in investing activities was $1,457,600 for the year ended December 31, 2020, as compared to $302,700 for the year ended December 31, 2019. Our net cash used in investing activities consisted entirely of purchases of property and equipment.

Net cash used in investing activities increased by a total of $1,154,900 in the year ended December 31, 2020 from December 31, 2019. This was primarily driven by equipment additions and leasehold improvements attributed to our Clean Room and Vivarium current good manufacturing practices facilities located in our Houston office.

Cash flows from financing activities

Net cash provided by financing activities was $15,805,600 during the year ended December 31, 2020 as compared to $4,761,400 for the year ended December 31, 2019. For the year ended December 31, 2020, the net cash provided by financing activities primarily consisted of net proceeds from the initial public offering of $12,332,700 and proceeds from preferred stock issuance in the amount of $3,000,000. In addition, there were proceeds from a note payable of $362,400 net of repayments, and loan payable of $105,600, net of repayments. For the year ended December 31, 2019, the net cash provided by financing activities consisted of proceeds from the sale of convertible promissory notes for $250,000, proceeds from preferred stock issuance in the amount of $4,500,000, and exercise of stock options to purchase common stock for $11,400.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements for any of the periods presented.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP") requires our management to make assumptions, estimates and judgments that affect the amounts reported, including the notes thereto, and related disclosures of commitments and contingencies, if any. We have identified certain accounting policies that are significant to the preparation of our financial statements. These accounting policies are important for an understanding of our financial condition and results of operation. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require management's difficult, subjective, or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Certain accounting estimates are particularly sensitive because of their significance to financial statements and because of the possibility that future events affecting the estimate may differ significantly from management's current judgments. We believe the following critical accounting policies involve the most significant estimates and judgments used in the preparation of our financial statements:

Fair Value Measurements—The carrying value of our cash and cash equivalents, unbilled receivables from the granting agency, prepaid expenses and other assets, accounts payable, accrued expenses and other current liabilities approximate their fair value due to their short-term nature.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In estimating the fair value of an asset or a liability, we take into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date.

We account for financial instruments in accordance with Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices, and inputs that are not directly observable but are corroborated by observable market data.

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2019 and 2018.

Stock-Based Compensation—We record stock compensation expense related to our 2017 Equity Incentive Plan in accordance with ASC 718, *Compensation—Stock Compensation*. We measure and recognize stock compensation expense for all stock-based awards, including stock options and restricted stock units ("RSUs").

Stock compensation expense for RSUs is estimated based on the number of units that vest multiplied by the fair value of the Company's common stock on the vesting date. Stock compensation expense for stock options is based on estimated fair values recognized using the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model. The calculation of stock-based compensation expense requires that we make assumptions and judgments about the variables used in the Black- Scholes option-valuation model, including the fair value of our common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

We estimate the grant-date fair value of stock options using the Black-Scholes option-valuation model. During the years ended December 31, 2020 and 2019, all equity grants under the 2017 Equity Incentive Plan were granted when we were a non-public company. The assumptions used to value such stock options were determined as follows:

Expected Term. The expected term represents the period that our stock options are expected to be outstanding. Equity grants during the years ended December 31, 2020 and 2019 had limitations on the sale or transfer of our common stock as a privately held company. Prior to becoming publicly traded, we did not believe our historical exercise pattern was indicative of future exercise patterns. We have consequently used the SAB No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period. We do not plan to continue to use the SAB 110 simplified method after we have sufficient trading history as a publicly traded company.

Risk-Free Interest Rate. We base the risk-free interest rate used in the Black-Scholes option-valuation model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the stock options for each stock option group.

Volatility. We determine the price volatility based on the historical volatilities of industry peers as we have limited trading history for our common stock price. We intend to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on our current expectations about our anticipated dividend policy. To date, we have not declared any dividends and, therefore, we used an expected dividend yield of zero.

Common Stock Valuations. During the years ended December 31, 2020 and 2019, the fair value of the common stock underlying our stock-based compensation grants was determined by our board of directors, with input from management and third-party valuations. We believe that the board of directors had the relevant experience and expertise to determine the fair value of our common stock. Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately- Held Company Equity Securities Issued as Compensation*, the board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

- valuations of the common stock performed by third-party specialists;
- the prices, rights, preferences, and privileges of our Series A-1 Preferred Stock and Series B Preferred Stock relative to those of our common stock;
- lack of marketability of the common stock;
- current business conditions and projections;

- hiring of key personnel and the experience of management;
- our stage of development;
- likelihood of achieving a liquidity event, a merger or acquisition of our company given prevailing market conditions, or other liquidation event;
- the market performance of comparable publicly traded companies; and
- the U.S. and global capital market conditions.

In valuing our common stock, the board of directors determined the equity value of our business using various valuation methods including combinations of income and market approaches. The income approach estimates value based on the expectation of future cash flows that a company will generate. These future cash flows are discounted to their present values using a discount rate derived from an analysis of the cost of capital of comparable publicly traded companies in our industry or similar business operations as of each valuation date and is adjusted to reflect the risks inherent in our cash flows. The market approach references actual transactions involving (i) the subject being valued, or (ii) similar assets and/or enterprises.

For each valuation, the equity value determined by the income and market approaches was then allocated to the common stock using either the option pricing method, or OPM, or probability—weighted expected return model, or PWERM.

The option pricing method is based on the Black Scholes option valuation model, which allows for the identification of a range of possible future outcomes, each with an associated probability. The OPM is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts. In general, while simple in its application, management did not use the OPM approach when considering allocation techniques for the valuation of equity interests in early stage, privately held life science companies. Management determined that applying the OPM would violate the major assumptions of the Black Scholes option valuation model approach. Additionally, the simulation approach can generally be reasonably approximated by a scenario-based approach like the PWERM as described below.

PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM include an initial public offering, as well as non- initial public offering market-based outcomes. Determining the fair value of the enterprise using the PWERM requires us to develop assumptions and estimates for both the probability of an initial public offering liquidity event and stay private outcomes, as well as the values we expect those outcomes could yield. Since in February 2018, we have valued our common stock based on a PWERM.

Application of our approach involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding expected future revenue, expenses, and future cash flows, discount rates, market multiples, the selection of comparable companies, and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact valuations as of each valuation date and may have a material impact on the valuation of our common stock.

For valuations going forward, the board of directors will determine the fair value of each share of underlying common stock based on the closing price of the common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in assumptions or market conditions.

Warrants Underlying Shares IPO common stock—We record warrants to purchase shares of common stock underlying our shares of IPO common stock in accordance with ASC 470, *Debt with conversion and other options*. The fair value of the warrants was estimated on the IPO date using the Black-Scholes option- valuation model. The calculation of warrants requires that we make assumptions and judgments about the variables used in the Black-Scholes option-valuation model, including the fair value of our common stock, expected term, expected volatility of the underlying common stock, risk-free interest rate, and exercise price.

We estimate the fair value of warrants using the Black-Scholes option-valuation model and the assumptions used to value such warrants are determined as follows:

Expected Term. The expected term represents the period that our warrants are expected to be outstanding. The expected term was calculated by taking the average of the vesting period and contract period.

Risk-Free Interest Rate. We base the risk-free interest rate used in the Black-Scholes option-valuation model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the warrants.

Volatility. We determine the price volatility based on the historical volatilities of industry peers as we had one day of trading history as of the initial public offering date. We intend to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on our current expectations about our anticipated dividend policy. To date, we have not declared any dividends and, therefore, we used an expected dividend yield of zero.

Common Stock Valuations. The fair value of our common stock when the warrants were issued is equal to the IPO common stock issuance price of $12.00 per share.

Exercise Price. The representative warrants' exercise price to purchase common stock is $15.00 per share.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On April 8, 2020, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On April 8, 2020, the FASB has changed the effective date of this standard applicable to the Company as an emerging growth company to

January 1, 2023. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

On January 1, 2019, the Company adopted ASU 2016-15 (Topic 230), *Classification of Certain Cash Receipts and Payments*, a new standard providing guidance on statement of cash flow classification on specific issues. The standard is effective for financial statements issued for fiscal periods beginning after December 15, 2018. It is required to be applied on a retrospective approach. The Company determined that this standard had no impact on its financial position, results of operations, and cash flows for the years ended December 31, 2020 and 2019.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our balance sheet as of December 31, 2020 includes cash and cash equivalents of $10,150,500. We do not participate in any foreign currency hedging activities and we do not have any other derivative financial instruments. We did not recognize any significant exchange rate losses during the years ended December 31, 2020 and 2019.

We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents does not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K and incorporated herein by reference.

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 (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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. Under the supervision, and with the participation, of our current management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), we evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2020. Based on this evaluation of our disclosure controls and procedures, our management, including our CEO and CFO, have concluded that our disclosure controls and procedures were not effective as of December 31, 2020 because of the material weaknesses in our internal control over financial reporting described below.

