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FINANCIAL STATEMENTS

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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-238153

1,250,000 Shares

Common Stock

Kiromic BioPharma, Inc.

This is a firm commitment initial public offering of shares of common stock of Kiromic BioPharma, Inc. Prior to this offering, there has been no public market for our common stock. We are offering 1,250,000 shares of our common stock at an initial public offering price of $12.00 per share.

Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "KRBP."

We are an "emerging growth company" under the federal securities laws and have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 29.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$12.00	$15,000,000
Underwriting discounts and commissions[(1)]	$0.90	$1,125,000
Proceeds to us, before expenses	$11.10	$13,875,000

(1) Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1.0% of the initial public offering price payable to the underwriters. We refer you to "Underwriting" beginning on page 167 for additional information regarding underwriters' compensation.

We have granted a 45-day option to the representative of the underwriters to purchase up to 187,500 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers on or about October 20, 2020.

Sole Book-Running Manager

ThinkEquity
a division of Fordham Financial Management, Inc.

Co-Manager
Paulson Investment Company, LLC

The date of this prospectus is October 15, 2020

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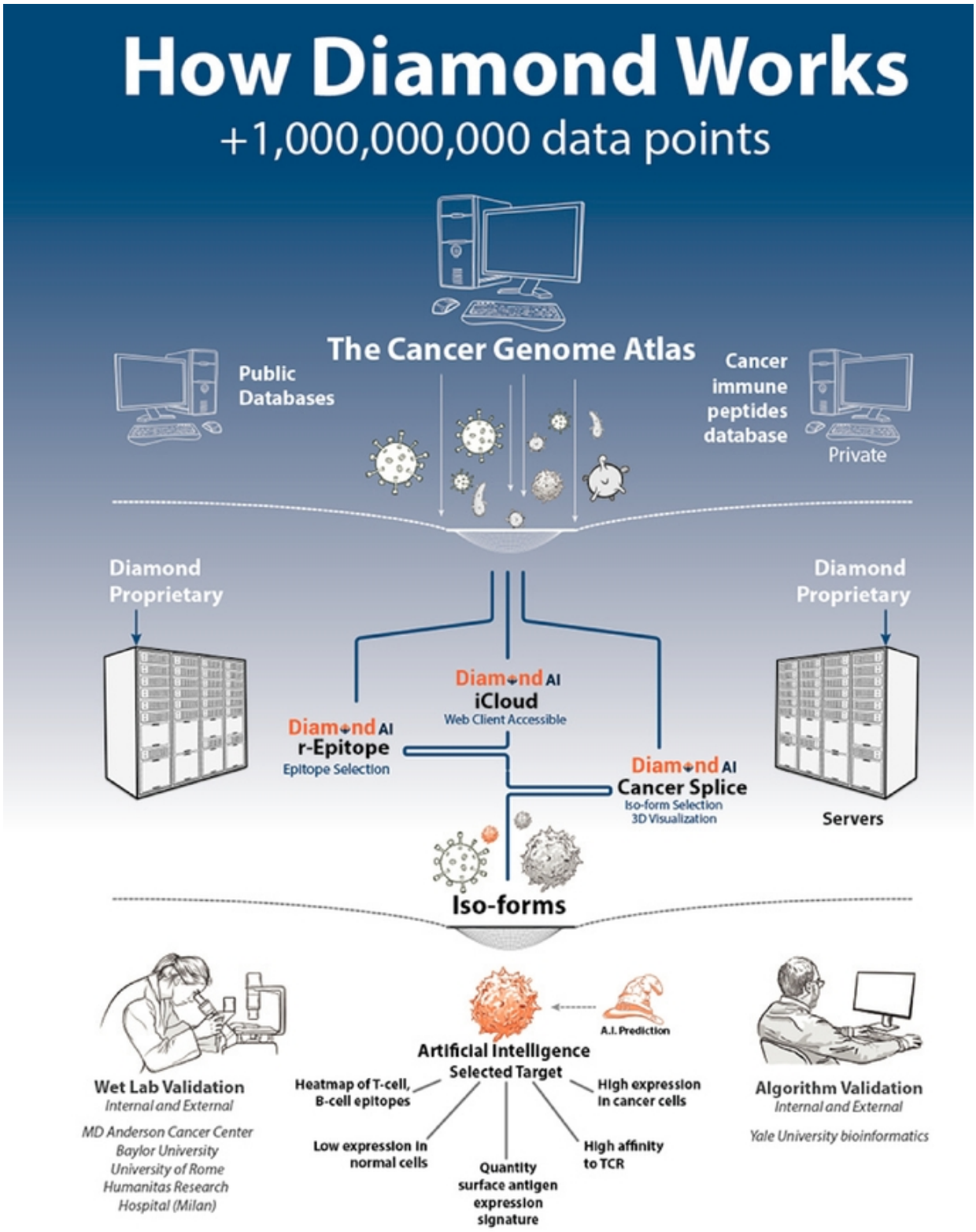

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You should rely only on the information contained in this prospectus or in any amended prospectus that we may authorize to be delivered or made available to you. We and the underwriters have not authorized anyone to provide you with different information. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where such offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of its delivery or any sale of shares of our common stock.

Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of the prospectus outside the United States. See "Underwriting."

PROSPECTUS SUMMARY

This summary highlights information that we present more fully in the rest of this prospectus. This summary does not contain all of the information you should consider before buying our shares in this offering. This summary contains forward-looking statements that involve risks and uncertainties, such as statements about our plans, objectives, expectations, assumptions or future events. These statements involve estimates, assumptions, known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from any future results, performances or achievements expressed or implied by the forward-looking statements. See "Special Note Regarding Forward-Looking Statements." You should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and the notes to those statements.

THE COMPANY

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."

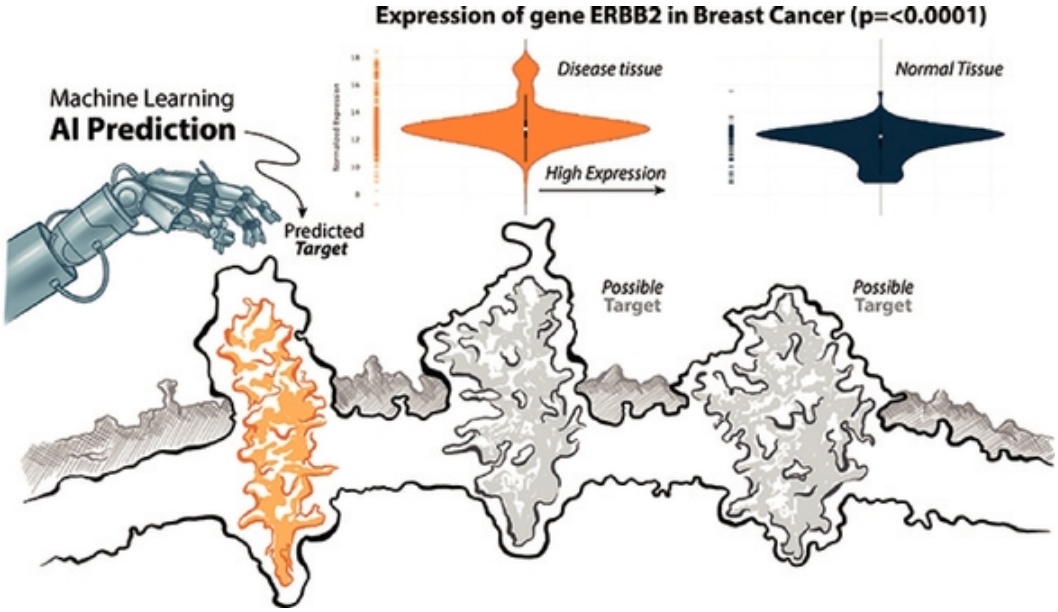
Kiromic's Diamond is big data science meeting target identification, dramatically compressing man-years and billions of drug development dollars to develop a live drug.

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)

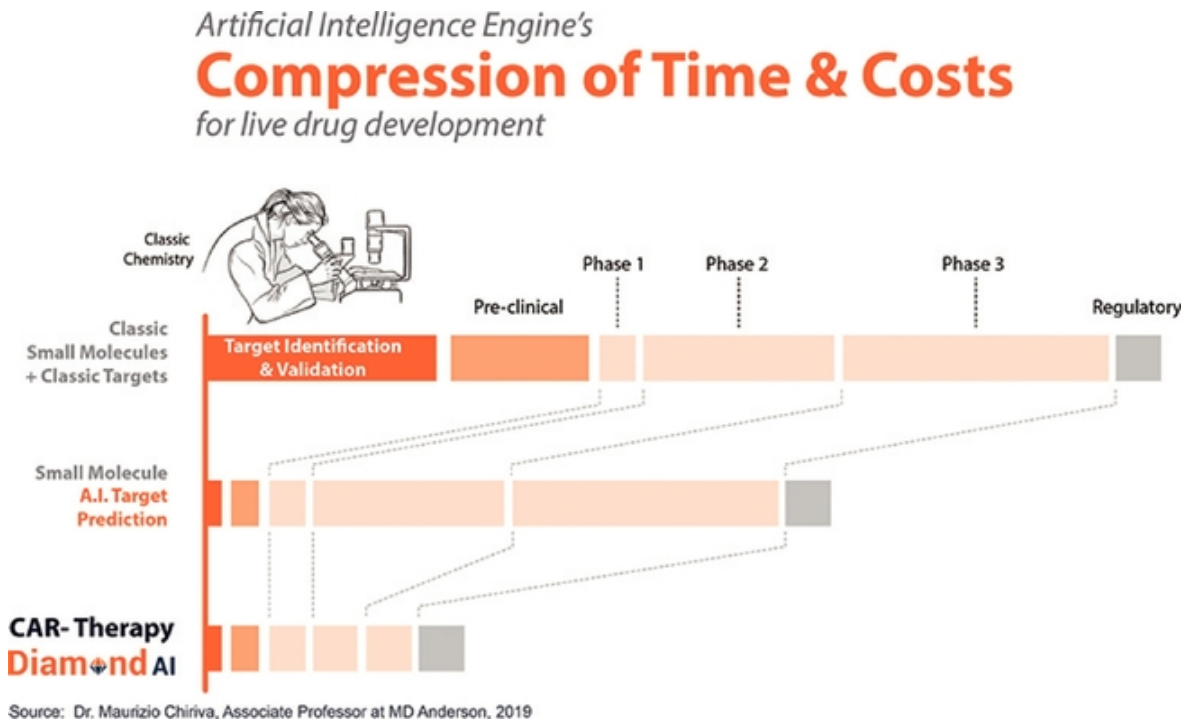
Diamond is a computational platform and a neural network that can identify new cancer immunological targets for T cells and B cells. Diamond is an artificial intelligence and machine learning approach that can identify novel surface tumor targets. It uses public and proprietary samples and can expand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

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



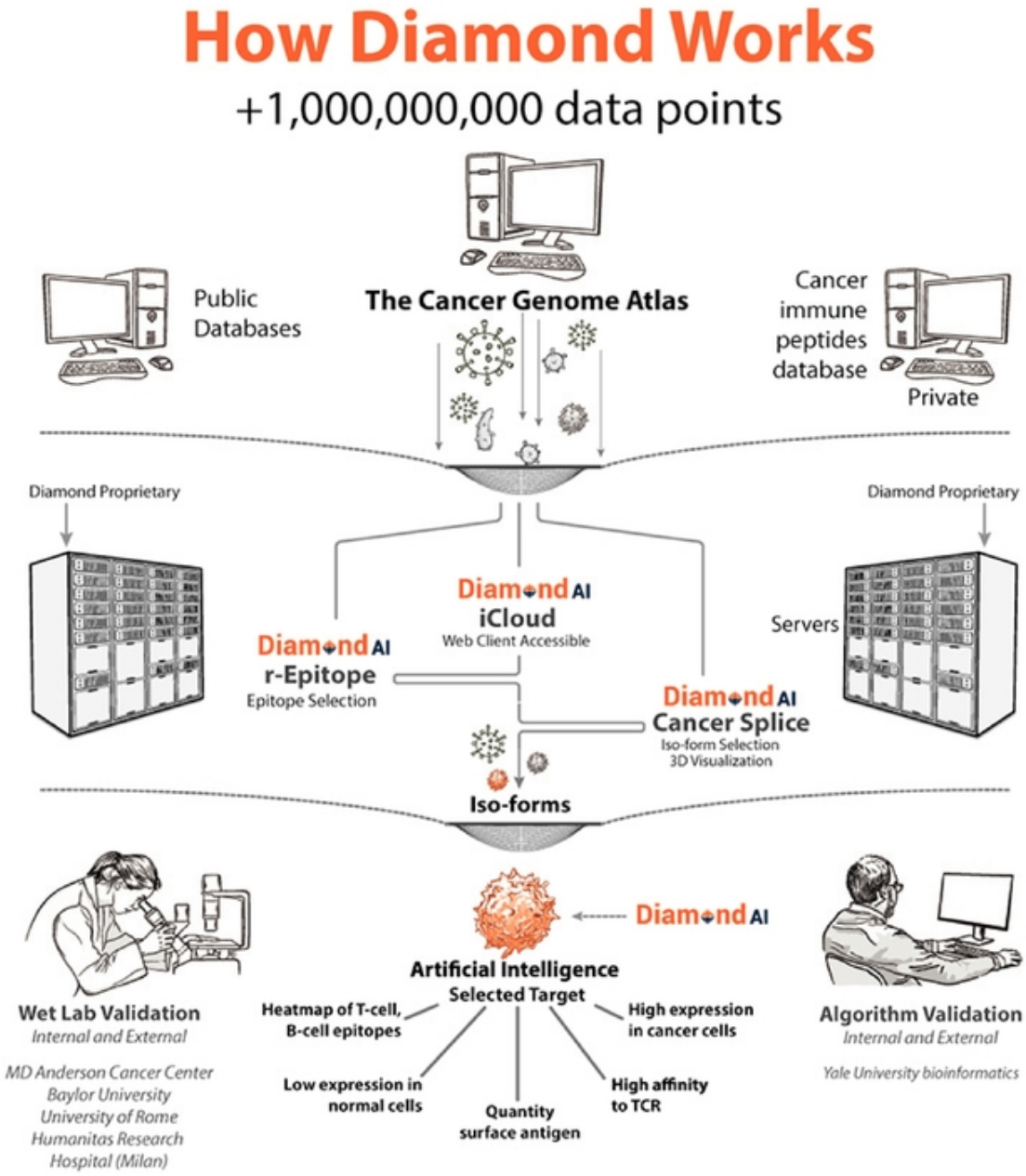
Diamond generates a prioritized list of cancer immunological targets for T cells and B cells. These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR-T cell therapies and vaccine therapies.

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.



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.