Management's Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. However, in connection with the audit of our financial statements for the years ended December 31, 2020 and 2019, prior to our initial public offering, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses are because we do not have a formal process for period end financial closing and reporting, and also because we have insufficient resources to conduct an effective monitoring and oversight function independent from our operations. These material weaknesses result in an increased risk of material misstatement in the financial statements.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Remediation Plan

We believe we are addressing these weaknesses through measures including:

- implementation of additional internal control processes and procedures regarding the financial close and reporting process, procure to pay process, and human resources and payroll process;

- designing those controls with the appropriate segregation of duties; and

- the recruitment of a full time accounting and finance personnel, including, but not limited to, personnel focused upon enhanced scrutiny of accounting entries in the areas where we have observed material weaknesses in our internal control over financial reporting.

Our management intends to monitor these weaknesses and evaluate whether the remedial actions taken by the Company have remediated these weaknesses when it completes its first evaluation of the Company's internal control over financial reporting for the fiscal year ending December 31, 2021.

Changes in Internal Control over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

We have no information to disclose that was required to be in a report on Form 8-K during the three months ended December 31, 2020 but was not reported.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to our annual meeting of stockholders to be held in 2021 (the "2021 Annual Meeting of Stockholders"), which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

ITEM 14. PRINCIPAL ACCOUNTANT'S FEES AND SERVICES.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2020.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits.

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
3.1	Fourth Amended and Restated Certificate of Incorporation of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 21, 2020)
3.2	Second Amended and Restated Bylaws of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
4.1*	Description of Securities
10.1†	Employment Agreement between Kiromic BioPharma, Inc. and Tony Tontat (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.2#	License Agreement, dated December 1, 2016, between Mercer University and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.3#	License Agreement, dated September 14, 2018, between CGA 369 Intellectual Holdings, Inc. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.4#	Amendment to License Agreement, dated October 16, 2019, between CGA 369 Intellectual Holdings, Inc. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.5#	Collaboration Agreement, dated February 6, 2020, between University of Texas MD Anderson Cancer Center and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.6†	Employment Agreement dated January 1, 2020 between Kiromic BioPharma, Inc and Scott Dahlbeck (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.7†	Employment Agreement between Kiromic BioPharma, Inc. and Gianluca Rotino (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)

10.8†	Employment Agreement between Kiromic BioPharma, Inc. and Maurizio Chiriva Internati (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.9†	Kiromic, Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.10#	Joint venture agreement, dated 4.06.2020, between Molipharma S.R.L. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.11†	Form of Director Services Agreement between Kiromic BioPharma, Inc. and all independent directors (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.12†	Amended and Restated License Agreement by and between the Company and Longwood University, dated as of November 30, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 29, 2021)
10.13	Strategic Alliance Agreement by and between the Company and Leon Office (H.K.) Ltd, effective as of January 28, 2021 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 12, 2021)
21.1*	List of Subsidiaries
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm
31.1*	Certifications of Principal Executive Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certifications of Principal Financial Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of Principal Executive Officer furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certifications of Principal Financial Officer furnished 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
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 – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

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*Filed herewith
† Executive Compensation Plan or Agreement

Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2021

KIROMIC BIOPHARMA, INC.

/s/ Maurizio Chiriva-Internati

Name: Maurizio Chiriva-Internati

Title: Chief Executive Officer

(Principal Executive Officer)

/s/ Tony Tontat

Name: Tony Tontat

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Kiromic BioPharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kiromic BioPharma, Inc. and subsidiary (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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 has incurred significant losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audit 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.

/s/ Deloitte & Touche LLP

Houston, Texas

March 31, 2021

We have served as the Company's auditor since 2016.

KIROMIC BIOPHARMA, INC.
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,150,500	$ 1,929,100
Inventories	—	22,200
Prepaid expenses and other current assets	588,800	89,100
Total current assets	10,739,300	2,040,400
Property and equipment, net	2,066,000	587,900
Other assets	24,400	24,400
Total Assets	$ 12,829,700	$ 2,652,700
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 665,200	$ 452,400
Accrued expenses and other current liabilities	334,200	221,300
Interest payable	200	—
Loan payable	105,600	—
Note payable	362,400	—
Total current liabilities	1,467,600	673,700
Total Liabilities	1,467,600	673,700
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Series A-1 Preferred Stock, $0.0001 par value: 24,000,000 shares authorized as of December 31, 2020 and 2019; 0 and 21,822,301 shares issued and outstanding as of December 31, 2020 and 2019, respectively	—	9,134,700
Series B Preferred Stock, $0.0001 par value: 16,500,000 and 14,130,435 shares authorized as of December 31, 2020 and 2019, respectively; 0 and 9,869,659 shares issued and outstanding as of December 31, 2020 and 2019, respectively	—	1,306,900
Preferred Stock, $0.0001 par value: 19,500,000 and 21,869,565 shares authorized as of December 31, 2020 and 2019, respectively; 0 shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.001 par value: 300,000,000 shares authorized as of December 31, 2020 and 2019; 7,332,999 and 2,863,812 shares issued and outstanding as of December 31, 2020 and 2019, respectively	1,200	—
Additional paid-in capital	52,988,700	13,965,000
Accumulated deficit	(41,627,800)	(22,427,600)
Total Stockholders' Equity	11,362,100	1,979,000
Total Liabilities and Stockholders' Equity	$ 12,829,700	$ 2,652,700

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Operations

	Years Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 5,052,900	$ 1,201,700
General and administrative	14,144,000	2,503,700
Total operating expenses	19,196,900	3,705,400
Loss from operations	(19,196,900)	(3,705,400)
Other expense		
Interest expense	(3,300)	(22,500)
Total other expense	(3,300)	(22,500)
Net loss	$ (19,200,200)	$ (3,727,900)
Net loss per share, basic and diluted	$ (4.42)	$ (1.39)
Weighted average common shares outstanding, basic and diluted	4,505,867	2,862,809

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Stockholders' Equity

	Series A-1 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
Balance at January 1, 2019	20,886,782	$ 8,727,400	—	$ —	2,863,093	$ —	$ 10,237,600	$ (18,699,700)	$ 265,300
Conversion of convertible promissory notes and accrued interest into Series A-1 Preferred Stock	935,519	407,300	—	—	—	—	—	—	407,300
Issuance of Series B Preferred Stock	—	—	9,782,609	1,056,300	—	—	—	—	1,056,300
Series B Preferred Stock discount amortization	—	—	—	210,600	—	—	(210,600)	—	—
Warrants underlying Series B Preferred Stock issuance	—	—	—	—	—	—	3,443,700	—	3,443,700
Accretion and settlement of Series B Preferred Stock dividend	—	—	87,050	40,000	—	—	(40,000)	—	—
Exercised stock options	—	—	—	—	1,719	—	11,400	—	11,400
Stock compensation expense	—	—	—	—	—	—	522,900	—	522,900
Net loss	—	—	—	—	—	—	—	(3,727,900)	(3,727,900)
Balance at December 31, 2019	21,822,301	9,134,700	9,869,659	$ 1,306,900	2,864,812	$ —	$ 13,965,000	$ (22,427,600)	$ 1,979,000
Issuance of Series B Preferred Stock	—	—	6,521,738	331,700	—	—	—	—	331,700
Series B Preferred Stock discount amortization	—	—	—	692,700	—	—	(692,700)	—	—
Warrants underlying Series B Preferred Stock issuance	—	—	—	—	—	—	2,668,300	—	2,668,300
Exercise of warrants	—	—	—	—	1,399,921	—	4,900	—	4,900
Common stock issuance net of issuance costs and discount amortization	—	—	—	—	1,250,000	1,200	11,974,200	—	11,975,400
Warrants underlying common stock discount amortization	—	—	—	—	—	—	(19,700)	—	(19,700)
Warrants underlying common stock issuance	—	—	—	—	—	—	377,000	—	377,000
Series A-1 Preferred Stock conversion to common stock and fractional shares adjustments from stock split and conversion	(21,822,301)	(9,134,700)	—	—	624,594	—	9,134,700	—	—
Series B Preferred Stock conversion to common stock and fractional shares adjustments from stock split and conversion	—	—	(16,391,397)	(2,331,300)	469,136	—	2,331,300	—	—
Common stock issuance to employees and non-employees	—	—	—	—	725,536	—	9,432,000	—	9,432,000
Stock compensation expense	—	—	—	—	—	—	3,813,700	—	3,813,700
Net loss	—	—	—	—	—	—	—	(19,200,200)	(19,200,200)
Balance at December 31, 2020	—	$ —	—	$ —	7,333,999	1,200	52,988,700	(41,627,800)	11,362,100

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (19,200,200)	$ (3,727,900)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	200,000	87,500
Stock compensation expense	13,245,700	522,900
Non-cash interest	200	20,500
Inventory obsolescence impairment	22,200	—
Changes in operating assets and liabilities:		
Unbilled receivables from granting agency	—	24,300
Inventories	—	(5,900)
Prepaid expenses and other current assets	(499,700)	46,200
Other assets	—	(6,600)
Accounts payable	(7,700)	293,400
Accrued expenses and other current liabilities	112,900	(151,300)
Deferred rent	—	(19,000)
Convertible promissory notes derivative liability	—	2,000
Net cash used for operating activities	(6,126,600)	(2,913,900)
Cash flows from investing activities:		
Purchases of property and equipment	(1,457,600)	(302,700)
Net cash used for investing activities	(1,457,600)	(302,700)
Cash flows from financing activities:		
Proceeds from sale of convertible promissory notes	—	250,000
Exercise of stock options	—	11,400
Proceeds from issuance of common stock	15,000,000	—
Issuance costs	(2,667,300)	—
Proceeds from warrant exercise	4,900	—
Proceeds from loan payable	115,600	—
Repayments of loan payable	(10,000)	—
Borrowings from note payable	540,500	—
Repayments of note payable	(178,100)	—
Proceeds from Series B Preferred Stock issuance	3,000,000	4,500,000
Net cash provided by financing activities	15,805,600	4,761,400
Net change in cash and cash equivalents	8,221,400	1,544,800
Cash and cash equivalents:		
Beginning of year	1,929,100	384,300
End of year	$ 10,150,500	$ 1,929,100
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	$ 220,500	$ 74,700
Cash paid for interest on note payable	$ 3,100	$ —
Conversion of accounts payable into convertible promissory notes	$ —	$ 134,800
Conversion of convertible promissory notes and accrued interest into Series A-1 Preferred Stock	$ —	$ 407,300
Accretion and settlement of Series B Preferred Stock dividend	$ —	$ 40,000

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Notes to Consolidated Financial Statements

1. ORGANIZATION

Nature of Business

Kiromic BioPharma, Inc. and subsidiary (the "Company") is a preclinical stage biopharmaceutical company formed under the Texas Business Organizations Code in December 2012. On May 27, 2016, the Company converted from a Texas limited liability company into a Delaware corporation and changed its name from Kiromic LLC to Kiromic Inc. On December 16, 2019, the Company amended and restated its certificate of incorporation charter to re-name the company, Kiromic BioPharma, Inc.

The Company is a target discovery and gene-editing company utilizing artificial intelligence and our proprietary neural network platform with a therapeutic focus on immuno-oncology. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

The Company's wholly-owned subsidiary, GreenPlanet Pharma, Inc., operates an oral healthcare business. It has developed a mouthwash using a high quality, safe, and natural ingredient formulation to provide effective symptomatic relief for a wide range of oral irritations and health concerns. This business has not generated any revenues.

Going Concern—The accompanying consolidated financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flows from operations of $6,126,600 for the year ended December 31, 2020, and an accumulated deficit of $41,627,800 as of December 31, 2020. To date, the Company has relied on equity and debt financing to fund its operations. The Company's product candidates are still in the early stages of development, and substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization, if any, of its product candidates. Although the Company completed its initial public offering on October 15, 2020 and received net proceeds of $12,332,700, the Company does not have sufficient cash on hand or available liquidity to meet its obligations through the twelve months following the date the consolidated financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Given its projected operating requirements and its existing cash and cash equivalents, the Company plans to complete an additional financing transaction in fiscal year 2021 in order to continue operations. Management is currently evaluating different strategies to obtain the required funding of future operations. These strategies may include, but are not limited to, additional funding from current or new investors. However, there can be no assurance that the Company will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

NIH Grant—In August 2018, the National Institute of Health ("the NIH"), the primary agency of the U.S. government responsible for biomedical and public health research, awarded a Phase I/II grant to the Company in the amount of $2,235,000 for the development and non-clinical testing of a new anti-arteriosclerosis gene therapy delivered by engineered adeno-associated viral vectors. Phase I of the grant approved amounts of $851,000 and covered the period September 2018 through August 2019, entitled the Company to reimbursement for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees. The Company did not complete Phase I by August 2019, but was granted an extension to complete Phase I by the NIH through August 2021. Starting after Phase I completion in

2021, Phase II of the grant covers reimbursements for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees of $1,384,000.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All intercompany balances were eliminated upon consolidation. Operating results for the year ended December 31, 2020 are not necessarily indicative of results to be expected for any future year.

On December 17, 2019, the Company completed a 1-for-10 reverse stock split of its outstanding common stock. On June 17, 2020, the Company completed a 1-for-3.494 reverse stock split of its outstanding common stock. Accordingly, unless otherwise noted, all share and per share information has been restated to retroactively show the effect of these stock splits.

Use of Estimates—The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include determination of the fair value of common stock and related stock-based compensation, the fair value of convertible promissory notes and the related embedded derivative liability, warrants to purchase common stock underlying shares of Series B Preferred Stock, and estimating services incurred by third-party service providers used to recognize research and development expense.

Cash and Cash Equivalents—As of December 31, 2020 and 2019, cash and cash equivalents consisted entirely of cash on hand and bank deposits. The Company considers all highly liquid instruments with remaining maturities at purchase of 90 days or less to be cash equivalents.

Concentrations of Credit Risk and Other Uncertainties—Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Substantially all of the Company's cash and cash equivalents were deposited in accounts at a small number of national financial institutions. Account balances may at times exceed federally-insured limits. The Company has not incurred losses related to these cash and cash equivalents deposited at financial institutions and management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held.

The Company is subject to certain risks and uncertainties from changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company's product candidates; the performance of third-party clinical research organizations and manufacturers; protection of the intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; the Company's ability to attract and retain employees necessary to support commercial success; and changes in the industry or customer requirements including the emergence of competitive products with new capabilities.

The Company records receivables resulting from activities under its research grant from the NIH. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the granting agency.

Deposit—In connection with one of the Company's facility leases, a deposit is held by the lessor per the terms of the noncancelable agreement. The deposit has been recorded as a long-term asset on the Company's consolidated balance sheets.

Inventories—Inventories consist entirely of finished products. The balances presented are stated at the lower of cost or market and is determined using the first-in, first-out method. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory quantity in excess of expected requirements. The estimate of write downs to inventory from obsolescence, costs in excess of inventory net realizable value, and inventory quantity in excess of expected requirements is subjective and primarily dependent on the estimates of future demand for a particular product. Adjustments generally increase as demand decreases due to market conditions and product life-cycle changes. As of December 31, 2020, the Company recorded a

reserve for inventory obsolescence of $22,200 as the inventory was near its expiration date with no significant marketing activities taking place. As of December 31, 2019 no such adjustments have been recorded.

Deferred Initial Public Offering Costs—During the year ended December 31, 2020, the Company began incurring costs in connection with the filing of a Registration Statement on Form S-1/A for an initial public offering ("IPO"), which were deferred in other current assets in accordance with ASC 505-10-25, *Equity,* in the consolidated balance sheet. Upon completion of the IPO, these costs have been offset against proceeds received. Offering costs consist of legal, accounting, and other costs directly related to the Company's efforts to raise capital.

During the year ended December 31, 2020, the Company classified deferred offering costs of $2,667,300 as a reduction to additional paid-in capital upon completion of the Company's IPO on October 15, 2020. As of December 31, 2020 and 2019, there were no deferred offering costs recorded on the Company's consolidated balance sheets.

Property and Equipment—Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from 1 to 8 years. Major replacements and improvements are capitalized as leasehold improvements, while general repairs and maintenance are expensed as incurred. Estimated useful lives of leasehold improvements are the shorter of the remaining lease term or the estimated useful economic life of the specific asset.

Estimated useful lives of property and equipment are as follows for the major classes of assets:

Asset Description	Estimated Lives
Laboratory Equipment	3 - 8
Leasehold Improvements	1 - 7
Office Furniture, Fixtures, and Equipment	5
Software	3 - 5

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company capitalized software development costs of approximately $10,200 and $20,000 for the years ended December 31, 2020 and 2019, respectively.

Impairment of Long-Lived Assets—The Company reviews its long-lived assets, including property and equipment, for impairment indicators. If indicators are noted, the Company compares the carrying amount of the asset to its estimated undiscounted cash flows. If the carrying amount exceeds its estimated undiscounted cash flows, an impairment loss is recognized to adjust the long-lived asset to fair value. There has been no impairment losses on the Company's long-lived assets since inception.

Comprehensive Loss—Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For all periods presented, there was no difference between net loss and comprehensive loss.

Income Taxes—The Company files federal and state income tax returns, utilizing the accrual basis of accounting. Income taxes are provided for the tax effects of transactions reported in the consolidated financial statements and consist of taxes currently due and deferred taxes. Certain transactions of the Company may be subject to accounting methods for income tax purposes, which differ from the accounting methods used in preparing these consolidated financial statements in accordance with GAAP. Accordingly, the net income or loss of the Company reported for income tax purposes may differ from the balances reported for those same items in the accompanying consolidated financial statements.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which such temporary differences are expected to be recovered or settled. The Company records valuation allowances to reduce deferred income tax assets to the amount that is more likely than not to be realized.

The Company records uncertain tax positions in accordance with ASC 740, *Income Taxes*, on the basis of a two-step process in which (1) the Company determines whether it is more-likely-than-not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations. No such interest or penalties were recognized during the years ended December 31, 2020 and 2019.

Research and Development Expense—The Company expenses research and development costs as incurred. Research and development expenses include personnel and personnel-related costs, costs associated with the Company's pre-clinical development activities including costs of outside consultants and contractors, the submission and maintenance of regulatory filings, equipment and supplies used in developing products prior to market approval and an allocation of certain overhead costs such as facility and related expenses.