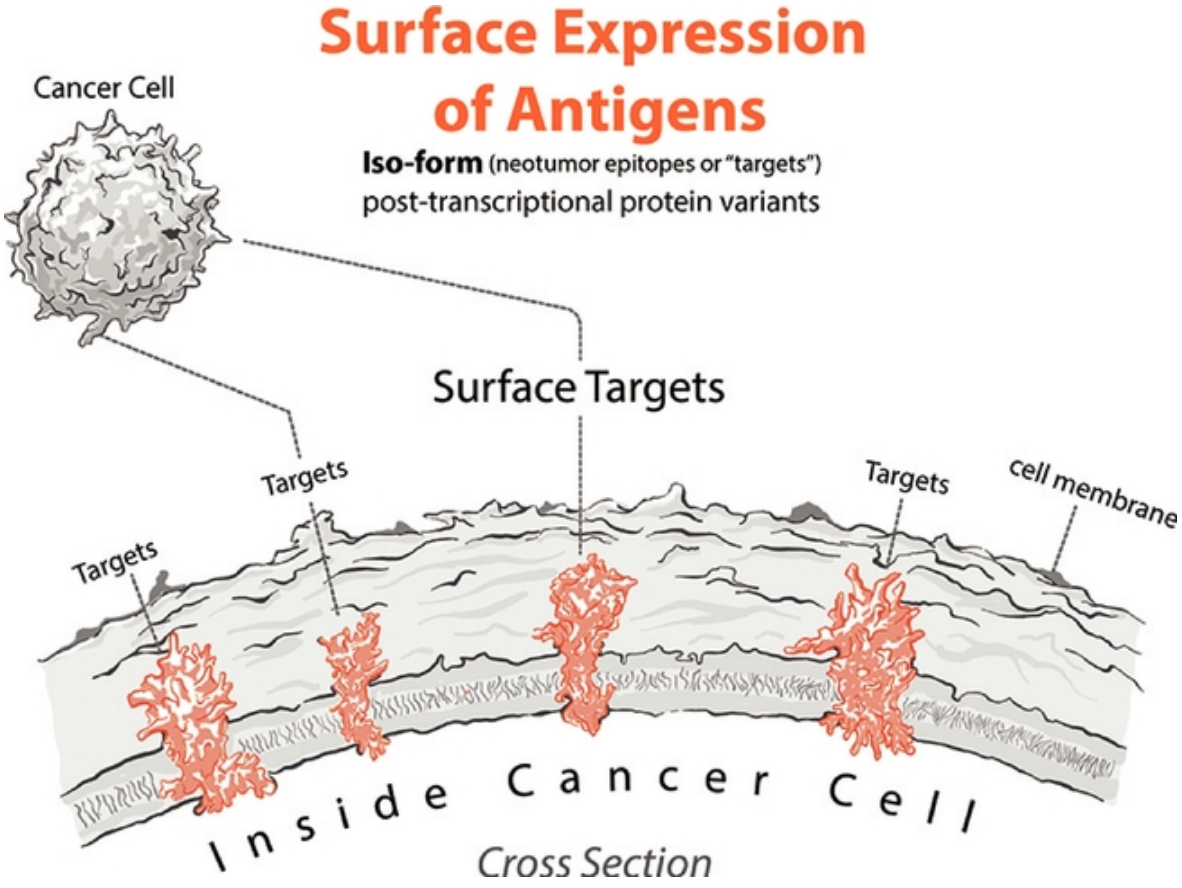
Predict Isoform Targets. Cancer cells will down regulate or shed targets in order to avoid detection and destruction by T cells (the immune system). These variations are known as isoforms. CancerSplice also shows a box plot by tissue of expression of the isoform in normal cancer genome atlas tissues 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.

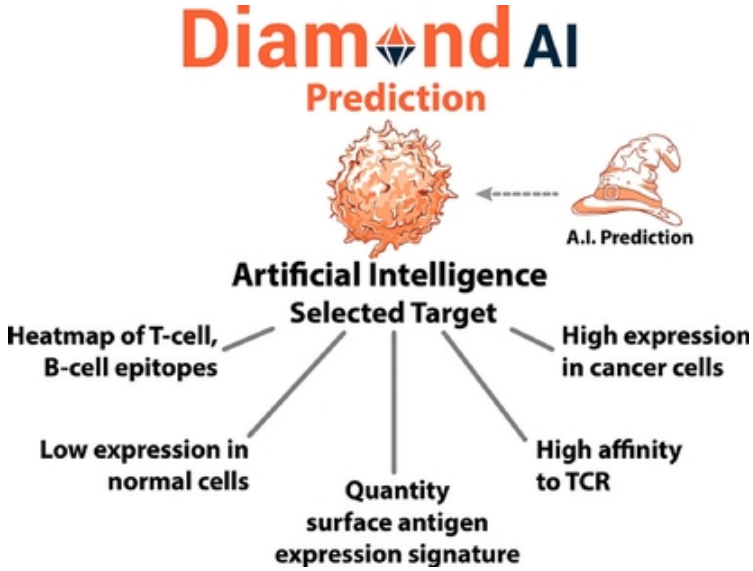
Target isoforms are protein variants of the same targets that occur during the normal processing of immature gene transcripts to the mature form.

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.

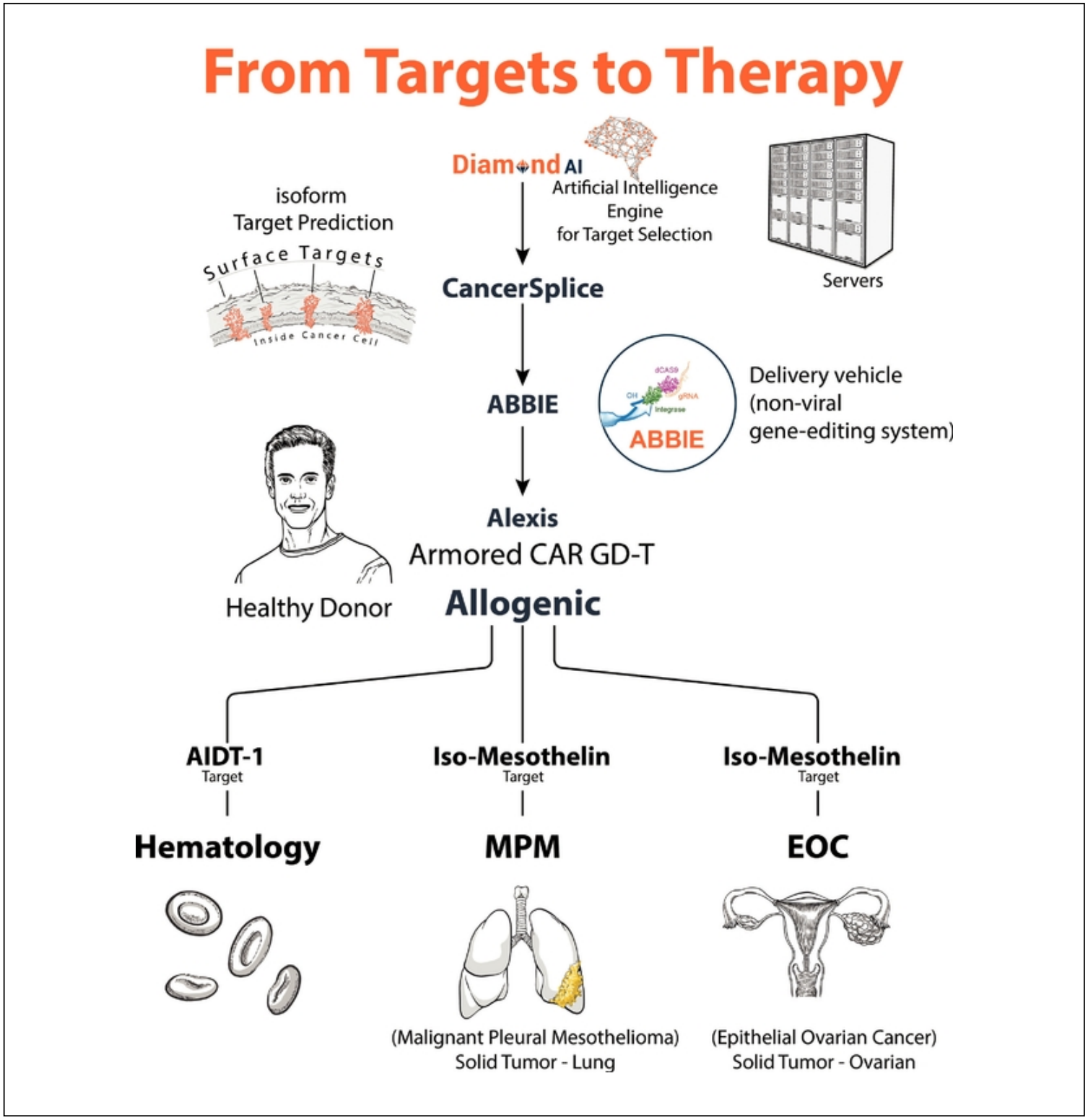
Allogenic engineered T cells are manufactured in a similar manner as autologous, but with two key differences: (1) allogenic T cells are derived from healthy donors, not cancer patients, and (2) allogenic T cells must also be genetically engineered to minimize the risk of graft-versus-host disease, a 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 validating different tumor-specific immunotherapy product candidates for refractory CAR-T cell patients. Refractory CAR-T cell patients are those who have received CAR-T cell treatments for their indication, however, they either showed low or no benefit from this treatment. 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.


From Targets to Therapy
Diamond AI
Artificial Intelligence Engine for Target Selection
Servers
isoform Target Prediction
Surface Targets
Inside Cancer Cell
CancerSplice
ABBIE
dCAS9
gRNA
Integrase
ABBIE
Delivery vehicle (non-viral gene-editing system)
Alexis
Armored CAR GD-T
Allogenic
Healthy Donor
AIDT-1
Target
Iso-Mesothelin
Target
Iso-Mesothelin
Target
Hematology
MPM
EOC
(Malignant Pleural Mesothelioma)
Solid Tumor - Lung
(Epithelial Ovarian Cancer)
Solid Tumor - Ovarian

ABBIE (Delivery Vehicle)

ABBIE Summary

ABBIE is a novel gene-editing system for inserting therapeutic genes safely into the genome of a host cell.

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.

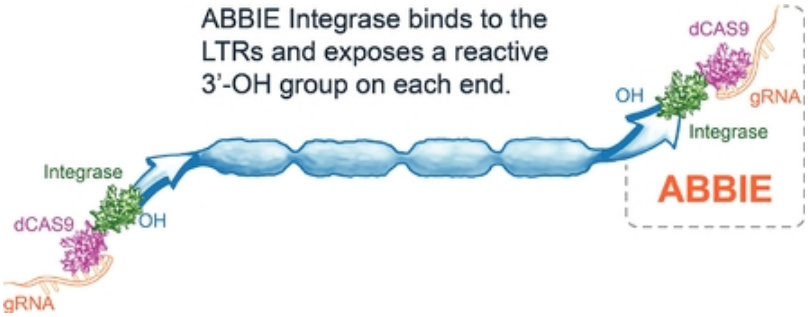
Due to this targeting ability, ABBIE can also be used to remove unwanted, inhibitory genes. CAR expression on the Gamma-Delta T cells allows them to detect and destroy the antigen-expressing targeted cells.

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. If no major obstacles are encountered, we expect to be able to begin producing effector cells for in vitro testing using ABBIE by December 2020.

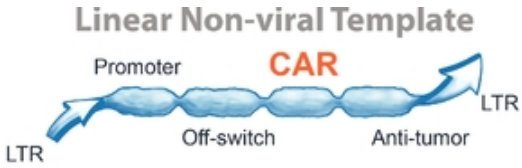


Figure 1. Our ABBIE gene-editing technology begins with the transgene template plasmid. Plasmid DNA is cut with restriction enzyme, ScaI, liberating the transgene template along with the retroviral-derived long-terminal repeats (LTRs), which is purified away from the plasmid DNA and ScaI protein.

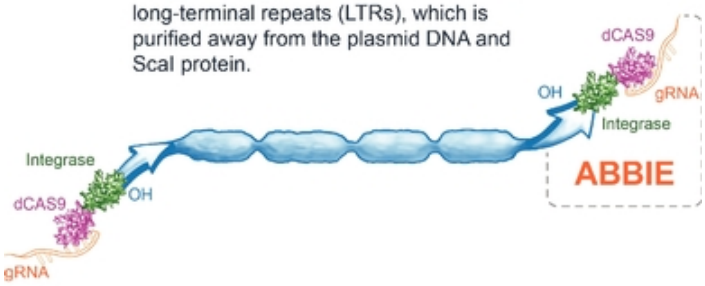


Figure 2. The ABBIE integrase, derived from HIV, is added, which binds to the LTRs and exposes a reactive 3'-OH group on each end.

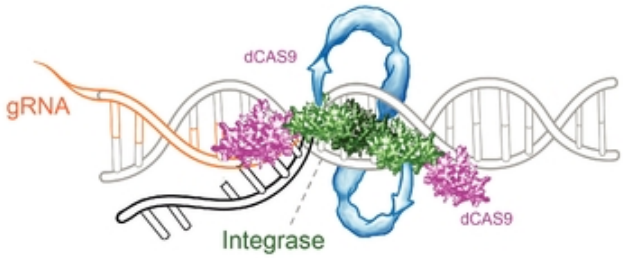


Figure 3. The guide RNA (gRNA) tethers ABBIE-bound template to the target site via DCas9, and Integrase helps to attach the exposed 3'OH groups to the target site on both strands without causing a dsDNA break.

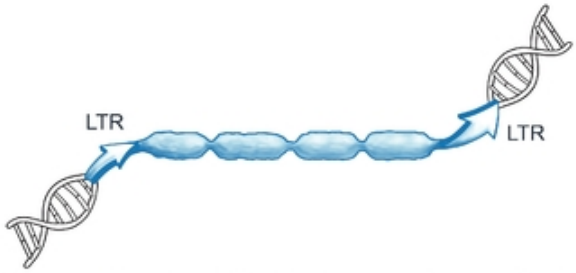
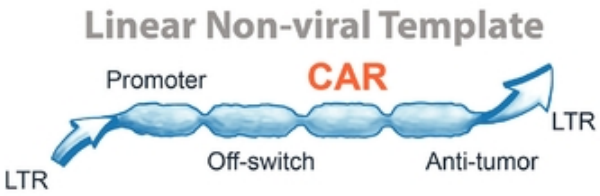


Figure 4. Following stable integration of the template into the target DNA locus, a short DNA duplication is present on each end.

Up-Armoring

Accessory proteins can "up-armor" cellular therapies

Strategic choice of proteins to improve cellular function and neutralize anti-immune responses



* Activated signaling molecules chosen to enhance cell persistence by stimulating cytokine pathways
* Targeting the immunosuppressive "reactive" stroma can enable tumor targeting by therapeutic cells while increasing anti-tumor efficacy

SWITCHES

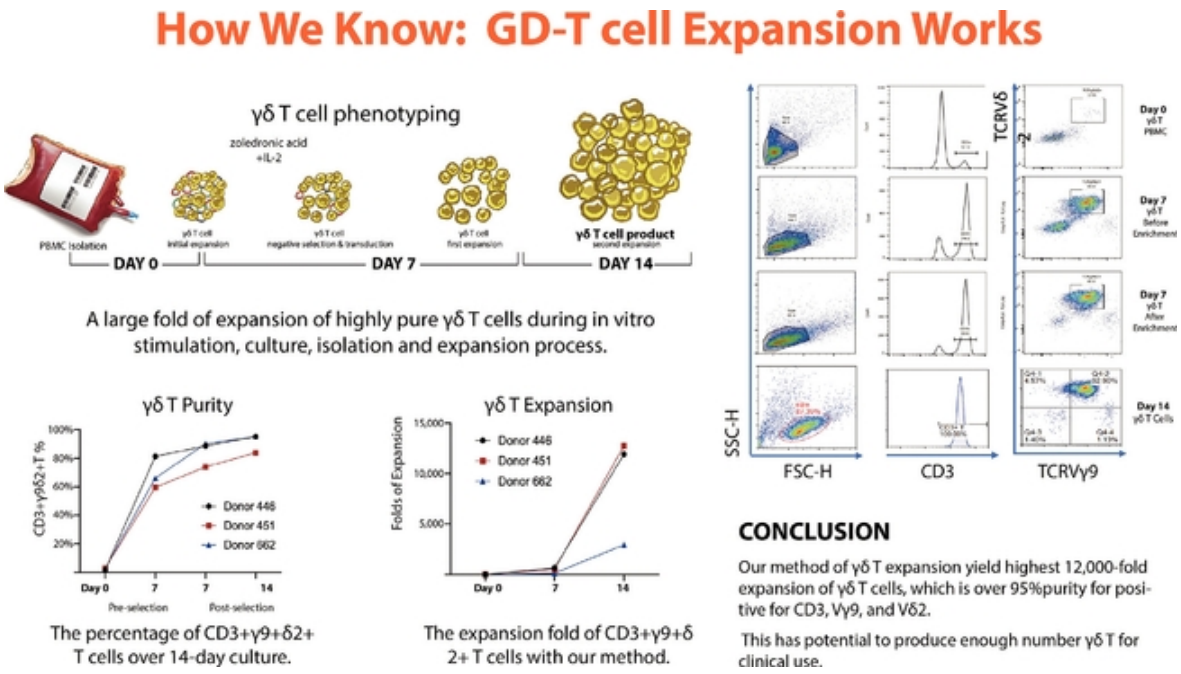
ACTIVATION Switch. A rapidly deployed activation switch can provide a survival and proliferation signal to the therapeutic cells to enhance their efficacy and persistence in vivo.