The Company accrues and expenses costs of services provided by contract research organizations in connection with preclinical studies and contract manufacturing organizations engaged to manufacture clinical trial material, costs of licensing technology, and costs of services provided by research organizations and service providers. Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred if the technology is not expected to have any alternative future uses other than the specific research and development project for which it was intended. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed rather than when the payment is made.

Proceeds from Grants—During the years ended December 31, 2020 and 2019, the Company recognized $142,400 and $298,000, respectively, as reductions to research and development expense within the consolidated statements of operations pursuant to its grant from the NIH.

Convertible Promissory Notes Derivative Liability—During the year ended December 31, 2019, the Company recorded an embedded derivative liability related to the discount on the per share selling price the holders of the convertible promissory notes would receive at the time of conversion in connection with the Company's next equity financing ("the Next Financing Close"). The embedded derivative liability was initially recorded at fair value, with gains and losses arising from changes in fair value recognized in interest expense in the consolidated statements of operations at each period end while such instruments are outstanding. The embedded derivative liability was valued using a probability weighted expected return model. See Note 8.

Upon repurchase of convertible promissory notes, ASC 470, *Debt*, requires the Company to allocate total settlement consideration, inclusive of transaction costs, amongst the liability components of the instrument based on the fair value of the liability component immediately prior to repurchase. The difference between the settlement consideration allocated to the liability component and the net carrying value of the liability component would be recognized as gain (loss) on extinguishment of debt in the consolidated statements of operations.

Fair Value Measurements—The carrying value of the Company's cash and cash equivalents, unbilled receivables from the granting agency, prepaid expenses and other assets, accounts payable, and accrued expenses and other current liabilities approximate their fair value due to their short-term nature.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In estimating the fair value of an asset or a liability, the Company takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date.

The Company accounts for financial instruments in accordance with ASC 820, *Fair Value Measurements*. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

> Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices, and inputs that are not directly observable but are corroborated by observable market data.

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no changes in the fair value hierarchy levels during the years ended December 31, 2020 and 2019.

The Company's liabilities that were measured at fair value on a non-recurring and recurring basis converted into Series A-1 Preferred Stock as of December 31, 2019. Per ASC 820, the fair values of the convertible promissory notes are measured on a non-recurring basis at the relevant measurement date. The fair value of convertible promissory notes embedded derivative liability is measured on a recurring basis at the end of each reporting period.

Rollforward of Level 3 Liabilities Measured at Fair Value on a Non-Recurring Basis:

	December 31, 2020	December 31, 2019
Convertible promissory notes		
Beginning balance	$ —	$ —
Amounts allocated to the embedded derivative liability at inception (at fair value)	—	(21,000)
Conversions from accounts payable into convertible promissory notes	—	134,800
Proceeds from issuances of convertible promissory notes	—	250,000
Conversions into Series A-1 Stock	—	(363,800)
Ending balance	$ —	$ —

Rollforward of Level 3 Liabilities Measured at Fair Value on a Recurring Basis:		
Convertible promissory note embedded derivative liability		
Beginning balance	$ —	$ —
Realized and unrealized gains and losses	—	2,000
Fair value of embedded derivative liability at inception	—	21,000
Amounts derecognized upon conversion of the related convertible promissory notes	—	(23,000)
Ending balance	$ —	$ —

Nonvested Stock Options and Restricted Stock Units—Pursuant to the Company's 2017 Stock Incentive Plan (the "Plan"), the Company has the ability to issue a variety of share-based payments and incentives to members, employees, and non-employees through grants of nonvested stock options.

The vesting conditions for stock options include annual, and monthly options. Annual vesting conditions are for four years. Monthly vesting conditions range from 10 to 48 months. When nonvested options are vested, they become exercisable over a 10 year period from grant date.

The vesting conditions for restricted stock units include cliff vesting conditions. Certain restricted stock units vest with a range of 6 to 12 months following the expiration of employee lock-up agreements. Certain restricted stock units vest based on the later of achievement of key milestones or the expiration of employee lock-up agreements. When nonvested restricted stock units are vested, they become exercisable over a 10 year period from grant date.

Stock-Based Compensation—The Company records stock compensation expense related to the Plan in accordance with ASC 718, *Compensation—Stock Compensation*. The Company measures and recognizes stock compensation expense for all stock-based awards, including stock options, based on estimated fair values recognized using cliff vesting or the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model (the "Black-Scholes model"). The calculation of stock-based compensation expense requires that the Company make assumptions and judgments about the variables used in the Black-Scholes model, including the fair value of the Company's common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

Until the Company's common stock became publicly traded, the board of directors' approach to estimating the fair value of the Company's common stock includes utilizing methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately- Held Company Equity Securities Issued as Compensation*.

The Company estimates the grant-date fair value of stock options using the Black-Scholes model and the assumptions used to value such stock options are determined as follows:

Expected Term. The expected term represents the period that the Company's stock options are expected to be outstanding. Due to limitations on the sale or transfer of the Company's common stock under the lock-up agreements and market standoff components of the stock option agreements, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience after restricted periods expire. The Company has previously used the Staff Accounting Bulletin ("SAB") No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period.

Risk-Free Interest Rate. The Company bases the risk-free interest rate used in the Black-Scholes model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the stock options for each stock option group.

Volatility. The Company determines the price volatility based on the historical volatilities of industry peers as it has no trading history for its common stock price. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of its own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on the Company's current expectations about its anticipated dividend policy. To date, the Company has not declared any dividends and, therefore, the Company has used an expected dividend yield of zero.

Common Stock Valuations. During the years ended December 31, 2020 and 2019, the Company's board of directors, with input from management and third-party valuations, determined the fair value of the common stock underlying all stock-based compensation grants. The Company believes that the board of directors had the relevant experience and expertise to determine the fair value of the Company's common stock before the Company's common stock became publicly traded. On the date of the grants in the years ended December 31, 2020 and 2019, the fair value of the Company's common stock, was determined in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. The board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the Company's common stock at each grant date. These factors include:

- valuations of the common stock performed by third-party specialists;
- the prices, rights, preferences, and privileges of the Company's Series A-1 Preferred Stock and Series B Preferred Stock relative to those of the Company's common stock;
- lack of marketability of the common stock;
- current business conditions and projections;
- hiring of key personnel and the experience of management;
- the Company's stage of development;
- likelihood of achieving a liquidity event, such as an initial public offering, a merger or acquisition of the Company given prevailing market conditions, or other liquidation event;
- the market performance of comparable publicly traded companies; and
- the US and global capital market conditions.

In valuing the common stock, the board of directors determined the equity value of the Company's business using various valuation methods including combinations of income and market approaches. The income approach estimates value based on the expectation of future cash flows that a company will generate. These future cash flows are discounted to their present values using a discount rate derived from an analysis of the cost of capital of comparable publicly traded companies in the Company's industry or similar business operations as of each valuation date and is adjusted to reflect the risks inherent in the Company's cash flows. The market approach references actual transactions involving (i) the subject being valued, or (ii) similar assets and/or enterprises.

For each valuation, the equity value determined by the income and market approaches was then allocated to the common stock using either the option pricing method ("OPM") or probability—weighted expected return model ("PWERM").

The option pricing method is based on the Black-Scholes option valuation model, which allows for the identification of a range of possible future outcomes, each with an associated probability. The OPM is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts. In general, while simple in its application, management did not use the OPM approach when considering allocation techniques for the valuation of equity interests in early stage, privately held life science companies. Management determined that applying the OPM would violate the major assumptions of the Black Scholes option valuation model approach. Additionally, the simulation approach can generally be reasonably approximated by a scenario-based approach like the PWERM as described below.

PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM include an initial public offering, as well as non- initial public offering market-based outcomes. Determining the fair value of the enterprise using the PWERM requires the Company to develop assumptions and estimates for both the probability of an initial public offering liquidity event and stay private outcomes, as well as the values the Company expects those outcomes could yield. Since February 2018, the Company has valued its common stock based on a PWERM.

Application of the Company's approach involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding expected future revenue, expenses, and future cash flows, discount rates, market multiples, the selection of comparable companies, and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact valuations as of each valuation date and may have a material impact on the valuation of the common stock.

For valuations after the completion of an initial public offering, the fair value of each share granted by the board of directors will be equal to the closing price of the common stock on the date of grant.

Warrants Underlying Shares IPO common stock—The Company records warrants to purchase shares of common stock underlying shares of IPO common stock in accordance with ASC 470, *Debt with conversion and other options*. The fair value of the warrants was estimated on the IPO date using the Black-Scholes option- valuation model. The calculation of warrants requires that we make assumptions and judgments about the variables used in the Black-Scholes option-valuation model, including the fair value of our common stock, expected term, expected volatility of the underlying common stock, risk-free interest rate, and exercise price.

The Company estimated the fair value of warrants underlying shares of IPO common stock using the Black-Scholes option-valuation model and the assumptions used to value such warrants are determined as follows:

Expected Term. The expected term represents the period that warrants are expected to be outstanding. The expected term was calculated by taking the average of the vesting period and contract period.

Risk-Free Interest Rate. The Company based the risk-free interest rate used in the Black-Scholes option-valuation model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the warrants.