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.

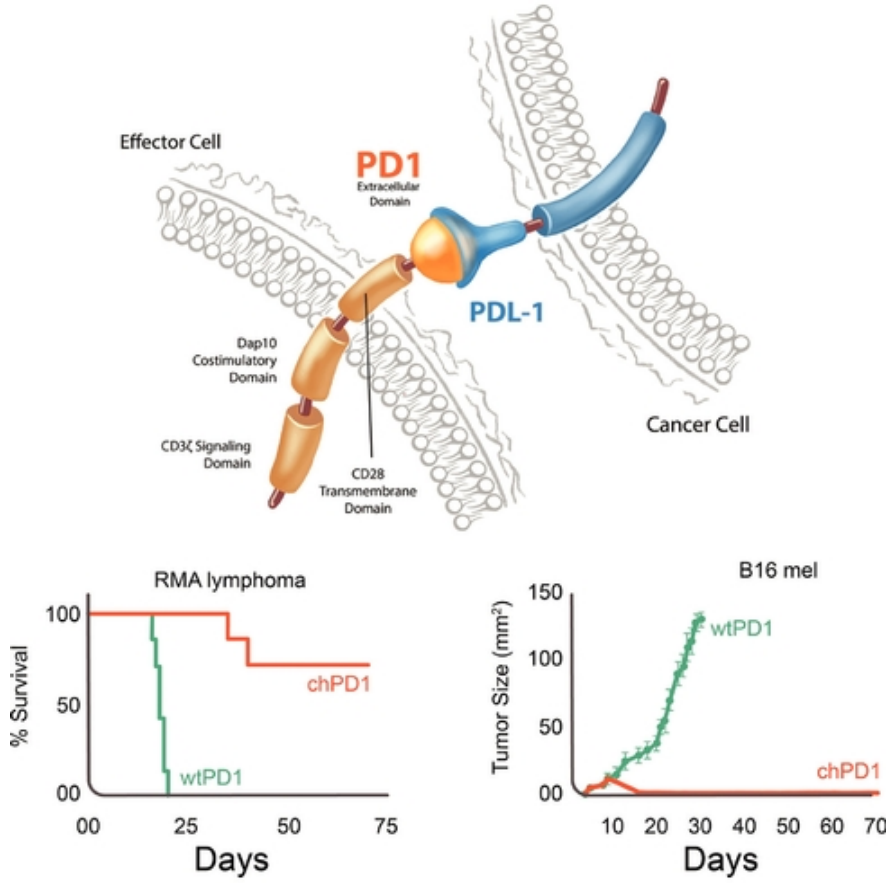
Manufacturing Allogeneic Effector Cells

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



PD-1: Avoiding Antigen Escape

To further boost the potency of our effector cells, we plan to explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, the chances for the tumor to escape treatment are greatly reduced.



chPD1 = chimeric PD1

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

Checkpoint inhibitors block PD-1 and PD-L1.

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

chPD1-expressing T cells can efficiently lyse both hematologic and solid tumors expressing PD-L1 and/or PD-L2, leading to greatly improved survival with minimal toxicity in animal models.

chPD1 Receptor signaling also leads to cytokine release that can have widespread anti-tumor effects in the tumor microenvironment.

Step 1. Collection

The starting material for our engineered T/NK cell products is white blood cells. For our allogenic products, the T/NK cells are collected from a healthy donor. These are collected using a standard blood bank procedure known as leukapheresis. The collected cells are then sent to a central processing facility, where the peripheral blood mononuclear cells, including T/NK cells, are isolated from the other sample components. The T/NK cells for our allogenic products are isolated and stored frozen, creating an inventory of starting healthy donor cells for manufacturing.

Step 2. Gene Editing

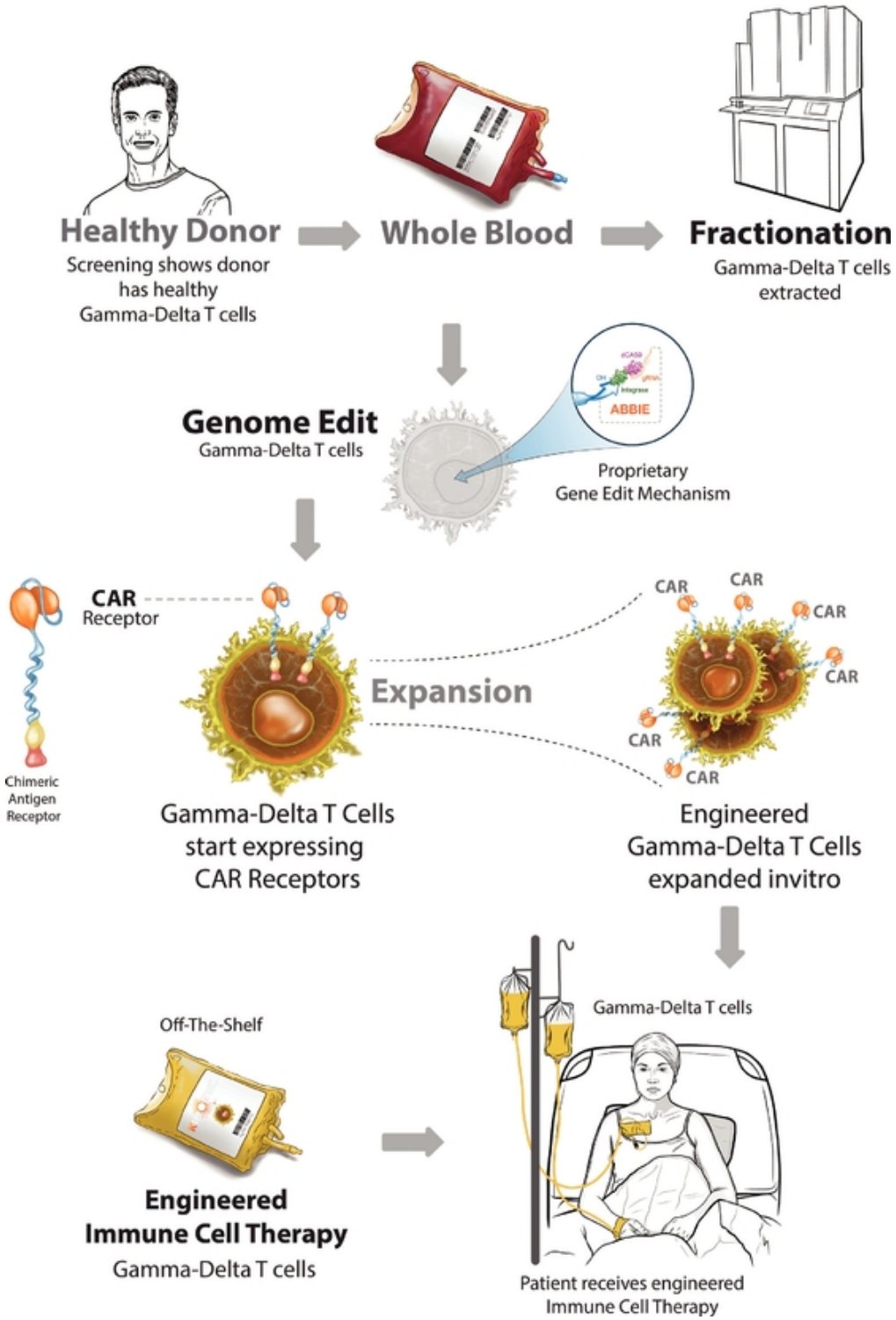
These cells are stimulated to proliferate, then transduced with a non-replicating retroviral vector to introduce the CAR gene into the patient's T/NK cells.

We are also currently developing ABBIE, which is a non-viral gene-editing mechanism to insert the target DNA template information into the T/NK cell genome. The CAR sequence will direct the expression of CAR proteins on the cell surface that allows the transduced T/NK 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 T/NK 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.



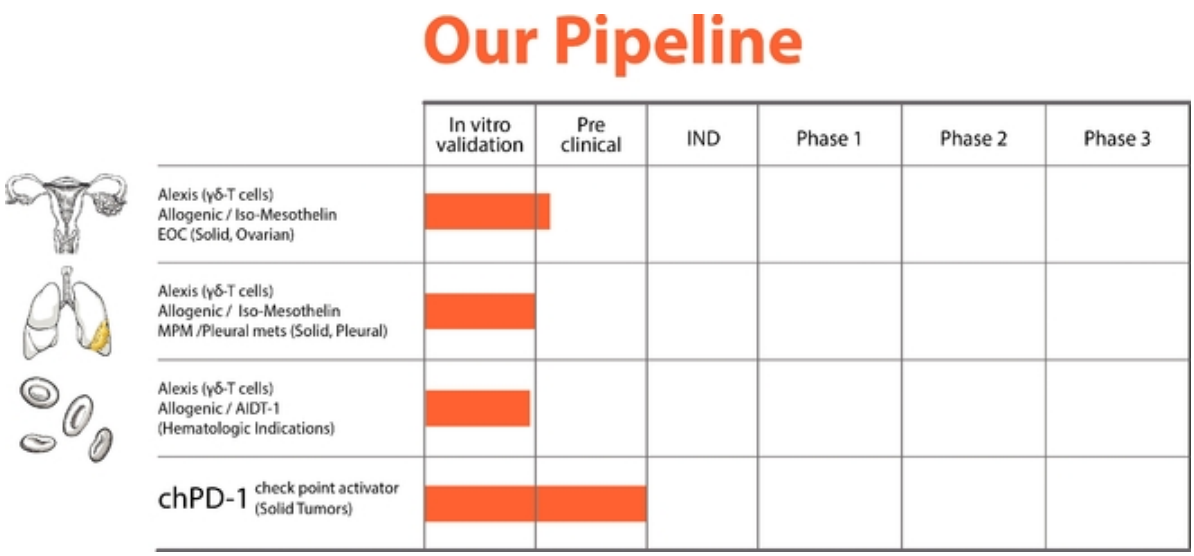
Note that we have not yet completed our ABBIE (gene editing) technology as shown in Step No. 5 above. Our clinical trial will be using the current industry standard retroviral vector.

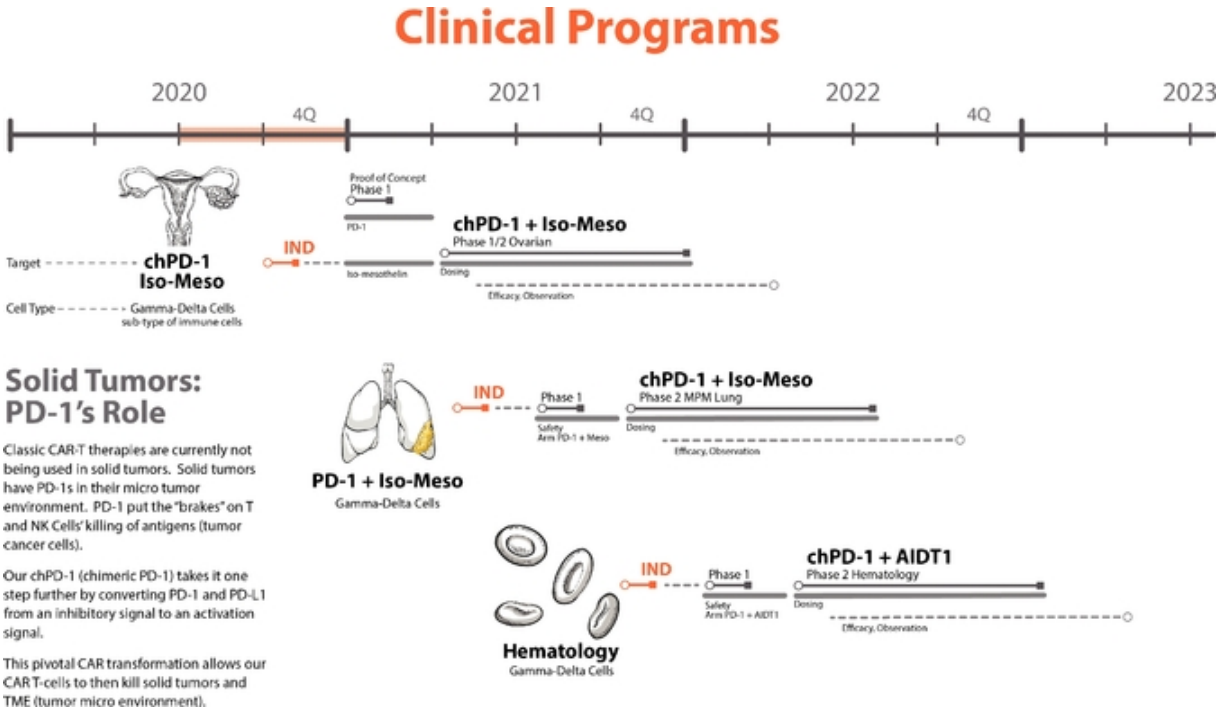
Our Product Pipeline and Development

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 or as off-the-shelf treatments for any patient with a particular cancer type. Each product candidate targets a selected antigen expressed on tumor cells and bears specific engineered attributes.

In the near term, we are progressing multiple product candidates directed at promising targets for blood cancers, including refractory large B cell lymphoma, and targets associated with solid tumors, such as malignant pleural mesothelioma (lung) and epithelial ovarian cancer.

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 particular requirements*) are represented in the diagrams below:





ALEXIS Iso Mesothelin EOC

ALEXIS Iso Mesothelin is our allogenic CAR cell product candidate targeting Iso Mesothelin.

ALEXIS Iso Mesothelin represents an innovative approach for stage III to stage IV platinum resistant epithelial ovarian cancer and involves the use of CAR effector cells.

Target Indications

ALEXIS Iso Mesothelin targets epithelial ovarian cancer, or EOC. According to the American Cancer Society, approximately 21,750 individuals are diagnosed with EOC in the U.S. each year, and 300,000 worldwide.

EOC generally affects elderly women over 60 years old. Genetic mutations and/or a family history of ovarian/breast/colorectal cancer increase the risk of EOC. EOC can metastasize to abdominal peritoneum, which is extremely difficult to treat. The median life expectancy after local recurrence is approximately 15 months.

In total, the standard treatment can cost approximately $100,000. Ovarian cancer is a deadly disease with stage IV patients having a 5-year overall survival rate of only 30%.

Out of 21,750 U.S. patients who are initially diagnosed with EOC each year, we believe that up to 15,400 (70%) will potentially be eligible for our CAR cell therapy.

In 2018, this market size reached $1.2 billion according to Grand View Research (July 2019).

This market is expected to grow at 6.2% annually compounded from 2019 to 2026 according to Data Monitor Healthcare.

Development Plan

ALEXIS Iso Mesothelin will be studied in a Phase 1 clinical trial for EOC patients. We plan to submit an IND in Q4 2020. We will be the sponsor of the clinical trials, which will be conducted by industry-

standard CROs and the trials will be conducted by leading academic institutions and experienced research facilities in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open-label, single arm, multi-center, dose-escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with platinum resistant EOC.

The primary goal will be to assess safety and tolerability at increasing dose levels in order to estimate the maximum tolerated and efficacious dose.

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 our intended target (Iso Mesothelin).

To further boost the potency of our effector cells, we plan to also explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, we believe the chances for the tumor to escape treatment are greatly reduced.

Consequently, we plan to also submit a Phase 1 IND for our PD-1 gamma delta reverse switch CAR T-cells for EOC in Q4 2020, followed by the submission of an IND for a Phase 1 combination PD-1/IsoMesothelin CAR clinical trial in Q3 2021.

ALEXIS Iso Mesothelin MPM

ALEXIS Iso Mesothelin MPM is our allogenic effector cell product candidate targeting Iso Mesothelin.

ALEXIS Iso Mesothelin MPM represents an innovative approach for malignant pleural mesothelioma and involves the use of CAR effector cells.