Volatility. The Company determined the price volatility based on the historical volatilities of industry peers as the Company had one day of trading history as of the initial public offering date. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of the Company's common stock price becomes available, or unless

circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on current expectations about anticipated dividend policy. To date, the Company has not declared any dividends and, therefore, it used an expected dividend yield of zero.

Common Stock Valuations. The fair value of common stock when the warrants were issued is equal to the IPO common stock issuance price of $12.00 per share.

Exercise Price. The representative warrants' exercise price to purchase common stock is $15.00 per share.

Segment Data—The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Recently Issued Accounting Pronouncements—From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.
In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On April 8, 2020, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On April 8, 2020, the FASB has changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2023. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

On January 1, 2019, the Company adopted ASU 2016-15 (Topic 230), *Classification of Certain Cash Receipts and Payments*, a new standard providing guidance on statement of cash flow classification on specific issues. The standard is effective for financial statements issued for fiscal periods beginning after December 15, 2018. It is required to be applied on a retrospective approach. The Company determined that this standard had no impact on its financial position, results of operations, and cash flows for the years ended December 31, 2020 and 2019.

3. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share is determined by dividing net loss less deemed dividends by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the stock options, convertible Series A-1 Preferred Stock, and the convertible Series B Preferred Stock have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average common shares outstanding used to calculate both basic and diluted loss per common shares are the same. The following table illustrates the computation of basic and diluted loss per share:

	Years Ended December 31,	
	2020	2019
Net loss	$ (19,200,200)	$ (3,727,900)
Less: Accretion and settlement of Series B Preferred Stock dividend	—	(40,000)
Less: Series B Preferred Stock discount amortization	(692,700)	(210,600)
Less: IPO Common Stock discount amortization	(19,700)	—
Net loss attributable to common shareholders, basic and diluted	$ (19,912,600)	$ (3,978,500)
Weighted average common shares outstanding, basic and diluted	4,505,867	2,862,809
Net loss per common share, basic and diluted	$ (4.42)	$ (1.39)

For the years ended December 31, 2020 and 2019, potentially dilutive securities excluded from the computations of diluted weighted-average common shares outstanding were (in shares):

	December 31, 2020	December 31, 2019
Stock options to purchase	1,647	75,405
Restricted Stock Units	95,815	—
Series A-1 Preferred Stock	—	624,594
Series B Preferred Stock	—	282,478
Warrants underlying Series B Preferred Stock	—	839,784
Total	97,462	1,822,261

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at December 31:

	2020	2019
Equipment	$ 780,500	$ 488,800
Leasehold improvements	1,229,700	302,700
Office furniture, fixtures, and equipment	16,600	16,600
Software	151,700	141,500
Construction in progress	449,200	—
	2,627,700	949,600
Less: Accumulated depreciation	(561,700)	(361,700)
Total	$ 2,066,000	$ 587,900

Depreciation expense was $200,000 and $87,500 for the years ended December 31, 2020 and 2019, respectively. Depreciation expense is allocated between research and development and general and administrative operating expenses on the consolidated statements of operations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at December 31:

	2020	2019
Accrued consulting and outside services	$ 143,200	$ 221,300
Accrued compensation	191,000	—
Total	$ 334,200	$ 221,300

6. CURRENT LOAN PAYABLE

On May 1, 2020, the Company received a loan in the principal amount of $115,600 (the “SBA Loan”) under the Paycheck Protection Program (“PPP”), which was established under the recently enacted Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) administered by the U.S. Small Business Administration (the “SBA”). The intent and purpose of the PPP is to support companies, during the COVID-19 pandemic, by providing funds for certain specified business expenses, with a focus on payroll. As a qualifying business as defined by the SBA, the Company is using the proceeds from this loan to primarily help maintain its payroll. The term of the SBA Loan promissory note (“the Note”) is two years, though it may be payable sooner in connection with an event of default under the Note. The SBA Loan carries a fixed interest rate of one percent per year, with the first payment due seven months from the date of initial cash receipt. Under the CARES Act and the PPP, certain amounts of loans made under the PPP may be forgiven if the recipients use the loan proceeds for eligible purposes, including payroll costs and certain rent or utility costs, and meet other requirements regarding, among other things, the maintenance of employment and compensation levels. The Company intends to use the SBA Loan for qualifying expenses and to applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. The SBA Loan was forgiven on February 16, 2021. See Note 14.

The Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, materially false or misleading representations to the SBA, and adverse changes in the Company’s financial condition or business operations that may materially affect its ability to pay the SBA Loan.

As the legal form of the Note is a debt obligation, the Company accounts for it as debt under ASC 470, *Debt*, and recorded $105,600 during year ended December 31, 2020 in the consolidated balance sheet. During year ended December 31, 2020, the Company received initial proceeds of $115,600 and made a repayment of $10,000 on the SBA Loan, bringing the balance to $105,600 as of December 31, 2020.

The Company accrued $200 of interest expense during the year ended December 31, 2020. The Company accrues interest over the term of the loan and does not impute additional interest at a market rate because the guidance on imputing interest in ASC 835-30, *Interest*, excludes transactions where interest rates are prescribed by a government agency. If any amount of the loan is ultimately forgiven, income from the extinguishment of debt would be recognized as a gain on loan extinguishment in the consolidated statement of operations.

7. NOTE PAYABLE

In November 2020, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of December 31, 2020, the remaining payable balance on the financed amount was approximately $362,400.

8. CONVERTIBLE PROMISSORY NOTES

Starting in June 2016, the Company sold convertible promissory notes to certain investors to help finance its operations. The convertible promissory notes were in amounts ranging from $12,500 to $500,000, earning annual interest between 6% and 17% and all maturing either on June 1, 2019, January 2, 2020, or June 30, 2020 (the “Maturity Date”).

The convertible promissory notes were convertible into shares issued in the Company’s Next Financing Close by dividing the total amount of convertible promissory notes, plus accrued interest (the “Balance”) by the applicable

conversion price, as defined in the convertible promissory notes. If the convertible promissory notes have not been converted, the Balance shall be payable in full if the Company consummates a change of control transaction. If there has not been a Next Financing Close or a change in control by the Maturity Date, then at the noteholders' option, the Company shall either repay the Balance then outstanding or convert into the Company's common stock at a set conversion price then in effect, as defined in the convertible promissory notes.

The estimated fair value of the conversion discount related embedded derivative was determined using a probability-weighted expected return model. The probability of a Next Financing Close occurring prior to the Maturity Date was determined to be 55% during the year ended December 31, 2019. The net present value of the conversion discount related embedded derivative was measured using a discount rate of 25% as of December 31, 2019. Below is a table that outlines the initial value of issuances and the bifurcated embedded derivative liability during the years ended December 31:

	2020	2019
Convertible promissory notes- issuances	$ —	$ 250,000
Conversion of accounts payable into convertible promissory notes	—	134,800
Total issuances and conversions into convertible promissory notes	—	384,800
Embedded derivative liability		
Initial fair value upon issuance of convertible promissory notes	—	21,000
Realized and unrealized gains and losses	—	2,000
Converted embedded derivative liability into Series A-1 Preferred Stock	—	(23,000)
Embedded derivative liability balance at December 31	$ —	$ —

On August 15, 2019, each holder of convertible promissory notes issued during 2019 agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of Series A-1 Preferred Stock. See Note 10 for further details. No additional convertible promissory notes were issued for year ended December 31, 2020 following the conversion on August 15, 2019.

9. COMMITMENTS AND CONTINGENCIES

Facility Lease Agreements—The Company leases its premises in Houston, Texas under a noncancelable operating lease expiring in May 2021. The lease renewal, which occurred in 2019, resulted in an expansion to the lease of approximately 4,100 square feet.

On November 19, 2020, the Company's board of directors approved the lease renewal of its premises in Houston, Texas. Once the current lease expires in May 2021, the renewed lease agreement will commence under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after 90 days notice of cancellation.

The total lease payments per month will be $21,353 beginning January 1, 2020. The total lease payments per month will be $22,477 and $23,039 beginning May 1, 2021 and May 1, 2022, respectively. The Company records rent expense on a straight-line basis over the term of the leases.

As of December 31, 2020, future minimum commitments under the facility lease agreement are as follows:

	Amount
2021	$ 265,200
2022	269,700
2023	274,200
2024	230,400
Total	$ 1,039,500

Annual rent expense for the facility lease agreements was $262,900 and $129,100 for the years ended December 31, 2020 and 2019, respectively, and is included as an allocation between research and development and general and administrative expense in the consolidated statements of operations.

License Agreements—The Company has entered into a number of licensing arrangements for various intellectual property and licensed patent rights for technologies being developed for commercial sale. As part of these arrangements, the Company is subject to contingent milestone payments in accordance with agreed-upon development objectives, as well as future royalty payments on product sales of the underlying assets. As of December 31, 2020 and 2019, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Legal Proceedings—In the normal course of business, the Company may have various claims in process and other contingencies. The Company regularly assesses all contingencies and believes, as of December 31, 2020, the Company was not involved in any matters that would have a material effect on the Company's financial position, results of operations and cash flows.

10. STOCKHOLDERS' EQUITY

On December 16, 2019, the Company amended and restated its certificate of incorporation to, among other things, (i) complete a 1-for-10 reverse split of the Company's outstanding shares of common stock; (ii) increase the Company's authorized Preferred Stock to 60,000,000 shares and (iii) change the par value of the Preferred Stock from $0.01 to $0.0001 per share.

On June 17, 2020, the Company filed an amendment to its amended and restated certificate of incorporation to complete a 1-for-3.494 reverse split of the Company's outstanding shares of common stock.

Accordingly, unless otherwise noted, all share and per share information has been restated to retroactively show the effect of these stock splits during the years ended December 31, 2020 and 2019.

As of December 31, 2020 and 2019, the Company was authorized to issue 300,000,000 shares of common stock and 60,000,000 shares and of Preferred Stock, of which 24,000,000 shares were designated as Series A-1 Preferred Stock. Additionally, 16,500,000 shares and 14,130,435 shares were designated as Series B Preferred Stock as of December 31, 2020 and 2019, respectively.

Common Stock—As of December 31, 2020 and 2019, the Company has a single class of common stock.

On October 15, 2020, the Company received net proceeds of $12,332,700 from its IPO, after deducting underwriting discounts and commissions of $1,275,000 and other offering expenses of $1,392,300 incurred. The Company issued and sold 1,250,000 shares of common stock in the IPO at a price of $12.00 per share. In connection with the IPO, all shares of the Company's Series A-1 Preferred Stock and Series B Preferred Stock were converted into 624,594 and 469,136 shares of common stock, respectively.

Below is a table that outlines the initial value of issuances allocated to the IPO common stock, the IPO common stock discount amortized, and value of IPO common stock that was converted into additional-paid-in-capital during the year ended December 31, 2020:

	2020
Common Stock	
Balance at January 1,	$ —
Common stock IPO proceeds, net of issuance costs	12,332,700
Common stock IPO discount	(377,000)
Common stock IPO discount amortization	19,700
Balance at December 31,	$ 11,975,400

On June 8, 2020, the Company agreed to amend the warrant vesting schedule such that the warrants became immediately exercisable for each warrant holder. On June 8, 2020, warrant holders exercised their option to purchase 335,982 shares of common stock for proceeds of $1,200. Then, on June 10, 2020, warrant holders exercised their option to purchase an

additional 1,063,939 shares of common stock for proceeds of $3,700. There were 0 and 839,952 warrants outstanding as of December 31, 2020 and 2019, respectively.

On June 8, 2020, the Company issued 3,106 and 430 shares of common stock to the Company's Chief Medical Officer and another employee, respectively. In addition, on June 19, 2020, the Company issued 402,000 and 320,000 shares of common stock to the Company's Chief Financial Officer and Chief Operating Officer ("the CFO and COO") and Chief Strategy and Innovation Officer ("the CSIO"), respectively. The shares were issued in exchange for services rendered and no cash considerations. These issuances resulted in $9,432,000 in stock compensation expenses.

Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

The Company has never paid dividends and has no plans to pay dividends on common stock. As of December 31, 2017, the Company adopted the Plan. On September 25, 2019, the board of directors approved an additional 10,000,000 shares to be reserved and authorized under the Plan. This approval increased the total number of authorized shares from 20,000,000 to 30,000,000. After the reverse stock splits, the total number of authorized shares was updated to 858,615. On June 19, 2020, the board of directors approved an additional 850,000 shares to be reserved and authorized under the Plan. This approval increased the total number of authorized shares from 858,615 to 1,708,615.

There were 270,933 shares and 258,813 shares available for issuance as of December 31, 2020 and 2019, respectively.

Series A-1 Preferred Stock—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or the occurrence of a liquidation the holders of the shares of Series A-1 Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to $0.50, the original issue price.

On matters submitted to a vote of the stockholders of the Company, Series A-1 Preferred Stock and common stock vote together as one class, with the vote of the Series A-1 Preferred Stock on an as-converted basis. Each holder of Series A-1 Preferred Stock shall have a number of votes equal to the shares of common stock into which the shares of Series A-1 Preferred Stock held by such holder are then convertible.

With respect rights on liquidation, winding up and dissolution, shares of the Series A-1 Preferred Stock rank senior to all shares of common stock.

Each share of Series A-1 Preferred Stock is convertible at any time at the option of the holder at the then current conversion rate. In addition, upon the closing of the sale of shares of common stock to the public in an initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate.

In connection with the IPO, all shares of the Company's Series A-1 Preferred Stock were converted into 624,594 shares of common stock.

Series B Preferred Stock—On September 13, 2019, the Company amended and restated its certificate of incorporation to authorize the issuance of up to 14,130,435 shares of Series B Preferred Stock. On September 13, 2019, the Company sold 7,608,696 shares of Series B Preferred Stock for $3,500,000. On November 13, 2019, the Company issued an additional 2,173,913 shares of Series B Preferred Stock for $1,000,000. In connection with the sale of the Series B Preferred Stock, each investor was issued warrants to purchase 0.0859 shares of common stock for each share of Series B Preferred Stock purchased at a price of $0.003494 per share of common stock ("Warrants"). See below for further details.

Until the filing of the amended and restated certificate of incorporation on December 16, 2019, shares of Series B Preferred Stock had accrued unpaid dividends at an annual rate of 6% per share. The amended and restated certificate of incorporation eliminated the clause requiring the dividend accrual. In addition, on December 6, 2019, the Series B Preferred Stock investors voted in favor of forfeiting all accrued and unpaid dividends, along with all future dividends. In exchange, the Company issued 87,050 shares of Series B Preferred Stock to the investors. The Company treated this transaction as accretion and settlement of a Series B Preferred Stock dividends in the amount of $40,000. Accordingly, additional paid-in capital was reduced by $40,000.

The Series B Preferred Stock conversion price is initially equal to the Series B Preferred Stock original issuance price of $0.46 per share divided by the rate at which shares of Series B Preferred Stock may be converted into shares of common stock. The holders of the Series B Preferred Stock held a special redemption right. In the event the Company had not filed an initial registration statement with the United States Securities and Exchange Commission and submitted an application to be listed on the Nasdaq Stock market on or prior to November 15, 2019, subject to Delaware law governing distributions to stockholders and the Company's ability to redeem its shares, all or part of the shares of Series B Preferred Stock held by any holder of record as of such date of shares of Series B Preferred Stock with an aggregate purchase price of at least $1,000,000 would have been be redeemable at the option of such holders of record commencing any time on or after November 16, 2019 at a price equal to the purchase price paid for such shares plus all unpaid dividends accrued on such shares. Also, in the event that the Company was not ultimately approved for listing on a Nasdaq Stock Market tier lower than the Nasdaq Global Select Market, the special redemption right would remain in effect and may have been exercisable on any date thereafter. If the Company was unable to execute a redemption upon request of a holder, interest would accrue on the shares at rate of 14.6%, or warrants underlying the shares would be exercisable and the fair market value of the shares of common stock received in connection therewith would be treated as payment in exchange for the shares of Series B Preferred Stock submitted for redemption by such holder.

On November 12, 2019 and November 13, 2019, the Series B Preferred Stock investors signed waivers, which provided consent to the Company to eliminate the special redemption right. When the Company amended and restated its certificate of incorporation on December 16, 2019, the special redemption right provision was eliminated.

The elimination of the special redemption right allows for permanent equity classification for the Series B Preferred Stock. Since the Warrants are equity classified, the Company allocated the relative fair value of the cash proceeds between the Series B Preferred Stock and the Warrants. The fair value of the Warrants is offset by a contra account, which is classified as a discount to the Series B Preferred Stock. The discount is amortized using the effective interest method at an effective interest rate of 28% per annum.

On January 24, 2020, the Company issued 4,782,608 shares of Series B Preferred Stock for $2,200,000. On January 29, 2020, the Company filed a certificate of correction to its amended and restated its certificate of incorporation to authorize the issuance of up to 16,500,000 shares of Series B Preferred Stock. On January 31, 2020, the Company issued an additional 1,739,130 shares of Series B Preferred Stock for $800,000.

In connection with the IPO, all shares of the Company's Series B Preferred Stock were converted into 469,136 shares of common stock, and the value of the Series B Preferred Stock converted into additional-paid-in-capital.

Below is a table that outlines the initial value of issuances allocated to Series B Preferred Stock, the Series B Preferred Stock discount amortized, and value of Series B Preferred Stock that was converted into additional-paid-in-capital during the years ended December 31:

	2020	2019
Series B Preferred Stock		
Balance at January 1,	$ 1,306,900	$ 4,500,000
Series B Preferred Stock proceeds	3,000,000	(3,443,700)
Series B Preferred Stock discount	(2,668,300)	210,600
Series B Preferred Stock discount amortization	692,700	40,000
Series B Preferred Stock conversion to common stock	(2,331,300)	—
Balance at December 31,	$ —	$ 1,306,900

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or the occurrence of a liquidation, the holders of the shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to $0.46, the original issue price.

On matters submitted to a vote of the stockholders of the Company, Series B Preferred Stock, Series A-1 Preferred Stock, and common stock vote together as one class, with the vote of the Series B Preferred Stock on an as-converted basis. Each holder of Series B Preferred Stock shall have a number of votes equal to the shares of common stock into which the shares of Series B Preferred Stock held by such holder are then convertible.