Target Indications

ALEXIS Iso Mesothelin MPM targets malignant pleural mesothelioma, or MPM. Mesothelioma is a disease in which malignant (cancer) cells form in the thin layer of tissue that covers organs typically in the chest or abdomen. Pleura refers to the thin layer of tissue that lines the chest cavity and covers the lungs. The tumors often spread over the surface of organs often without spreading into the organ. They may spread to nearby lymph nodes or in other parts of the body. Malignant mesothelioma may also form in the testicles or heart, but this is rare.

According to the American Cancer Society, approximately 3,000 individuals are diagnosed with MPM in the U.S. each year, and 43,000 deaths globally each year.

MPM rates are high in the military, particularly for those involved in ship building, construction, mechanics, and insulation/textile production and installation. Due to these higher rates, corporations have set aside approximately $30 billion each year to settle job-related asbestos MPM for their personnel.

The standard treatment for MPM involves chemotherapy that costs approximately $90,000, surgery that costs approximately $20,000 - $30,000, and radiation that costs approximately $10,000 - $50,000. In total, the standard treatment can cost up to $170,000. Approximately 80% of patients undergoing this treatment will eventually relapse. The average life expectancy after refractory is approximately 7 months.

Out of the 3,000 U.S. patients who are initially diagnosed with MPM each year, we believe that approximately 2,400 (80%) will eventually be eligible for our effector cell therapy.

Mesothelioma statistics show there are about 3,000 new cases of mesothelioma diagnosed in the United States each year. According to the most recent data, 57,657 mesothelioma cases were reported between 1999 and 2016. Between 1999 and 2017, there were more than 47,600 mesothelioma-related deaths. Pleural mesothelioma is the most common form, accounting for 80 - 90% of all cases. (Source: https://www.mesothelioma.com/mesothelioma/statistics/)

Driscoll et al. estimated that as many as 43,000 people worldwide die from the disease each year. It has also been estimated that there are around 10,000 mesothelioma cases annually in Australia, Japan, North America and western Europe combined. (Source: See Bulletin of the Delgermaa et. al, World Health Organization 2011;89:716-724C.)

This market is expected to grow at 7.60% annually compounded from 2020 to 2026 according to MarketWatch (April 2, 2020).

This market size is expected to reach $300 million by 2025 according to Persistent Market Research (July 2017).

Development Plan

ALEXIS Iso Mesothelin MPM will be studied in a Phase 1 clinical trial for pleural mesothelioma. We plan to submit an IND in 2021, and the subsequent clinical trial will be conducted by leading academic institutions and experienced research facilities in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open label, single arm, multi-center, dose escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with mesothelioma, who are relapsed/refractory to maximal surgical reduction and standard of care chemotherapy +/– radiation therapy.

The primary goal will be to assess safety and tolerability at increasing dose levels in order to estimate the maximum tolerated and efficacious dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure that all the patients meet all the corresponding inclusion and exclusion criteria and express our intended target IsoMesothelin.

To further boost the potency of our effector cells, we also plan to explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, we believe the chances for the tumor to escape treatment are greatly reduced.

Utilizing the data accrued from the prior Phase 1 combination PD-1/Iso-Mesothelin CAR T-cell trial for EOC, we plan to subsequently submit a Phase 1 combination IND for our PD-1/IsoMesothelin CAR T-cells for MPM in Q3 2021.

ALEXIS AIDT-1

ALEXIS AIDT-1 is our allogenic CAR cell product candidate targeting AIDT-1. This product is currently undergoing pre-IND studies. Following subsequent IND-enabling studies, we will be applying for an IND with the FDA in 2022.

ALEXIS AIDT-1 targets AIDT-1, an antigen expressed on the surface of B cells, including malignant B cells. The product represents an innovative approach for relapsed hematologic malignancies such as B cell acute lymphoblastic leukemia and for diffuse large B cell lymphoma and involves the use of adoptive T cells expressing CARs against AIDT-1. We expect our strategy to target B cell malignancies that have become refractory to currently available therapies.

Target Indications

ALEXIS AIDT-1 targets NHL (ie, diffuse large B cell lymphoma, or DLBCL). According to the American Cancer Society, approximately 25,000 - 30,000 individuals are diagnosed with DLBCL in the U.S. each year, and 200,000 worldwide. The growth rate for DLBCL is relatively stable.

The standard treatment is R-CHOP chemotherapy, which is a combination treatment consisting of five separate drugs: rituximab (Rituxan), cyclophosphamide, doxorubicin hydrochloride, vincristine (Oncovin), and prednisolone. R-CHOP chemotherapy costs approximately $100,000 per year. Average life expectancy following the failure of R-CHOP chemotherapy is approximately 6 months.

The failure rate for R-CHOP chemotherapy is 30 - 50%. Up to 50% of failures cannot get stem cell transplants and are potential candidates for CAR therapy. Standard CAR-T therapy costs between approximately $375,000 to $475,000.

Out of the 30,000 U.S. patients who are initially diagnosed with DLBCL each year, we believe that approximately 3,000 will eventually be eligible for our CAR-T cell therapy.

Worldwide number of patients for Non-Hodgkin's Lymphoma is estimated at 509,590. (Source: Global cancer statistics 2018: Globocan estimates of incidence & mortality world-wide for 36 cancers in 185 countries) with 77,240 cases in the U.S. in 2020 according to the American Cancer Society 2020).

The number of diagnosed hematologic cases is expected to grow at 10.5% annually compounded according to Data Monitor Healthcare (Source: See Hematologic Malignancies Market Size, Share & Trends Analysis Report by Type (Leukemia, Lymphoma, Multiple Myeloma), By Therapy (Chemotherapy, Radiotherapy, Immunotherapy), And Segment Forecasts, 2018 - 2025.)

The market size for hematologic cancers is expected to reach $4.6 billion by 2025 according to BIS Research (November 21, 2019).

Development Plan

ALEXIS AIDT-1 will be studied in a Phase 1 clinical trial for DLBCL, primary mediastinal B cell lymphoma, and transformed follicular lymphoma. We plan to submit an IND in 2022, and the clinical trial will be conducted by leading academic institutions and experienced research facilities in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open-label, single-arm, multi-center, dose escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with DLBCL, who are relapsed or refractory to prior treatment with an anti-CD20 monoclonal antibody therapy and an anthracycline containing chemotherapy and/or an autologous stem cell transplant.

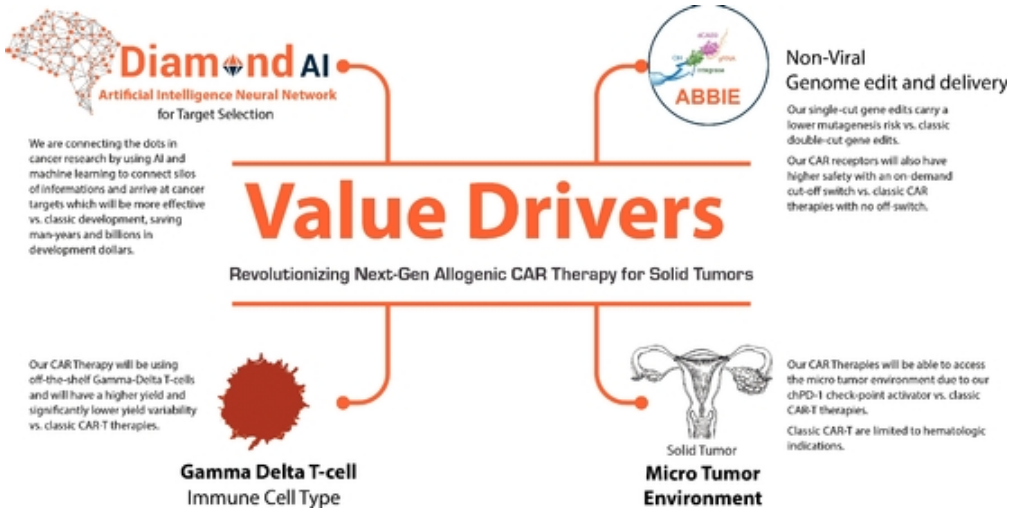
The primary endpoint will be to assess safety and tolerability at increasing dose levels in order to estimate the maximum tolerated and efficacious dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure than the patients are expressing our intended target (AIDT-1) and meet all corresponding inclusion and exclusion criteria.

To further boost the potency of our effector cells, we also plan to explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells

and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, we believe the chances for the tumor to escape treatment are greatly reduced.

Utilizing the data accrued from the prior Phase 1 combination PD-1/Iso-Mesothelin CAR T-cell trial for EOC and MPM, we plan to subsequently submit a Phase 1 combination IND for our PD-1/IsoMesothelin CAR T-cells for a to be determined pre-clinically validated hematologic malignancy in Q3 2022.



Our Risks and Challenges

Our prospects should be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by similar companies. Our ability to realize our business objectives and execute our strategies is subject to risks and uncertainties, including, among others, the following:

- 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.

In addition, we face other risks and uncertainties that may materially affect our business prospects, financial condition, and results of operations. You should consider the risks discussed in "Risk Factors" and elsewhere in this prospectus before investing in our common stock.

Our Corporate History

We were first organized as a corporation in the State of Texas on August 6, 2006 under the name "Kiromic, Inc." Between 2006 and 2012, we had minimal operations. On March 15, 2013, we converted to a limited liability company in the State of Texas under the name "Kiromic, LLC." On May 27, 2016, we converted to a corporation in the State of Delaware under the name "Kiromic, Inc." On December 16, 2019, we changed our name to "Kiromic BioPharma, Inc."

We have one wholly-owned subsidiary, GreenPlanet Pharma, Inc., which was incorporated in the State of Delaware on November 26, 2018. 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 subsidiary has not generated any revenues.

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 prospectus, 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.

Implications of Being an Emerging Growth Company

Upon the completion of this offering, we will qualify as an "emerging growth company" under Jumpstart Our Business Act of 2012, as amended, or the JOBS Act. As a result, we will be 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., an auditor discussion and analysis);
- 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, or the Securities Act, 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 from the date of the first sale of equity securities pursuant to an effective registration statement, 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, or 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.

Reverse Stock Splits

On December 17, 2019, we completed a 1-for-10 reverse stock split of our outstanding common stock. As a result of this stock split, our issued and outstanding common stock decreased from 100,060,000 to shares 10,006,005 shares.

On June 17, 2020, we completed a 1-for-3.494 reverse stock split of our outstanding common stock. As a result of this stock split, our issued and outstanding common stock decreased from 14,909,663 to 4,267,269 shares. Accordingly, unless otherwise noted, all share and per share information contained in this prospectus has been recast to retroactively show the effect of these stock splits.

THE OFFERING

Common stock offered by us	1,250,000 shares of common stock, $0.001 par value per share.
Initial public offering price	$12.00 per share.
Over-allotment option	The underwriters have an option for a period of 45 days to acquire up to an additional 187,500 shares of common stock from us at the public offering price, less the underwriting discount, solely for the purpose of covering over-allotments, if any.
Shares of common stock outstanding before this offering(1)	4,989,269 shares of common stock.
Shares outstanding after this offering	7,332,999 shares of common stock (or 7,520,499 shares of common stock if the underwriters exercise their over-allotment option in full), after the sale of 1,250,000 shares in this offering and after the Preferred Stock Conversions.
Use of proceeds	We estimate that we will receive net proceeds of approximately $12,689,000 (or approximately $14,747,800 if the underwriters exercise their over-allotment option in full) from the sale of common stock by us in this offering. We plan to use the net proceeds of this offering primarily for clinical trials for our ALEXIS Isoform Mesothelin EOC and PD-1 product candidates, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and general corporate purposes. The details of our plans are set forth in the "Use of Proceeds" section
Risk factors	Investing in our common stock involves a high degree of risk and purchasers of our common stock may lose part or all of their investment. See "Risk Factors" for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed trading market and symbol	Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "KRBP."

(1) The number of shares outstanding is based on shares outstanding as of October 6, 2020 and excludes the following:

- 618,510 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of $11.58 per share;
- 946,245 shares of our common stock issuable upon the vesting of restricted stock units with a weighted-average grant date fair value of $14.21 per share;
- 21,822,301 shares of Series A-1 Preferred Stock and 16,391,397 shares of Series B Preferred Stock which will convert into 624,594 and 469,136 shares of common stock, respectively, upon the closing of this offering (the "Preferred Stock Conversions");
- up to an additional 142,141 shares of our common stock issuable under our 2017 Equity Incentive Plan; and
- 62,500 shares of our common stock underlying the warrants to be issued to the representative of the underwriters in connection with this offering.

Except as otherwise indicated herein, all information in this prospectus assumes the following:

- no exercise of the underwriters' option to purchase up to an additional 187,500 shares of common stock to cover allotments, if any.

SUMMARY FINANCIAL INFORMATION

The following tables summarize our consolidated financial data. We have derived the summary consolidated statement of operations data for the years ended December 31, 2019 and 2018 and the balance sheet data as of December 31, 2019 from our audited consolidated financial statements included elsewhere in this prospectus. The interim condensed consolidated statements of operations data for the six months ended June 30, 2020 and 2019 and interim condensed consolidated balance sheet data as of June 30, 2020 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Such information should be read in conjunction with our financial statements and related notes included elsewhere in the prospectus and the information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

Our financial statements are prepared and presented in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. Our historical results for any period are not necessarily indicative of our future performance.

	Years Ended December 31,		Six Months Ended June 30	
	2019	2018	2020	2019
Statements of Operations Data				
Operating expenses:				
Research and development	$ 1,201,700	$ 1,424,900	$ 2,300,400	$ 329,400
General and administrative	2,503,700	1,757,700	10,919,200	326,900
Total operating expenses	3,705,400	3,182,600	13,219,600	656,300
Loss from operations	(3,705,400)	(3,182,600)	(13,219,600)	(656,300)
Other expense	(22,500)	(633,100)	—	(15,000)
Net loss	$ (3,727,900)	$ (3,815,700)	$ (13,219,600)	(671,300)
Net loss per share—basic and diluted	$ (1.39)	$ (1.33)	$ (4.52)	$ (0.23)

	June 30, 2020	
	Actual	As adjusted(1)
Balance Sheet Data		
Cash and cash equivalents	$ 1,683,500	$ 14,372,500
Working capital	744,200	13,433,200
Total assets	3,881,600	16,570,600
Total liabilities	1,786,300	1,786,300
Total stockholders' equity	2,095,300	14,784,300

(1) Gives effect on an as adjusted basis to (i) the Preferred Stock Conversions and (ii) the sale and issuance by us of 1,250,000 shares of common stock in this offering at the initial public offering price of $12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

The shares being offered by us are highly speculative in nature, involve a high degree of risk and should be purchased only by persons who can afford to lose the entire amount invested. Before purchasing any of our shares, you should carefully consider the following factors relating to our business and prospects. If any of the following risks actually occurs, our business, financial condition or operating results will suffer, the trading price of our stock could decline, and you may lose all or part of your investment.

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, 2019 and 2018, the Company had a net loss of $3,727,900 and $3,815,700 respectively. For the six months ended June 30, 2020 and 2019, the Company had a net loss of $13,219,600 and $671,300, 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 this offering or 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. Following the consummation of this offering, we will incur ongoing periodic expenses in connection with the administration of our organizational structure. The expenses incurred by public companies generally for reporting and corporate governance purposes have 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, 2019, 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.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes- Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Though we will be required to 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 our first annual report required to be filed with the SEC. However, 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 our first annual report required to be filed with the SEC 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 it is not effective.

Notwithstanding the foregoing, in connection with the audit of our financial statements for the year ended December 31, 2019, 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) our lack of a formalized internal control framework, (ii) our lack of segregation of duties in the financial reporting process, and (iii) our lack of qualified technical accounting personnel. These remain material weakness as of the date of this prospectus. 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 stock exchange on which our securities are listed, 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 Isoform Mesothelin EOC, PD-1, AIDT-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.

The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies.

All of our current product candidates and product development programs are still in the IND validation process. We may be unsuccessful in advancing those product candidates into clinical development or in identifying any developing additional product candidates.

Our ability to identify and develop product candidates is subject to the numerous risks associated with preclinical and early stage biotechnology development activities, including that:

- the use of Diamond and CancerSplice may be ineffective in identifying additional product candidates;
- the use of ABBIE may be ineffective in accurately inserting the product candidate into tumor-targeting effector cells;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- we may not be able to enter into collaborative arrangements to facilitate development of product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- our product candidates may be covered by third parties' patents or other exclusive rights;
- the regulatory pathway for a product candidate may be too complex, expensive or otherwise difficult to navigate successfully; or
- our product candidates may be shown to not be effective, have harmful side effects or otherwise pose risks not outweighed by such product candidate's benefits or have other characteristics that may make the products impractical to manufacture, unlikely to receive any required marketing approval, unlikely to generate sufficient market demand or otherwise not achieve profitable commercialization.

Even if we do commence clinical trials of product candidates and continue to identify new product candidates, such product candidates may never be approved. Failure to successfully identify and develop

new product candidates and obtain regulatory approvals for our products would have a material adverse effect on our business and financial condition and could cause us to cease operations.

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.

We sometimes estimate, or may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical or field trials, the submission of regulatory filings, the receipt of marketing approval or the realization of other commercialization objectives.

The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates.

If our collaborators or ourselves fail to achieve announced milestones in the expected timeframes, the commercialization of the product candidates may be delayed, our credibility may be undermined, our business and results of operations may be harmed, and the price of our common stock may decline.

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.

Risks Related to Our Organization, Structure and Operations

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.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and clinical trials or regulatory approvals for any of our product candidates could be suspended. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, our board committees or as our executive officers.

Insurance coverage is becoming increasingly expensive, and in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. A successful liability claim or series of claims brought against us could require us to pay substantial amounts and cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

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.

Our business and operations would suffer in the event of system failures or security breaches.

Despite the implementation of security measures, our computer systems, as well as those of third parties with which we have relationships, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters, terrorism, war and telecommunication and electrical failures. If we were to experience a system failure, accident or security breach such an event caused interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs.

For example, the loss of trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals, and U.S. federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use and dissemination of data. In the ordinary course of our business, we and third parties with which we have relationships collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance or other disruptions, and any such breach could compromise our or their networks and the information stored there could be accessed, publicly disclosed, lost or stolen.

Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant costs, including regulatory penalties, fines and legal expenses, 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 such third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

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 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.

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.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and expect that we will rely on outside vendors for at least a portion of the manufacturing process of product candidates that we or our collaborators may develop. The facilities used by our contract manufacturers to manufacture product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. To the extent that we or our collaborators engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing providers for compliance with cGMP requirements for manufacture of the product candidates.

We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that are safe and effective. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to

find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market any of our or our collaborators' potential products.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.

Our research and product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements for the development and potential commercialization of current and future product candidates or the development of ancillary technologies.

We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, by the USDA, the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense.

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 ISOFORM 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.

We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, 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 and social media.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. President's administration may impact our business and industry. Namely, the current U.S. President's administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

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.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services, or the CMS, revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payers, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. 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 government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, 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.

The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates, if approved, profitably. In particular, in 2010 the Affordable Care Act was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by

manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute. We are still unsure of the full impact that the Affordable Care Act will have on our business.

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 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 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". 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 and our business.

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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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.

In addition, 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, review the relationship between pricing and manufacturer patient assistance 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. Further, the current U.S. President's administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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 U.S. Department of Health and Human Services, or 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 current 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.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our product candidates, thereby potentially extending the term of marketing exclusivity for such product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process.

In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements.

Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

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.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.

Our commercial success depends in part upon our ability to develop, manufacture, market and sell product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical, biotechnology is common, including patent infringement lawsuits, and such interference, derivation, reexamination, post-grant review, inter parties review and opposition proceedings before the USPTO and corresponding international patent offices.

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors.

Numerous United States, EU and other internationally issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

For example, we are aware of certain patents held by third parties relating to the modification of CAR-T/NK cells, including the production of CAR-T/NK cells. Although conducting clinical trials and other development activities with respect to our CAR-T/NK product candidates is not considered an act of infringement in the United States, if and when any of our CAR-T/NK product candidates are

approved by the FDA, those third parties may seek to enforce their patents by filing a patent infringement lawsuit against us.

As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from a third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights.

These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we or our collaborators could be prevented from commercializing one or more product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly.

We or our collaborators might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Further, if a patent infringement suit is brought against us, our collaborators or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims has in the past and may in the future cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights.

These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We have been and may in the future be subject to third-party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our or our collaborators' ability to further develop or commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technologies, compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those technologies, compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our or our collaborators' ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we or our collaborators obtain a license.

Competitors may infringe our patents. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits, which can be expensive and time-consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, being found to be unenforceable, and/or being interpreted narrowly and could put our patent applications at risk of not issuing and/or could impact the validity or enforceability positions of our other patents.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology.

Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We 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.

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, which will be effective immediately prior to the closing of this offering, 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.

Risks Related to this Offering and 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 initial public offering price.

After this offering, the market price for our common stock is likely to be volatile, in part because our shares have not been traded publicly. 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.

The public offering price of our common stock has been determined by us based upon many factors and may not be indicative of prices that will prevail following the closing of this offering. Volatility in the market price of our common stock may prevent investors from being able to sell their shares at or above the initial public offering 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.

As our initial public offering price is substantially higher than our net tangible book value per share, you will experience immediate and substantial dilution.

If you purchase shares in this offering, you will pay more for your shares of common stock than the amount paid by our existing stockholders for their shares on a per share basis. As a result, you will experience immediate and substantial dilution in net tangible book value per share in relation to the price that you paid for your shares. We expect the dilution as a result of the offering to be $9.82 per share to new investors purchasing our shares in this offering. In addition, you will experience further dilution to the extent that our shares are issued upon the exercise of any warrants or exercise of stock options under any stock incentive plans. See "Dilution" for a more complete description of how the value of your investment in our shares will be diluted upon completion of this offering.

We have considerable discretion as to the use of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.

We intend to the proceeds from this offering primarily for the clinical trials for our ALEXIS Isoform Mesothelin EOC and PD-1 product candidates, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and general corporate purposes. However, we have considerable discretion in the application of the proceeds. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of this offering. The net proceeds may be used for corporate or other purposes with which you do not agree or that do not improve our profitability or increase our share price. The net proceeds from this offering may also be placed in investments that do not produce income or that lose value.

We do not expect to pay dividends in the foreseeable future after this offering, 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.

We will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies and our stockholders could receive less information than they might expect to receive from more mature public companies.

Upon the completion of this offering, we will be required to publicly report on an ongoing basis as an "emerging growth company" (as defined in the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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 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 expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We would remain an emerging growth company for up to five years from the date of the first sale of equity securities pursuant to an effective registration statement, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time, we would cease to be an emerging growth company as of the following December 31.

Because we will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, our stockholders could receive less information than they might expect to receive from more mature public companies. We cannot predict if investors will find our common stock less attractive if we elect to rely on these exemptions, or if taking advantage of these exemptions would result in less active trading or more volatility in the price of our common stock.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and/or debt financings and collaborations, licensing agreements or other strategic arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

To the extent that we raise additional capital through debt financing, it would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends.

To the extent we raise additional capital through arrangements with collaborators or otherwise, we may be required to relinquish some of our technologies, research programs, product development activities, product candidates and/or future revenue streams, license our technologies and/or product candidates on unfavorable terms or otherwise agree to terms unfavorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or product candidates.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts are forward-looking statements. The forward-looking statements are contained principally in, but not limited to, the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our goals and strategies;
- our future business development, financial condition and results of operations;
- expected changes in our revenue, costs or expenditures;
- growth of and competition trends in our industry;
- our expectations regarding demand for, and market acceptance of, our products;
- our expectations regarding our relationships with investors, institutional funding partners and other parties we collaborate with;
- our expectation regarding the use of proceeds from this offering;
- fluctuations in general economic and business conditions in the markets in which we operate; including those fluctuations caused by COVID-19; and
- relevant government policies and regulations relating to our industry.

In some cases, you can identify forward-looking statements by terms such as "may," "could," "will," "should," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "project" or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading "Risk Factors" and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

This prospectus also contains certain data and information, which we obtained from various government and private publications. Although we believe that the publications and reports are reliable, we have not independently verified the data. Statistical data in these publications includes projections that are based on a number of assumptions. If any one or more of the assumptions underlying the market data is later found to be incorrect, actual results may differ from the projections based on these assumptions.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. Although we will become a public company after this offering and have ongoing disclosure obligations under United States federal securities laws, we do not intend to update or otherwise revise the forward-looking statements in this prospectus, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 1,250,000 shares of common stock that we are selling in this offering will be approximately $12,689,000, or approximately $14,747,800 if the underwriters exercise their over-allotment option in full, and after deducting estimated underwriting discounts and commissions and our estimated offering expenses based on an initial public offering price of $12.00 per share.

We plan to use the net proceeds of this offering for (i) the initiation clinical trials for our ALEXIS Isoform Mesothelin EOC and PD-1 product candidates (approximately $4,827,700), (ii) intellectual property protection and reinforcement (approximately $258,000), and the remainder for (iii) working capital and general corporate purposes.

With anticipated net proceeds of $12,689,000, we believe we will complete approximately 18.4% of the clinical trials using ALEXIS Isoform Mesothelin and PD-1 for EOC.

We may also use a portion of the net proceeds of this offering to acquire or invest in complementary businesses, products, or technologies, or to obtain the right to use such complementary technologies. We have no commitments with respect to any acquisition or investment, and we are not currently involved in any negotiations with respect to any such transaction.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the status of our product development efforts, sales and marketing activities, technological advances, amount of cash generated or used by our operations and competition. Accordingly, our management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

Pending use of the proceeds from this offering as described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities or certificates of deposit.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the near future. See also "Risk Factors—Risks Related to this Offering and the Market for Our Common Stock—Because we do not expect to pay dividends in the foreseeable future after this offering, you must rely on price appreciation of your shares for return on your investment." We may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock.

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

CAPITALIZATION

The following table sets forth our total capitalization as of June 30, 2020:

- on an actual basis;
- on an as adjusted basis giving further effect to (i) the Preferred Stock Conversions and (ii) the sale and issuance by us of 1,250,000 shares of common stock in this offering at the initial public offering price of $12.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our consolidated financial statements, the related notes included elsewhere in this prospectus and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	June 30, 2020	
	Actual	As adjusted
Cash and cash equivalents	$ 1,683,500	$ 14,372,500
Long-term debt	—	—
Stockholders' equity:		
Series A-1 Preferred Stock	9,134,700	—
Series B Preferred Stock	2,331,300	—
Common Stock	—	—
Additional paid-in capital	26,276,500	50,431,500
Accumulated deficit	(35,647,200)	(35,647,200)
Total stockholders' equity	2,095,300	14,784,300
Total capitalization	2,095,300	14,784,300

DILUTION

If you purchase shares of our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share and our net tangible book value per share after this offering. Dilution results from the fact that the initial public offering price per share is substantially in excess of the net tangible book value per share attributable to the existing stockholders for our presently outstanding common stock.

Our net tangible book value was approximately $1,992,800 or $0.40 per share, as of June 30, 2020. Our net tangible book value represents the amount of our total consolidated tangible assets (which is calculated by subtracting net intangible assets, deferred tax assets, and prepaid offering expenses from our total consolidated assets), less the amount of our total consolidated liabilities.

After giving effect to (i) the Preferred Stock Conversions and (ii) the sale and issuance by us of 1,250,000 shares of common stock in this offering at the initial public offering price of $12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2020 would have been $15,956,800 or $1.78 per share. This represents an immediate increase in net tangible book value of $2.18 per share to our existing stockholders, and an immediate dilution in net tangible book value of $9.82 per share to new investors. The following table illustrates this per share dilution:

Initial public offering price per share		$ 12.00
Net tangible book value as of June 30, 2020	$ 0.40	
Increase in net tangible book value attributable to this offering	$ 1.78	
As adjusted net tangible book value, after this offering		$ 2.18
Dilution to new investors in this offering		$ 9.82

If the underwriters' over-allotment option is exercised in full, our, as adjusted net tangible book value per share after this offering would be $2.43 and dilution per share to new investors purchasing common stock in this offering would be $9.57 at the initial public offering price of $12.00 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information discussed above is illustrative only. Our net tangible book value following the completion of this offering is subject to adjustment based on the actual initial public offering price of our shares and other terms of this offering determined at pricing.

The following tables summarize the differences between our existing stockholders and the investors purchasing shares in this offering with respect to the number of shares purchased from us, the total consideration paid and the average price per share paid, at the initial public offering price of $12.00 per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	%	Amount	%	
Common Stock	4,989,269	68.04%	$ 6,224,600	16.44%	$ 1.25
Series A-1 Preferred Stock	624,594	8.52%	9,132,700	24.12%	14.62
Series B Preferred Stock	469,136	6.40%	7,500,000	19.81%	15.99
New investors	1,250,000	17.05%	15,000,000	39.62%	12.00
Total	7,332,999	100.00%	$ 37,857,300	100.00%	

The number of shares outstanding is based on shares outstanding as of October 6, 2020, and except as noted above, excludes the following currently outstanding securities:

- 618,510 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of $11.58 per share;
- 946,245 shares of our common stock issuable upon the vesting of restricted stock units with a weighted-average grant date fair value of $14.21 per share;
- up to an additional 142,141 shares of our common stock issuable under our 2017 Equity Incentive Plan; and
- 62,500 shares of our common stock underlying the warrants to be issued to the representative of the underwriters in connection with this offering.

The table above assumes no exercise of the underwriters' over-allotment option. If the underwriters' over-allotment option is exercised in full, upon completion of this offering, the percentage of common stock held by existing common stockholders would be reduced to 66.34%, and the percentage of common stock held by new investors purchasing common stock in this offering would be increased to 19.11%.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion together with our financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that are based on our current expectations, estimates and projections about our business and operations. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those which we discuss under "Risk Factors" and elsewhere in this prospectus. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a pre-clinical stage immuno-oncology, target discovery and gene editing company developing tumor-specific cancer engineered immunotherapies to face and defeat multiple cancer types. 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 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-IND stage. We are currently going through the IND validation process and we expect that IND enabling trials 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., 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 filing, 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

As of the date of the audit report on our 2019 financial statements, conditions and events existed that raised substantial doubt with respect to the going concern assumption on the financial statements. Based on proceeds obtained from the Series B Preferred Stock round of financing and our plans to reduce discretionary spending, management projected it would have sufficient cash to support operations through at least April 7, 2021. As a result, the Company concluded that management's plans were probable of being implemented and alleviated substantial doubt about its ability to continue as a going concern.

After considering the registration statement filing date of October 6, 2020, management extended its consideration of the going concern assumption through October 6, 2021. 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.

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

Upon the completion of this offering, we will qualify as an "emerging growth company" under the JOBS Act. As a result, we will be 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., an auditor discussion and analysis);
- 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 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 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.

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 CROs 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, or CMOs, 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 AIDT-1 and Isomesothelin 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 AIDT-1 product candidate 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 AIDT-1 product candidate 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 AIDT-1 product candidate, 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. Following this offering, 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 Six Months Ended June 30, 2020 and 2019

The following table sets forth key components of our results of operations for the six months ended June 30, 2020 and 2019.