With respect rights on liquidation, winding up and dissolution, shares of Series B Preferred Stock rank senior to all shares of common stock, but not senior to Series A-1 Preferred Stock.

Each share of Series B Preferred Stock is convertible at any time at the option of the holder at the then current conversion rate. In addition, upon the closing of the sale of shares of common stock to the public in an initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate.

Conversion of Convertible Promissory Notes—On August 15, 2019, each holder of convertible promissory notes issued during 2019 agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of Series A-1 Preferred Stock. At the time of conversion, outstanding principal and accrued interest of the convertible promissory notes totaled $405,300. Per the convertible promissory notes, the notes containing a $250,000 principal balance with a 17% coupon rate had a conversion price of $0.43. Additionally, the Company settled an accounts payable with a vendor by issuing a convertible promissory note in the amount of $134,800 with a 6% coupon rate, with a conversion rate of $0.43. Accordingly, 935,519 shares were issued to convert the outstanding principal and accrued interest into Series A-1 Preferred Stock.

In connection with the IPO, all shares of the Company's Series A-1 Preferred Stock were converted into 624,594 shares of common stock.

Warrants Underlying Series B Preferred Stock—In connection with the sale of the Series B Preferred Stock, each investor was issued warrants to purchase 0.0859 shares of common stock for each share of Series B Preferred Stock purchased at a price of $0.003494 per share of common stock. Under the original terms of the warrant agreements, the warrants become have exercisable in accordance with the schedule set forth below following completion by the Company of an IPO and thereafter may be exercised at any time prior to expiration ten years from the date of issuance.

- 30% of the warrants beginning six months after the date on which the securities of the Company are first listed on a United States national securities exchange (such date, the "Listing Date");
- An additional 30% of the warrants beginning nine months after the Listing Date; and
- The remainder of the warrants beginning twelve months after the Listing Date.

As of December 31, 2019, the Company sold 9,782,609 shares of Series B Preferred Stock, which contained 839,952 underlying warrants to purchase common stock based on the exercise price and vesting schedule outlined above. During the year ended December 31, 2020, the Company sold an additional 6,521,738 shares of Series B Preferred Stock, which contained 559,969 underlying warrants to purchase common stock based on the exercise price and vesting schedule outlined above. These warrants were equity classified and the fair value of $5,208,700 is reflected as additional paid-in capital. On June 8, 2020, the Company agreed to amend the warrant vesting schedule such that the warrants became immediately exercisable for each warrant holder.

On June 8, 2020, warrant holders exercised their option to purchase 335,982 shares of common stock for proceeds of $1,200. Then, on June 10, 2020, warrant holders exercised their option to purchase an additional 1,063,939 shares of common stock for proceeds of $3,700. There are no warrants underlying Series B Preferred Stock outstanding as of December 31, 2020.

The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions for the years ended December 31:

	2020	2019
Risk-free interest rate	1.54% - 1.88 %	1.54% - 1.84 %
Expected volatility	71.95% - 72.71 %	71.95% - 72.20 %
Expected life (years)	10.00	10.00
Expected dividend yield	0 %	0 %

Representative's Warrants—In connection with the IPO, the Company granted the underwriters warrants (the "Underwriters' Warrants") to purchase an aggregate of 62,500 shares of common stock at an exercise price of $15.00 per

share, which is 125% of the initial public offering price. The Underwriters' Warrants have a five-year term and are not exercisable prior to April 13, 2021. All of the Underwriters' Warrants were outstanding at December 31, 2020.

These warrants were equity classified and the fair value of $377,000 is reflected as additional paid-in capital. The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions for the year ended December 31, 2020:

	2020
Risk-free interest rate	0.18 %
Expected volatility	94.08 %
Expected life (years)	2.74
Expected dividend yield	0 %

11. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan— Stock Options

The Black-Scholes option-pricing model was used to estimate the fair value of stock options with the following weighted-average assumptions for the years ended December 31:

	2020	2019
Risk-free interest rate	0.15% - 2.92 %	1.60% - 2.92 %
Expected volatility	72.29% - 82.52 %	72.29% - 78.16 %
Expected life (years)	4.93 – 6.07	4.93 – 6.07
Expected dividend yield	0 %	0 %

The fair value of the common shares underlying the stock options has historically been determined by the board of directors, with input from management. Because there was no public market for the Company’s common shares prior to October 15, 2020, the board of directors determined the fair value of the common shares at the time of grant of the stock option by considering a number of objective and subjective factors, including important developments in the Company’s operations, third-party valuations performed, sales of Series A-1 Preferred Stock, sales of Series B Preferred Stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company’s common shares, among other factors.

The following table summarizes the activity for all stock options outstanding at December 31 under the Plan:

	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	598,083	$ 11.04	520,517	$ 8.64
Granted	86,536	17.95	209,505	17.29
Exercised	—	—	(1,719)	6.64
Cancelled and forfeited	(194,901)	15.06	(130,220)	11.56
Balance at December 31	489,718	$ 10.03	598,083	$ 11.04
Options exercisable at December 31:	441,430	$ 9.50	368,527	$ 7.72
Weighted average grant date fair value for options granted during the year:		$ 17.43		$ 10.82

The following table summarizes additional information about stock options outstanding and exercisable at December 31, 2020 and 2019 under the Plan:

	Options Outstanding				Options Exercisable		
As of December 31,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2020	489,718	6.37	$ 10.03	$ 554,900	441,430	$ 9.50	$ —
2019	598,083	8.07	$ 11.04	$ 19,163,700	368,527	$ 7.72	$ 13,031,000

Total stock compensation expense recognized from stock-based compensation awards classified as stock options were recognized in the consolidated statements of operations for the years ended December 31, 2020 and 2019 as follows:

	2020	2019
Research and development	$ 1,008,000	$ 332,000
General and administrative	332,000	190,900
Total	$ 1,340,000	$ 522,900

On August 20, 2020, the board of directors canceled and terminated 15,792 stock options, granted during the quarter ended June 30, 2020 to four non-employees. Thereafter, on August 20, 2020, the board of directors granted 21,112 stock options to the same individuals with a grant date fair value of $12.81 per share. There were 3,959 stock option grants that were considered vested on the grant date. The effects of the stock option modifications resulted in $65,900 of stock compensation expense allocable to general and administrative for the year December 31, 2020. Included in that amount were $34,800 of incremental compensation costs resulting from the modifications for the year ended December 31, 2020.

As of December 31, 2020, total unrecognized stock compensation expense is $473,900, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 1.79 years.

2017 Stock Incentive Plan—Restricted Stock Units

In January 2017, the Company’s board of directors approved the adoption of the Plan. The Plan permits the Company to grant up to 1,708,615 shares of the Company’s common stock awards, including incentive stock options; non-statutory stock options; and conditional share awards to employees, directors, and consultants of the Company. All granted shares that are canceled, forfeited, or expired are returned to the Plan and are available for grant in conjunction with the issuance of new common stock awards. Restricted stock units (“RSUs”) vest over a specified amount of time or when certain performance metrics are achieved by the Company.

The fair value of the common shares underlying the RSUs has historically been determined by the board of directors, with input from management. As there was no public market for Company’s common shares prior to October 15, 2020, the board of directors determined the fair value of the common shares at the time of grant of the RSUs by considering a number of objective and subjective factors, including important developments in the Company’s operations, third-party valuations performed, sales of Series A-1 Preferred Stock, sales of Series B Preferred Stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company’s common shares, among other factors.

The following table summarizes the activity for all RSUs outstanding at December 31 under the Plan:

	2020	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	—	$ —
Granted	1,655,579	12.84
Vested	—	—
Cancelled and forfeited	(709,334)	12.87
Nonvested RSUs at December 31	946,245	$ 12.81

During the year ended December 31, 2020, 1,655,579 RSUs were granted and 709,334 RSUs were cancelled. During the year ended December 31, 2020, no RSUs vested. No RSUs were granted or vested in the year ended December 31, 2019.

On August 20, 2020, the board of directors canceled and terminated 709,334 RSUs, granted during the quarter ended June 30, 2020. The cancelled RSUs were originally granted to five individuals with a grant date fair value of $12.87 per share. Thereafter, on August 20, 2020, the board of directors granted 946,245 RSUs to the same individuals with a grant date fair value of $12.81 per share. None of the RSU grants were considered vested on the grant date. The RSU grants were modified for three employees and two non-employees. The effects of the RSU modifications resulted in $748,400 and $1,725,300 of stock compensation expense allocable to research and development and general and administrative, respectively, during the year ended December 31, 2020. Included in those amounts were incremental compensation costs of $166,900 and $402,700 of stock compensation expense allocable to research and development and general and administrative, respectively, during the year ended December 31, 2020.

12. INCOME TAXES

For the years ended December 31, 2020 and 2019, the Company recognized no provision or benefit from income taxes.

The following is a reconciliation of the effective income tax rate to the statutory federal income tax rate for the years ended December 31, 2020 and 2019.

	2020	2019
Federal income tax at statutory rates	21.00 %	21.00 %
Federal income tax rate reduction	— %	— %
Change in valuation allowance	(21.00)	(21.00)
Effective income tax rate	— %	— %

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company’s deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. The Company recorded a valuation allowance to fully offset the net deferred tax asset, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets as of December 31, 2020 and 2019 due to the significant uncertainty about the realization of the deferred tax asset until the Company can operate profitably.