	Six Months Ended June 30,		Increase (Decrease)	
	2020	2019	$	%
Operating expenses:				
Research and development	$ 2,300,400	$ 329,400	$ 1,971,000	598.36%
General and administrative	10,919,200	326,900	10,592,300	3,240.23%
Total operating expenses	13,219,600	656,300	12,563,300	1,914.26%
Loss from operations	(13,219,600)	(656,300)	12,563,300	1,914.26%
Other expense				
Interest expense	—	(15,000)	(15,000)	(100.00)%
Total other expense	—	(15,000)	(15,000)	(100.00)%
Net loss	$ (13,219,600)	$ (671,300)	$ 12,548,300	1,869.25%

	Six Months Ended June 30,		Increase (Decrease)	
	2020	2019	$	%
Direct research and development expenses by product candidate:				
AIDT-1 external development costs	$ 3,000	$ 20,100	$ (17,100)	(85.07)%
Isomesothelin external development costs	45,500	—	45,500	100.00%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	1,127,100	63,700	1,063,400	1,669.39%
Laboratory supplies and services	133,800	45,200	88,600	196.02%
Outsourced research and development	664,300	142,500	521,800	366.18%
Laboratory equipment and maintenance	27,300	—	27,300	100.00%
Facility-related costs	177,900	57,600	120,300	208.85%
Other research and development costs	121,500	300	121,200	n/m
Total research and development expenses	$ 2,300,400	$ 329,400	$ 1,971,000	598.36%

As illustrated above, the increase in research and development expenses resulted from (i) a $1,063,400 increase in employee related costs, which primarily included a $589,900 increase in wages, benefits and payroll taxes and a $459,400 increase in stock compensation expenses attributable to research and development employees; (ii) a $521,800 increase in outsourced research and development costs, which primarily included a $214,800 increase in research studies and other consulting fees along with a $307,000 increase in stock compensation expenses attributable to non-employees; (iii) a $120,300 increase in facility-related costs, primarily driven by a $95,400 increase in allocated rent net of granting agency reimbursements, and a $26,200 increase in allocated depreciation expenses with the remaining offsetting amount attributed to repairs, maintenance, and utilities; (iv) a $121,200 increase in other research and development costs, which were driven by intellectual property legal expenses and intellectual property filings; (v) a $88,600 increase in laboratory supplies in services, which primarily included a $89,000 increase in spending on disposables and consumables for in-vitro testing and validation of pipeline candidates, offset by $400 of reduced supplies spending; (vi) a $27,300 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.

These cost increases discussed were primarily incurred to support in-vitro testing and validation of our product candidates.

1. Augmented our research and development team: In the six months ended June 30, 2020 and 2019, our average headcount increased to 5.5 employees from 2 employees allocable to research and development and clinical trials preparation. In the three months ended June 30, 2020 and 2019, our average headcount increased to 7 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. Intellectual property augmentation: Longwood University, 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 six months ended June 30, 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. Starting in 2020, 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 six months ended June 30, 2020 and 2019, we recognized $0 and $188,300, 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 $10,592,300, or 3,240.23%, to $10,919,200 for the six months ended June 30, 2020 from $326,900 for the six months ended June 30, 2019. The increase primarily resulted from an increase in stock compensation expenses of $9,355,600, an increase in corporate finance and development expenses of $579,500, a $318,100 increase in professional services costs, and $230,300 of increased employee related expenses.

The increase in stock compensation expense was primarily driven by common stock issuances of 725,536 shares to our Chief Financial Officer, Chief Strategy and Innovation Officer, Chief Medical Officer, and another employee in exchange for services rendered totaling $9,432,000. The increase in corporate finance and development expenses are driven by consulting fees owed to our Chief Scientific and Innovation Officer and Chief Financial Officer. The increase in professional fees and legal expense were primarily driven by increased accounting expenses from auditing, and tax services.

Employee related expenses were impacted by increases to headcount and employee salary rates. During the six months ended June 30, 2020 and 2019, the headcount for employees allocated to general and administrative purposes increased to 4 employees from 3 employees, respectively. In addition, the Chief Executive Officer's salary increased to an annual rate of $380,000 from $280,000 for the six months ended June 30, 2020 and 2019, respectively.

Interest expense. Interest expense decreased by $15,000, to $0 for the six months ended June 30, 2020 from $15,000 for the six months ended June 30, 2019. The decrease is driven by the variance in the balance of convertible promissory notes during the six months ended June 30, 2020 and 2019.

During the six months ended June 30, 2019, we issued an additional $250,000 convertible promissory notes. In addition, in May 2019, the issued notes accrued interest at a rate of 17% per annum. Additionally, the Company settled an accounts payable with a vendor by issuing a convertible promissory note in the amount of $134,800 which accrued interest at a rate of 6% per annum. Total interest expense accrued on the notes in the six months ended June 30, 2019 totaled $15,000. 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 "—Liquidity and Capital Resources" below for more information.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased to $13,219,600 during the six months ended June 30, 2020 compared to $671,300 during the six months ended June 30, 2019.

Comparison of the Years Ended December 31, 2019 and 2018

The following table sets forth key components of our results of operations for the years ended December 31, 2019 and 2018.

	Years Ended December 31,		Increase (Decrease)	
	2019	2018	$	%
Operating expenses:				
Research and development	$ 1,201,700	$ 1,424,900	$ (223,200)	(15.66)%
General and administrative	2,503,700	1,757,700	746,000	42.44%
Total operating expenses	3,705,400	3,182,600	522,800	16.43%
Loss from operations	(3,705,400)	(3,182,600)	522,800	16.43%
Other expense				
Interest expense	(22,500)	(633,100)	(610,600)	(96.45)%
Total other expense	(22,500)	(633,100)	(610,600)	(96.45)%
Net loss	$ (3,727,900)	$ (3,815,700)	$ (87,800)	(2.30)%

Research and development expenses. Our research and development expenses decreased by $223,200, or 15.66%, to $1,201,700 for the year ended December 31, 2019 from $1,424,900 for the year ended December 31, 2018. The following table summarizes our research and development expenses by product candidate or development program:

	Years Ended December 31,		Increase (Decrease)	
	2019	2018	$	%
Direct research and development expenses by product candidate:				
AIDT-1 external development costs	$ 66,900	$ 3,900	$ 63,000	1,615.38%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	574,300	615,600	(41,300)	(6.71)%
Laboratory supplies and services	167,600	85,000	82,600	97.18%
Outsourced research and development	321,700	609,200	(287,500)	(47.19)%
Laboratory equipment and maintenance	17,100	6,400	10,700	167.19%
Facility-related costs	40,700	103,200	(62,500)	(60.56)%
Other research and development costs	13,400	1,600	11,800	737.50%
Total research and development expenses	$ 1,201,700	$ 1,424,900	$ (223,200)	(15.66)%

As illustrated above, the decrease in research and development expenses resulted from (i) a $287,500 decrease in outsourced research and development costs, which primarily included a $273,600 decrease in data administration fees, (ii) a $41,300 decrease in employee related costs driven primarily by reimbursements from granting agencies of $26,500 and reimbursements of social security payroll tax credits totaling $15,100 (ii) a $62,500 decrease in facility-related costs, primarily driven by a $52,700 decrease in clinical trials facility fees. These decreases were as a result of management concluding initial clinical trials testing in May 2019, which halted almost all expenses related to drug manufacturing and data administration that was associated with clinical trials. We also significantly reduced our research and development facility-related costs by obtaining a grant from the National Institute of Health (NIH). In August 2018, 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. Starting in 2020, 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, 2019 and 2018, we recognized $298,000 and $258,000, respectively, as reductions to research and development expense within the statements of operations pursuant to the grant from the NIH.

Those reductions were offset by a (i) $63,000 increase in AIDT-1 external development costs, primarily driven by increased spending on disposables and consumables attributable to AIDT-1; and (ii) a $82,600 increase in laboratory supplies and services, primarily driven by a $110,800 increase in disposables and consumables used for experimentation and validation, offset by reduced spending on supplies of $41,100 and reduced shipping, and postage costs. During 2019, we began in vitro testing and validation of our ABBIE delivery vehicle. Thus, higher laboratory supply costs and services were incurred.

General and administrative expenses. Our general and administrative expenses increased by $746,000, or 42.44%, to $2,503,700 for the year ended December 31, 2019 from $1,757,700 for the year ended December 31, 2018. The increase primarily resulted from an increase in professional services related expenses of $873,100, a $387,700 increase in corporate finance and development costs, and increased travel expenses of $34,100. These increases were offset by decreased employee related expenses of $354,200 from wages salaries and benefits and $112,000 reduced expenses from stock based compensation. Additionally, there were decreases of $32,800 from reduced intellectual property administrative expenses, and a $13,600 reduction to professional development costs. The remaining expense increases totaling $3,900 are associated with activities such as, supplies, and other costs associated with our business development.

The increase in professional fees was primarily driven by increased accounting expenses from auditing, tax, and accounting consulting fees to complete SEC filings that had previously not been required by us. Corporate development costs increases were directly related to corporate's legal counsel, SEC filing costs, and increased executive consulting fees compared to prior year. Increased travel expenses were incurred to attend medical conferences, and meetings with potential underwriters and market makers.

The reduction in wages and benefits was primarily driven a reduction in headcount expenses allocated to general and administrative expense January 1, 2018 and December 31, 2019. During those 24 months, headcount allocated to general and administrative expense decreased from 7 employees to 2 employees. Average headcount allocated to general and administrative activity in the years ended December 31, 2019 and 2018 was 2.5 and 5, respectively. The total number of options vesting attributed to general and administrative in the year ended December 31, 2019 and 2018 totaled 26,465 options and 42,819, respectively. That reduction in vested grants drove the decrease in stock compensation expense.

The reduction in intellectual property costs was driven by less required intellectual property filing and maintenance activity compared to prior years. The reduction in professional development costs was driven by fewer education and training requirements in the year ended December 31, 2019 compared to the year ended December 31, 2018.

Interest expense. Interest expense decreased by $610,600, or 96.45%, to $22,500 for the year ended December 31, 2019 from $633,100 for the year ended December 31, 2018. The decrease is driven by the variance in the balance of convertible promissory notes during the years ended December 31, 2019 and 2018. At December 20, 2018, there were outstanding convertible promissory notes totaling $6,725,000 which accrued interest at a rate of 7% and incurred $453,300 of interest expense. In addition, the convertible promissory notes embedded derivative liability increased interest expenses by approximately $167,000 during 2018 based on increases in the fair value of the liability prior to conversion.

The outstanding balance of convertible promissory notes converted into Series A-1 Preferred Stock on December 20, 2018. The remaining interest expense balance of $12,800 was driven by issuances of Series A-1 Preferred Stock. Between June 8, 2018 and August 17, 2018, we entered into agreements to issue preferred stock and received advances of $900,000. The advances received under the agreements were recorded as liabilities until the preferred stock was issued and bore interest at a rate of 6.5%. The agreements were amended on September 10, 2018, when, in exchange for additional preferred stock to be issued, the advances no longer bore interest. See "—Liquidity and Capital Resources" below.

During the year ended December 31, 2019, we issued and additional $250,000 convertible promissory notes, and we settled an account payable to a vendor for a convertible promissory note of $134,800. The issued notes accrued interest at a rate of 17% per annum, and the vendor settlement accrued interest at a rate of 6% per annum. Total interest expense accrued on the notes as of August 15, 2019 totaled $20,500. 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. The remaining interest of $2,000 is attributable to increases to the fair value of the associated embedded derivable liability prior to conversion. See "—Liquidity and Capital Resources" below for more information.

Net loss. As a result of the cumulative effect of the factors described above, our net loss decreased to $3,727,900 for year ended December 31, 2019 from $3,815,700 for the prior year.

Liquidity and Capital Resources

As of June 30, 2020, we had cash and cash equivalents of $1,683,500. As of December 31, 2019 and 2018, we had cash and cash equivalents of $1,929,100 and $384,300, respectively. 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 and preferred 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 our pursuit of an initial public offering through the date of this filing, we determined that our current levels of cash will not be sufficient to meet our anticipated cash needs for our operations through October 6, 2021. 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 CMOs 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, substantial doubt exists regarding the going concern assumption on our financial statements.

We are seeking significant additional capital funding to develop our platform and Pre-IND product lines, additional hiring of scientific professionals and 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. Management has the ability to eliminate certain forecasted discretionary costs that would not be in violation of the intended use of proceeds outlined in the Series B Preferred Stock purchase agreements. In consideration of our plans, substantial doubt cannot be alleviated with respect to our continued operations through October 6, 2021. 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 October 6, 2021.

Summary of Cash Flow for the six months ended June 30, 2020 and 2019

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

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (2,603,800)	$ (400,400)
Net cash used in investing activities	(762,300)	(20,000)
Net cash provided by financing activities	3,120,500	250,000
Net decrease in cash and cash equivalents	(245,600)	(170,400)
Cash and cash equivalents at beginning of the year	1,929,100	384,300
Cash and cash equivalents at end of the period	1,683,500	213,900

Cash flows from operating activities

Net cash used in operating activities was $(2,603,800) for the six months ended June 30, 2020, as compared to $400,400 for six months ended June 30, 2019. In the six months ended June 30, 2020, net loss of $13,219,600 and outflows from prepaid expenses and other current assets in the amount of $141,500, offset by stock compensation expenses from common stock issuances in the amount of $9,432,000, stock compensation expenses from stock options of $899,000, and accounts payable in the amount of $291,000 were the key drivers for operating activities.

For the six months ended June 30, 2019, the net loss of $671,300, outflows from accounts payable totaling $98,200, and NIH grant receivables of $25,300 were offset by stock compensation expenses in the amount of $209,000, convertible notes derivative liabilities of $135,800, and prepaid expenses and other current assets in the amount of $11,400 were the primary drivers of the net cash used in operating activities.

Net cash used in operating activities increased by a total of $2,203,400 period-over-period. The main driver for the increase is the $12,548,300 increase in net loss offset by non-cash inflows from increased stock compensation expenses in the amount of $10,122,000. 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 the "—Results of Operations" above for further details.

Cash flows from investing activities

Net cash used in investing activities was $762,300 for the six months ended June 30, 2020, as compared to $20,000 for the six months ended June 30, 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 $742,300 in the six months ended June 30, 2020 from June 30, 2019. This was primarily driven by $702,200 in cash outflows attributed to construction in progress on our Good Manufacturing Practices and Vivarium facilities in our Houston Facility. Those assets have not been placed in service yet.

Cash flows from financing activities

Net cash provided by financing activities was $3,120,500 during the six months ended June 30, 2020 as compared to $250,000 for the six months ended June 30, 2019. For the six months ended June 30, 2020, the net cash provided by financing activities primarily consisted of proceeds from preferred stock issuance in the amount of 3,000,000 and proceeds from a loan payable of $115,600. During the six months ended June 30, 2019, the net cash provided by financing activities consisted entirely of proceeds from the sale of convertible promissory notes in the amount of $250,000.

Summary of Cash Flow for the years ended December 31, 2019 and 2018

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

	Years Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (2,913,900)	$ (2,152,900)
Net cash used in investing activities	(302,700)	(137,300)
Net cash provided by financing activities	4,761,400	1,625,000
Net increase (decrease) in cash and cash equivalents	1,544,800	(665,200)
Cash and cash equivalents at beginning of the year	384,300	1,049,500
Cash and cash equivalents at end of the year	$ 1,929,100	$ 384,300

Net cash used in operating activities was $2,913,900 for the year ended December 31, 2019, as compared to $2,152,900 for year ended December 31, 2018. For the year ended December 31, 2019, the net loss of $3,727,900 and outflows from accrued expenses and other current liabilities in the amount of $151,300, offset by stock compensation expenses in the amount of $522,900, accounts payable of $293,400, depreciation expenses of $87,500, prepaid expenses and other current assets in the amount of $46,200, and NIH grant receivables of $24,300, were the primary drivers of the net cash used in operating activities. For the year ended December 31, 2018, the net loss of $3,815,700 and interest payable in the amount of $363,400, offset by stock compensation expenses in the amount of $633,000, non-cash interest of 633,100, prepaid expenses and other current assets in the amount of $212,500, convertible promissory notes derivative liability in the amount of $369,000, and accrued expenses and other current liabilities in the amount of $149,400, were the primary drivers of the net cash used in operating activities.

Net cash used in operating activities decreased by a total of $761,000 year-over-year. However, this variance was primarily driven by non-cash transactions. The main driver for the decrease is $612,600 decrease in non-cash interest. See the "—Results of Operations" above for further details. However, it is noted that management decided to finance operations primarily using preferred stock instead of interest bearing convertible promissory notes. Accordingly, fewer interest expense was incurred as a result. In addition, reductions to stock compensation expense resulted in a reduction of $110,100 of cash inflows. These reductions to cash inflows were offset by $6,600 of increased cash inflows from depreciation expense.

This remaining reduction in cash flows from operations was driven by reduced cash outflows from net loss and reduced cash inflows from changes in operating assets, offset by increased cash inflows from operating liabilities.

Cash outflows from net loss were reduced by $87,800. See the "—Results of Operations" above for further details.

Reduced cash inflows from changes in operating assets were driven by $166,300 from decreased prepaid and other current assets. Most of this impact is driven by a reclassification of prepaid expenses to accounts payable of $134,800. We ultimately settled that accounts payable with the vendor by converting the balance to a convertible note payable. In addition, there was reduced cash flow impact of $5,900 from inventories, and $3,600 from other non-current assets. These were offset by increased cash inflows of $43,200 from reimbursements under the NIH Grant.

Increased cash inflows from operating liabilities were impacted by $297,800 in accounts payable. This inflow is primarily driven by our management reaching terms with a vendor to delay payment totaling $176,900. In addition, there was increased cash inflow impact of $363,400 from interest payable. These were offset by decreased cash inflows from the convertible promissory notes derivative liability of $367,000. There were also offsetting increases in cash outflows of $300,700 from accrued expenses and other current liabilities.

Net cash used in investing activities was $302,700 for the year ended December 31, 2019, as compared to $137,300 for the year ended December 31, 2018. Our net cash used in investing activities consisted entirely of purchases of property and equipment.

Net cash provided by financing activities was $4,761,400 during the year ended December 31, 2019 as compared to $1,625,000 for the year ended December 31, 2018. 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. During the year ended December 31, 2018, the net cash provided by financing activities consisted of proceeds from the sale of convertible promissory notes in the amount of $725,000 and proceeds from preferred stock issuance in the amount of $900,000.

Convertible Promissory Notes

Starting in June 2016, we sold convertible promissory notes to certain investors to help finance our operations. The notes were in amounts ranging from $12,500 to $500,000, earning annual interest at 7% and all maturing on either June 1, 2019 or January 1, 2020. As of December 31, 2017, the combined carrying amount of the convertible promissory notes and the carrying amount of the related embedded derivative liability on the convertible promissory notes was $6,106,000. During the year ended December 31, 2018, an additional $725,000 convertible promissory notes were issued, earning annual interest at 7% and all maturing on June 1, 2019. The notes were convertible into shares issued in our next financing (as defined in the notes) by dividing the total amount of notes payable, plus accrued interest, by the applicable conversion price (defined generally as 80% of the lowest per share selling price in the next financing).

On December 20, 2018, following the issuance of shares of Series A-1 Preferred Stock described below, the outstanding principal and accrued interest was converted into shares of Series A-1 Preferred Stock. At the time of conversion, the outstanding principal and accrued interest of the notes totaled approximately $7,541,600. Accordingly, the notes were converted into an aggregate of 18,854,033 shares of Series A-1 Preferred Stock at a conversion price of $0.40 per share. No additional convertible promissory notes were outstanding as of December 31, 2018 following the conversion on December 20, 2018.

During 2019, we issued additional convertible promissory notes in the aggregate principal amount of $250,000 to certain investors. The notes accrued interest at a rate of 17% and were to mature on June 1, 2021. These notes were convertible into shares issued in our next financing (as defined in the

notes) by dividing the total amount of notes payable, plus accrued interest, by the applicable conversion price (defined generally as 85% of the lowest per share selling price in the next financing). Prior to the issuance of shares of Series B Preferred Stock (as discussed below), each holder agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of Series A-1 Preferred Stock. Therefore, on August 15, 2019, these notes were converted into an aggregate of 632,123 shares of Series A-1 Preferred Stock at a conversion price of $0.43 per share.

In addition, during 2019, we settled an outstanding account payable with a vendor in the amount of $134,800 by issuing to that vendor a convertible promissory note for the amount owed. That convertible promissory note accrued interest at a rate of 6% and was to mature on June 30, 2020. This note was convertible into shares issued in our next financing (as defined in the note) by dividing the total amount of notes payable, plus accrued interest, by the applicable conversion price (defined generally as 90% of the lowest per share selling price in the next financing). Prior to the issuance of shares of Series B Preferred Stock (as discussed below), the holder agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of Series A-1 Preferred Stock. Therefore, on August 15, 2019, this note was converted into 303,396 shares of Series A-1 Preferred Stock at a conversion price of $0.45 per share.

Series A-1 Preferred Stock Financing

Between June 8, 2018 and August 14, 2018, we entered into agreements to issue preferred stock and received advances of $900,000. The advances received under the agreements were recorded as liabilities until the preferred stock was issued and bore interest at a rate of 6.5%. The agreements were amended on September 10, 2018, when, in exchange for additional preferred stock to be issued, the advances no longer bore interest. On December 20, 2018, 2,032,749 shares of Series A-1 Preferred Stock were issued for $912,800, representing the advances received and accrued interest through September 10, 2018. See "Description of Securities" for more information regarding our Series A-1 Preferred Stock.

Series B Preferred Stock Financing

On September 7, 2019, we entered into a Series B Preferred Stock purchase agreement with certain investors for the sale of shares of our Series B Preferred Stock at a price of $0.46 per share. On September 13, 2019, we sold an aggregate of 7,608,696 shares for total gross proceeds of approximately $3,500,000. On November 13, 2019, we sold an additional 2,173,913 shares for gross proceeds of $1,000,000. The shares of Series B Preferred Stock had accrued unpaid dividends at an annual rate of 6% per share. 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, we issued 87,050 shares of Series B Preferred Stock to the investors.

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, we 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 warrants have an exercise price of $0.003494 per share and expire ten years after the date of issuance. The warrants are exercisable as follows: (i) 30% of the shares underlying the warrants are exercisable from the date that is six months after the date on which our securities are first listed on a U.S. national securities exchange, (ii) an additional 30% of the shares underlying the warrants are exercisable nine months after such listing date, and (iii) the remaining shares underlying the warrants are exercisable twelve months after such listing date. On June 8, 2020, we agreed to amend the warrant vesting schedule outlined above, 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. See "Description of Securities" for more information regarding our Series B Preferred Stock and the warrants issued in this financing.

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 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 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, 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 and the assumptions used to value such stock options are determined as follows:

Expected Term. The expected term represents the period that our stock options are expected to be outstanding. Due to limitations on the sale or transfer of our common stock as a privately held company, we do not believe our historical exercise pattern is indicative of the pattern we will experience as a future publicly traded company. 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 plan to continue to use the SAB 110 simplified method until 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 no 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. The fair value of the common stock underlying our stock-based compensation grants has historically been determined by our board of directors, with input from management and third-party valuations. We believe that the board of directors has 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, such as an initial public offering, 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 after the completion of an initial public offering, 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 of Series B Preferred Stock—We record warrants to purchase shares of common stock underlying our shares of Series B Preferred Stock in accordance with ASC 470, *Debt with conversion and other options*. The fair value of the warrants is estimated on the purchase 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, and risk-free interest rate.

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 warrants become exercisable in accordance with the schedule set forth below following completion by the Company of an initial public offering 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.

Since the vesting schedule is contingent upon completion of an initial public offering, we assessed the expected term of the warrants to be ten years.

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 have no 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. The fair value of the common stock underlying our warrants has historically been determined by our board of directors, with input from management and third-party valuations. We believe that the board of directors has 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, such as an initial public offering, 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.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or 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, or 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 June 3, 2020, the FASB changed the effective date of this standard to January 1, 2022. We are currently evaluating the potential impact of this standard on our financial position, results of operations, and cash flows.

In March 2016, FASB issued ASU 2016-09, *Stock Compensation—Improvements to Employee Share-Based Payment Accounting*. On January 1, 2018, we adopted the amendments to ASC 718, which simplify accounting for share based payment transactions. As part of the amendment, we have elected to recognize the actual forfeitures by reducing the employee share-based compensation expense in the same period as the forfeitures occur. The adoption did not result in a material impact on our financial statements and related disclosures.

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 October 16, 2019, the FASB changed the effective date of this standard to January 1, 2023. We are currently evaluating the potential impact of this standard on our financial position, results of operations, and cash flows.

On January 1, 2018, we adopted ASU 2018-07, *Improvements to Non-employee Share-Based Payment Accounting* (Topic 718). This standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. FASB clarified that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606, *Revenue from Contracts with Customers*. Since we have not generated any revenue to date, this adoption did not result in a material impact on our financial statements and related disclosures.

On January 1, 2019, we 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. We determined that this standard had no impact on its financial position, results of operations, and cash flows for the years ended December 31, 2019 and 2018, respectively.

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."

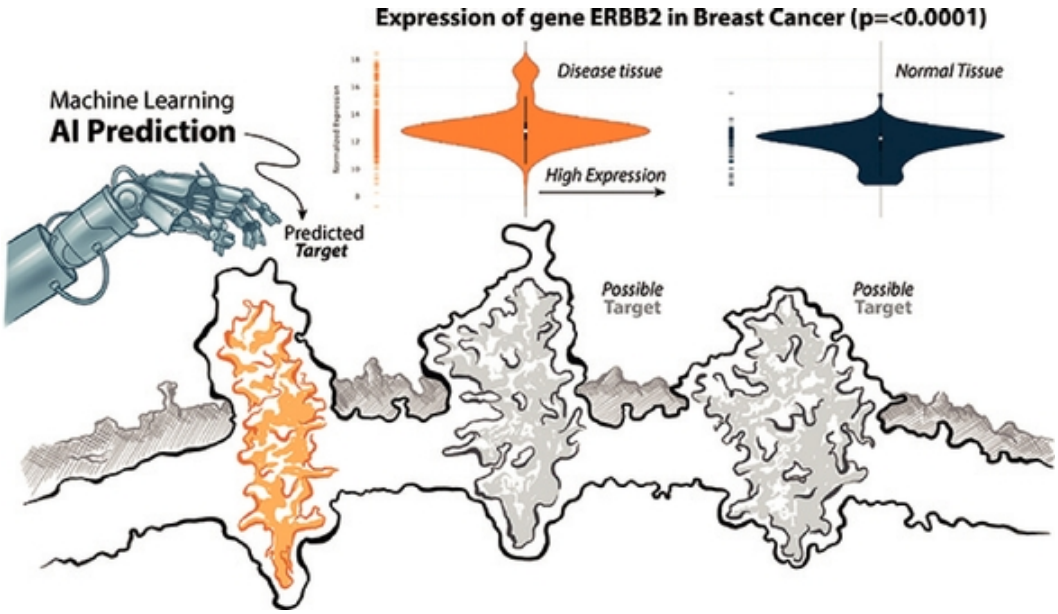
Kiromic's Diamond is big data science meeting target identification, dramatically compressing man-years and billions of drug development dollars to develop a live drug.

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)

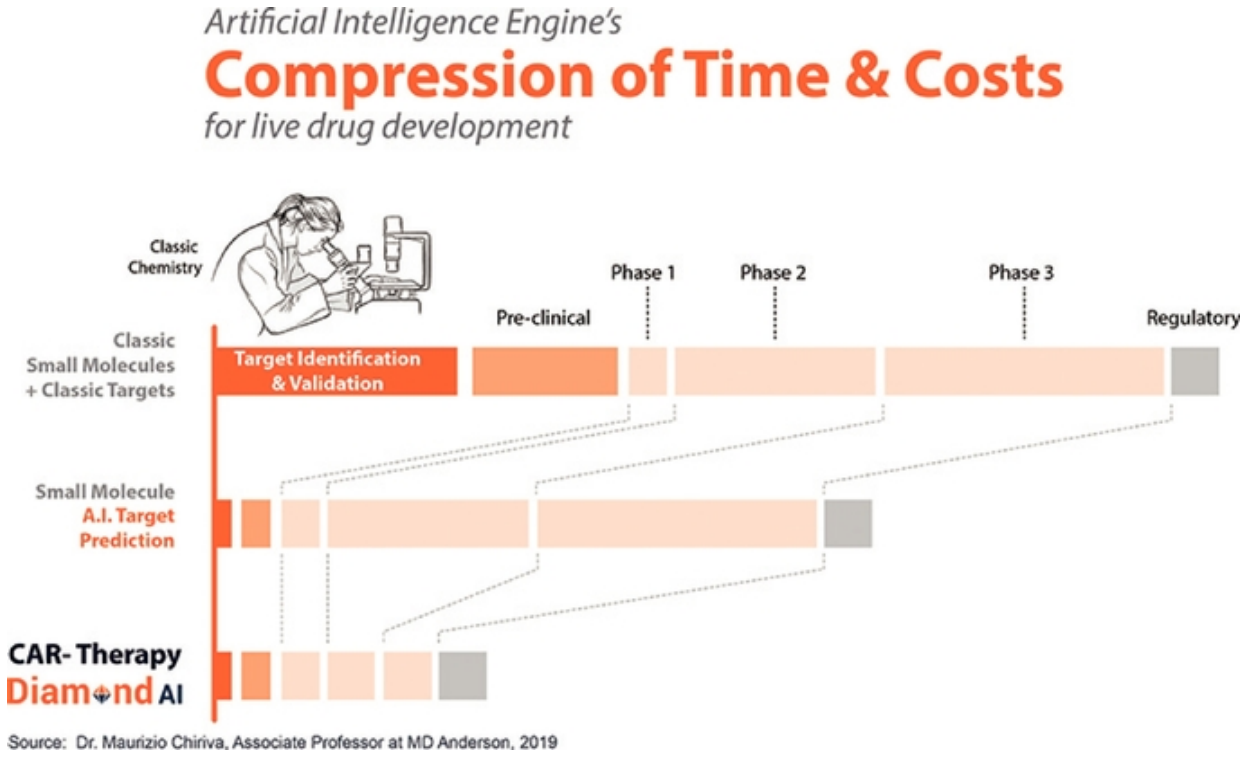
Diamond is a computational platform and a neural network that can identify new cancer immunological targets for T cells and B cells. Diamond is an artificial intelligence and machine learning approach that can identify novel surface tumor targets. It uses public and proprietary samples and can expand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

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



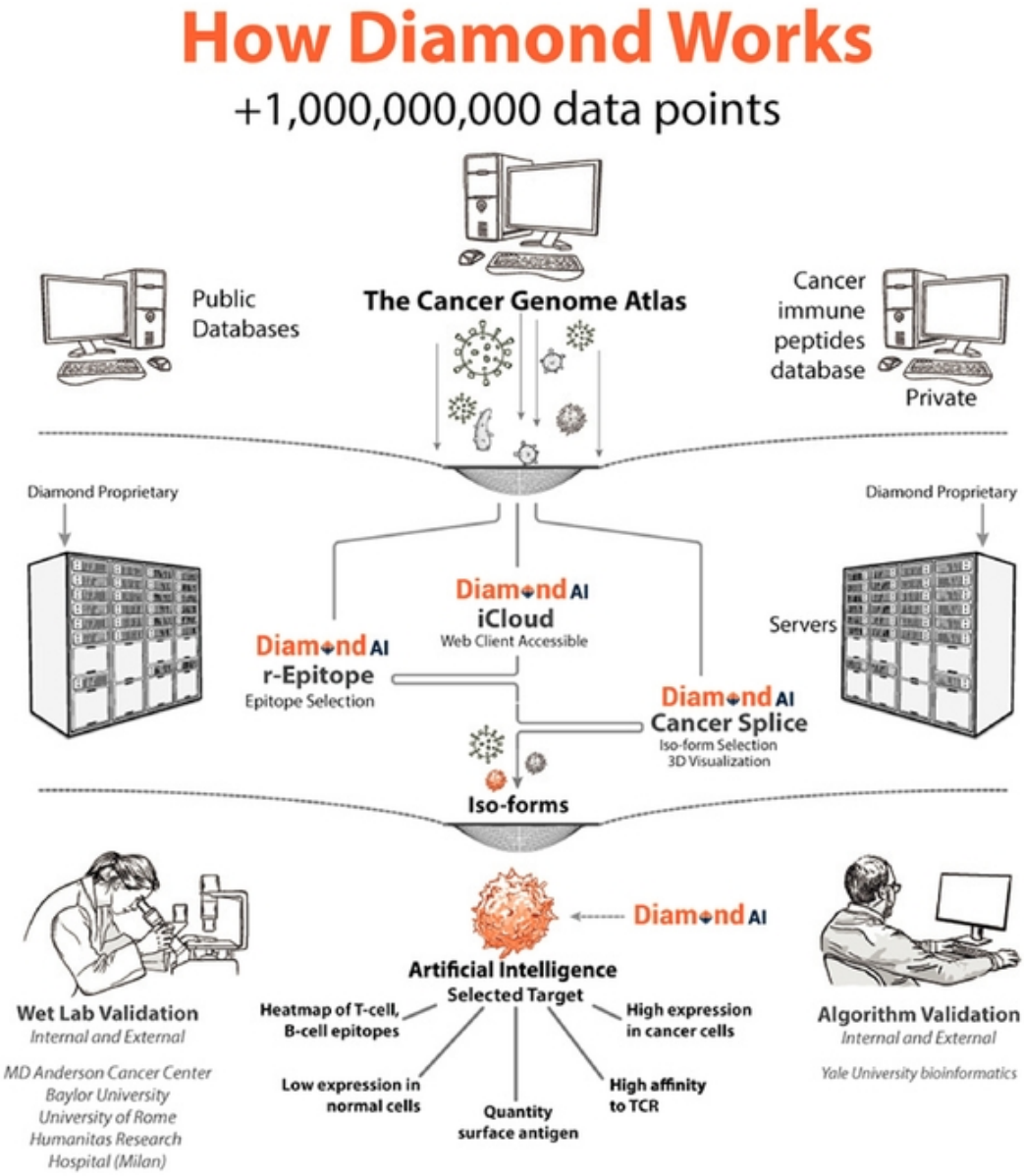
Diamond generates a prioritized list of cancer immunological targets for T cells and B cells. These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR-T cell therapies and vaccine therapies.