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows as of December 31:

	2020	2019
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 3,842,900	$ 2,605,400
Stock compensation expense	3,379,000	597,400
Intangible assets	23,600	27,800
Total gross deferred tax assets	7,245,500	3,230,600
Valuation allowance	(7,061,600)	(3,198,100)
Property and equipment	(183,900)	(32,500)
Net deferred tax assets (liabilities)	—	—

As of December 31, 2020 and 2019, the Company has a US net operating loss ("NOL") carryforward of $18,299,500 and $12,406,800, respectively. The NOL carryforwards may be subject to annual limitations due to "change in ownership" provisions of Internal Revenue Code Section 382 ("Section 382") that can be triggered due to future ownership changes. Additionally, the NOL loss carryforwards are subject to examination and adjustments by the Internal Revenue Service until the statute of limitations closes on the year in which the NOL is utilized.

As of December 31, 2020 and 2019, there were no material uncertain tax positions taken by the Company. Additionally, the Company does not expect any unrecognized tax benefits to change significantly over the next twelve months.

As of December 31, 2020, the Company is not currently under audit by any income tax authority.

On March 27, 2020, in response to the COVID-19 pandemic, the president of the United States signed the CARES Act. The Company does not expect there to be any significant benefit to its income tax provision as a result of the CARES Act, and the Company continues to monitor for any potential tax legislation related to the COVID-19 pandemic.

13. RELATED PARTY TRANSACTIONS

During the year ended December 31, 2020, the Company maintained two separate consulting agreements with the Company’s CSIO and the Company’s CFO and COO. Those consulting agreements were terminated after the completion of the IPO in October 2020.

Beginning in the year ended December 31, 2014, the Company entered into its first consulting agreement with the CSIO. Pursuant to the amended agreement dated July 20, 2018, the CSIO was entitled to a consulting fee of $400 per hour, provided that he is limited to nineteen (19) hours per month unless he obtains approval from the Company’s Chief Executive Officer. The consulting agreement indicates that the CSIO will provide a leadership role for the Company’s business development strategies. The consulting fees paid to the CSIO totaled $579,700 and $207,800 in the years ended December 31, 2020 and 2019, respectively. In addition, the Company issued the CSIO 320,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations. See Note 10.

Beginning in the year ended December 31, 2018, the Company entered into its first consulting agreement with the CFO and COO. Initially, his title was "Consultant", and the Company changed his title to CFO and COO on October 25, 2019. The CFO and COO was elected as a director of the Company on January 17, 2020. Pursuant to the agreement on April 18, 2018 and amended on September 4, 2019, the CFO and COO is entitled to a consulting fee of $2,500 per month amended to $10,000 per month plus discretionary bonuses approved by management. The consulting fees paid to the CFO and COO totaled $140,000 and $67,500 in the years ended December 31, 2020 and 2019, respectively. In addition, the Company issued the CFO and COO 402,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations. See Note 10.

On June 8, 2020, the Company issued the Chief Medical Officer and another employee 3,106 and 430 shares of common stock, respectively. The shares were issued in exchange for services rendered and no cash considerations. See Note 10.

14. SUBSEQUENT EVENTS

Strategic Alliance Agreement with Leon Office (H.K.)

On January 28, 2021, the Company executed a strategic alliance agreement with Leon Office (H.K.) ("Leon") a company established under existing laws of Hong Kong. It is intended that Leon acts as an independent business development advisor on behalf of the Company. Leon will seek to introduce organizations and individuals that will create business development opportunities for the Company, to expand the Company's reach to international markets with a focus on certain Asian markets and to increase brand recognition and exposure through developing liaisons, collaborations, branches and subsidiaries. The cost of the agreement is $360,000 annually, payable in four quarterly installments.

Loan Payable Forgiveness

During the year ended December 31, 2020, the Company applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. On February 16, 2021 the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,600 and $300, respectively.

Lease Facility Expansion

On March 22, 2020, the Company's board of directors approved a lease expansion within its premises in Houston, Texas. The amended lease agreement will commence on August 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 15,385 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after 90 days notice of cancellation.

If the Company exercises the cancellation option, the Company must also pay the lessor a termination payment equal to three months of base rent.

The future minimum commitments under the amended lease agreement will be as follows:

	Amount
2021	$ 380,600
2022	546,700
2023	551,100
2024	461,200
Total	$ 1,939,600

Legal Complaint Filed Against the Company

A complaint was filed on March 22, 2021 in the Court of Chancery of the State of Delaware against the Company by a former consultant and director. The complaint alleges, among other things, that the plaintiff is entitled to additional stock options and he is seeking declaratory judgment and specific performance. The Company believes that all of the claims in the complaint are without merit and the Company intends to defend vigorously against them.

Exhibit 4.1

DESCRIPTION OF SECURITIES

Kiromic BioPharma, Inc (“Company”, “we”, “us” and “our”) has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, namely our common stock, par value $0.001 per share.

The following is a summary of the rights of our common and of certain provisions of our Amended and Restated Certificate of Incorporation (“Certificate of Incorporation”) and Bylaws (“Bylaws”). For more detailed information, please see our Certificate of Incorporation and Bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K to which this description is an exhibit.

Common Stock

Our Certificate of Incorporation authorizes us to issue up to 300,000,000 shares of common stock, $0.001 par value per share. As of March 31, 2021, we had 7,332,999 shares of common stock outstanding, held by 115 stockholders of record. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Holders of shares of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders generally. The holders of shares of common stock have no preemptive, conversion, subscription rights or cumulative voting rights.

Preferred Stock

Our Certificate of Incorporation authorizes us to issue up to 60,000,000 shares of preferred stock, $0.0001 par value per share, of which no shares were issued or outstanding as of March 31, 2021, Our board of directors is authorized to issue from time to time, without stockholder authorization, in one or more designated series or classes, any or all of the authorized but unissued shares of preferred stock with such dividend, redemption, conversion and exchange provisions as may be provided in the particular series. Any series of preferred stock may possess voting, dividend, liquidation and redemption rights superior to that of the common stock. The rights of the holders of common stock will be subject to and may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. Issuance of a new series of preferred stock, while providing desirable flexibility in connection with possible acquisition and other corporate purposes, could make it more difficult for a third party to acquire, or discourage a third party from acquiring, a majority of the outstanding voting stock of our company.

Dividends

We have never paid cash dividends on our common stock and we do not anticipate the payment of cash dividends on our common stock in the foreseeable future.

Anti-Takeover Effects of Certain Provisions of Delaware Law

Set forth below is a summary of the provisions of the Certificate of Incorporation and the Bylaws that could have the effect of delaying or preventing a change in control of the Company.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination’’ with an “interested stockholder’’ for a period of three years after the date of the transaction in which such stockholder became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a “business combination’’ includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an “interested stockholder’’ is a stockholder who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of the voting stock.

Board of Directors Vacancies. Our bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors will be permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This will make it more difficult to change the composition of our board of directors and will promote continuity of management.

Stockholder Action; Special Meeting of Stockholders. A holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Our bylaws further provide that special meetings of our stockholders may be called only by our board of directors, the chairman of our board of directors, our president or chief executive officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our bylaws provide advance notice procedures for 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. Our bylaws will also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

No Cumulative Voting. The Delaware General Corporation Law provides that stockholders are not entitled to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our certificate of incorporation does not provide for cumulative voting.

Issuance of Undesignated Preferred Stock. Our board of directors will have the authority, without further action by our stockholders, to issue up to 60,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC, 18 Lafayette Place Woodmere, New York 11598.

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction
GreenPlanet Pharma, Inc	United States

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-252341 on Form S-8 of our report dated March 31, 2021, relating to the financial statements of Kiromic BioPharma, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Houston, Texas
March 31, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Maurizio Chiriva-Internati, certify that:

1. I have reviewed this annual report on Form 10-K of Kiromic BioPharma, 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 registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 registrant, 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 registrant'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: March 31, 2021

/s/ Maurizio Chiriva-Internati

Maurizio Chiriva-Internati
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Tony Tontat, certify that:

1. I have reviewed this annual report on Form 10-K of Kiromic BioPharma, 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 registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 registrant, 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 registrant'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: March 31, 2021

/s/ Tony Tontat
Tony Tontat
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

The undersigned Chief Executive Officer of KIROMIC BIOPHARMA, INC. (the "Company"), DOES HEREBY CERTIFY that:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2020 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement on March 31, 2021.

/s/ Maurizio Chiriva-Internati
Maurizio Chiriva-Internati
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Kiromic BioPharma, Inc. and will be retained by Kiromic BioPharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

The undersigned Chief Financial Officer of KIROMIC BIOPHARMA, INC. (the "Company"), DOES HEREBY CERTIFY that:

1. The Company's Annual Report on Form 10-K for the quarter ended December 31, 2020 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement on March 31, 2021.

/s/ Tony Tontat
Tony Tontat
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Kiromic BioPharma, Inc. and will be retained by Kiromic BioPharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.