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.



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.

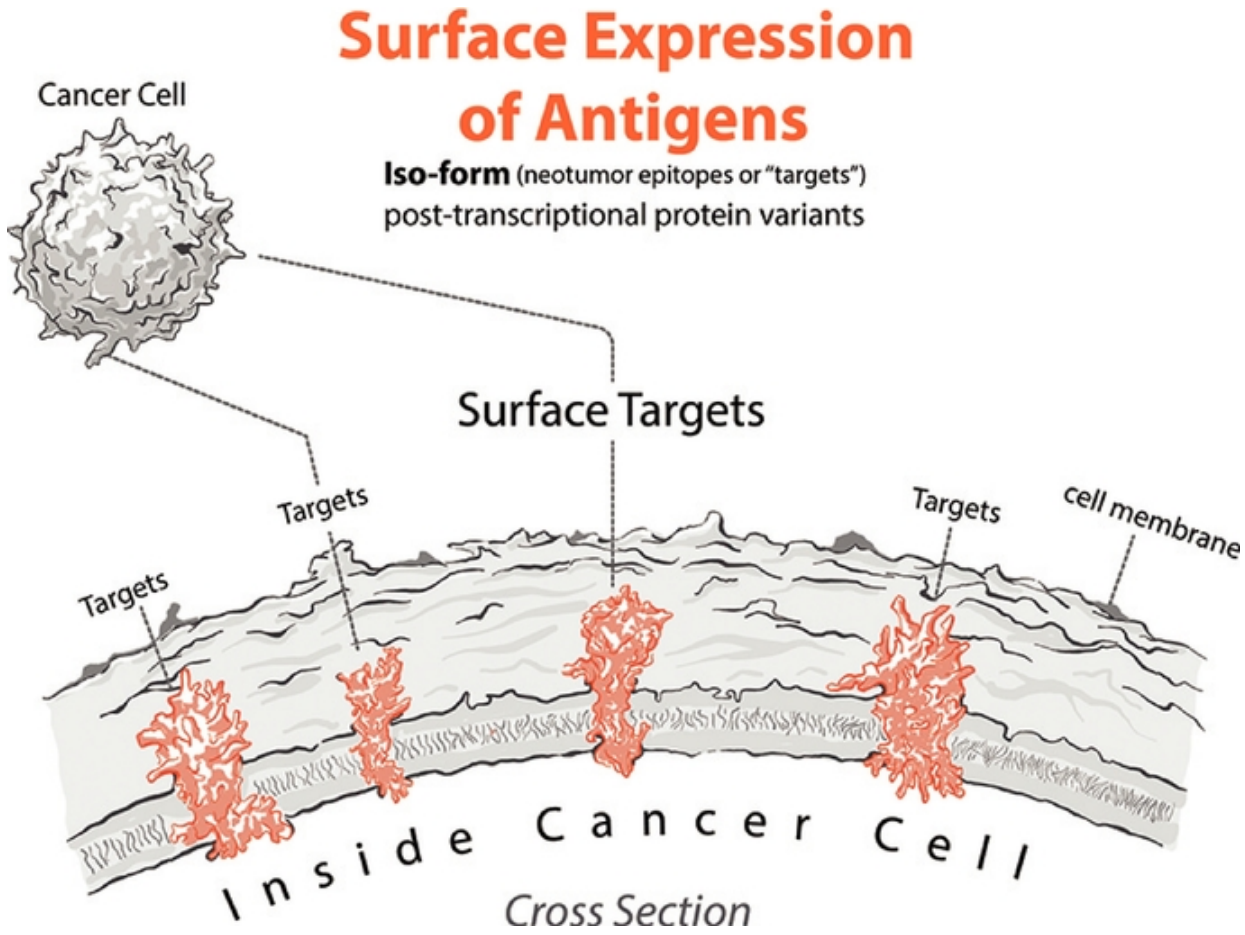
Performs Meta Analysis. Diamond performs meta-analysis and convolution studies while standardizing and normalizing data across multiple and variable experimental platforms, then allows for the visualization of consistent and accurate results in a user-friendly fashion.

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.

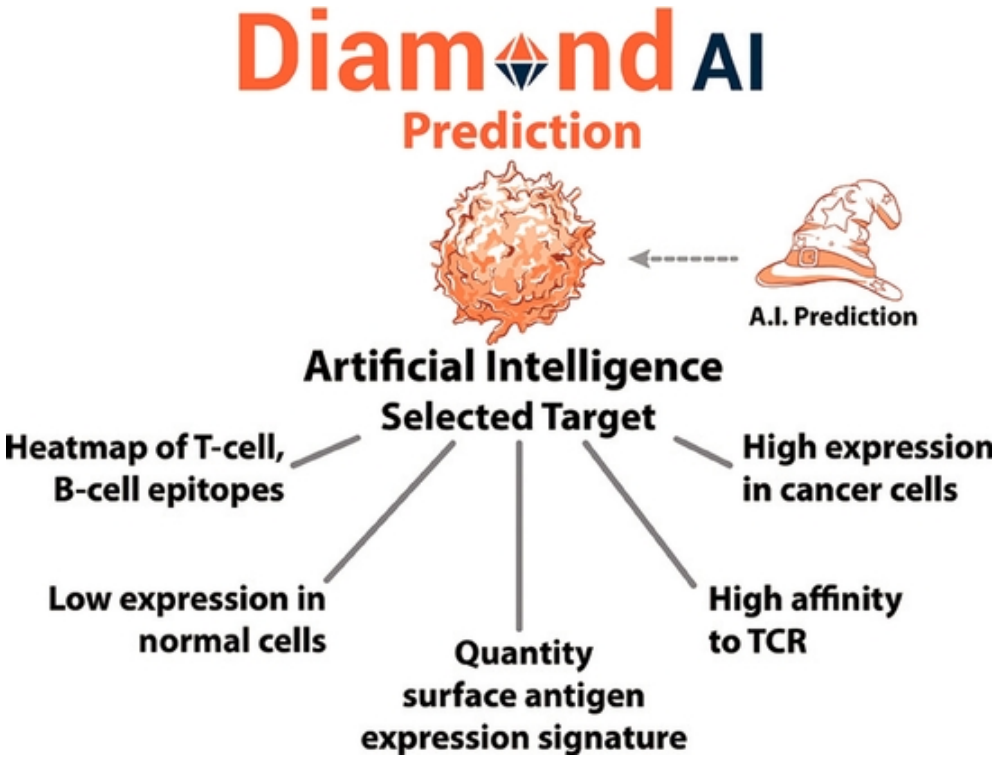
Target isoforms are protein variants of the same targets that occur during the normal processing of immature gene transcripts to the mature form.

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.

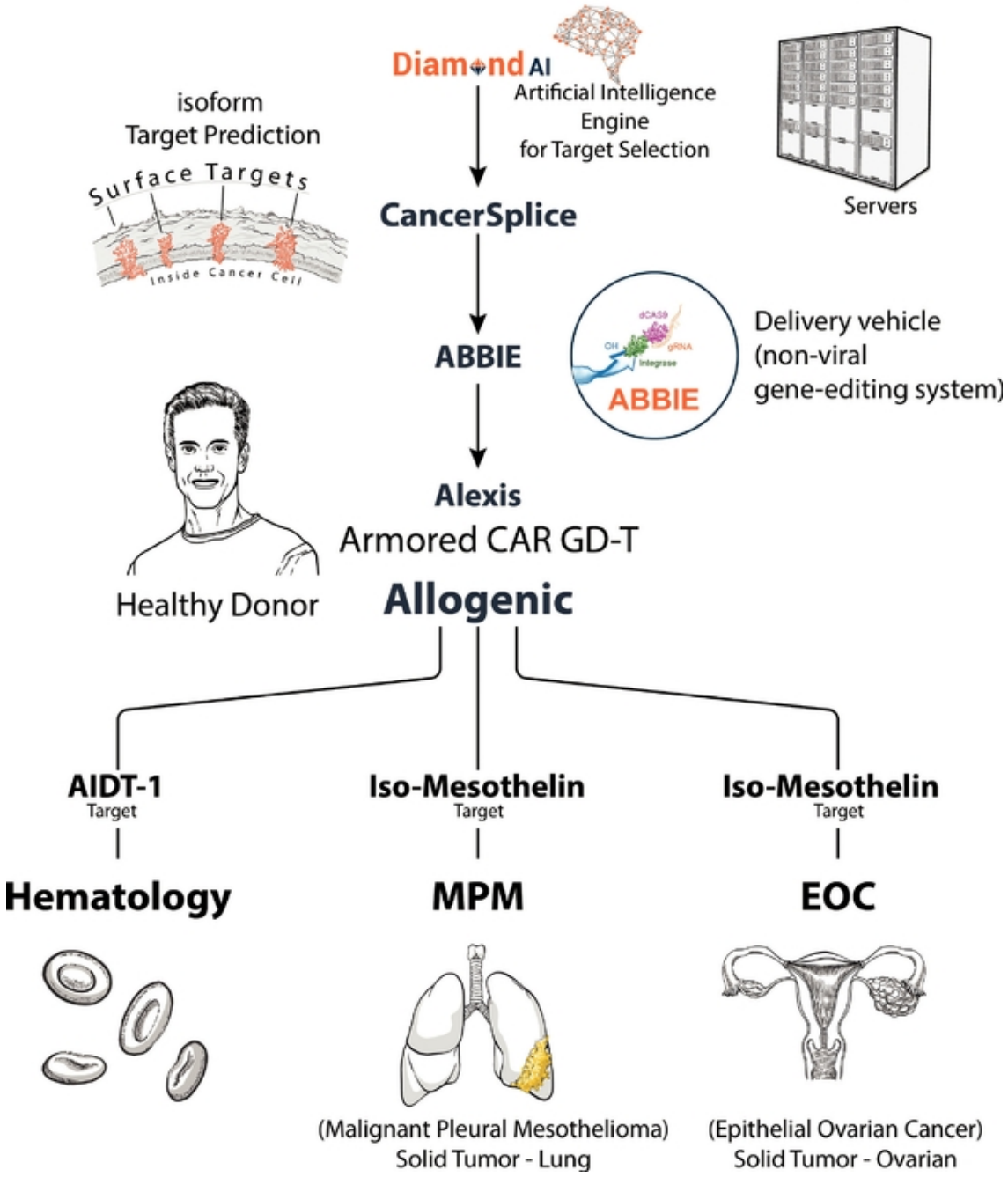
Our Approach

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 validating different tumor-specific immunotherapy product candidates for refractory CAR-T cell patients. Refractory CAR-T cell patients are those who have received CAR-T cell treatments for their indication, however, they either showed low or no benefit from this treatment. 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.

From Targets to Therapy



ABBIE (Delivery Vehicle)

ABBIE Summary

ABBIE is a novel gene-editing system for inserting therapeutic genes safely into the genome of a host cell.

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.

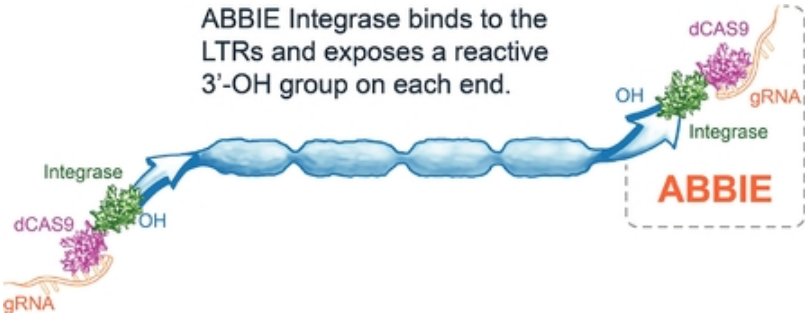
Due to this targeting ability, ABBIE can also be used to remove unwanted, inhibitory genes. CAR expression on the Gamma-Delta T cells allows them to detect and destroy the antigen-expressing targeted cells.

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. If no major obstacles are encountered, we expect to be able to begin producing effector cells for in vitro testing using ABBIE by December 2020.

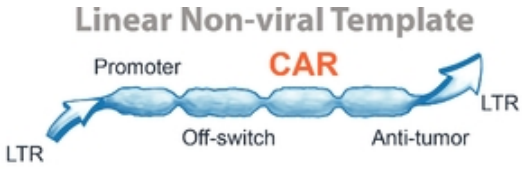


Figure 1. Our ABBIE gene-editing technology begins with the transgene template plasmid. Plasmid DNA is cut with restriction enzyme, ScaI, liberating the transgene template along with the retroviral-derived long-terminal repeats (LTRs), which is purified away from the plasmid DNA and ScaI protein.

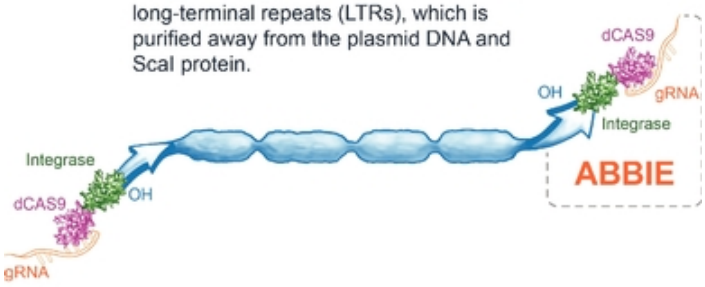


Figure 2. The ABBIE integrase, derived from HIV, is added, which binds to the LTRs and exposes a reactive 3'-OH group on each end.

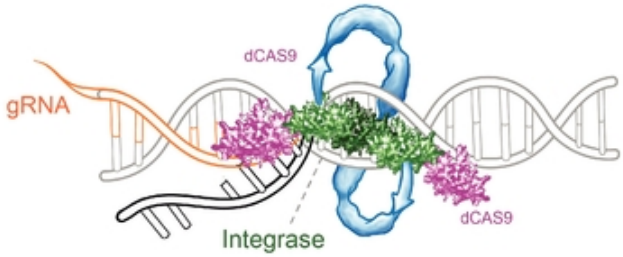


Figure 3. The guide RNA (gRNA) tethers ABBIE-bound template to the target site via DCas9, and Integrase helps to attach the exposed 3'OH groups to the target site on both strands without causing a dsDNA break.

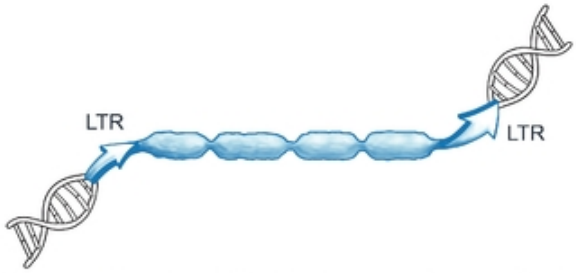
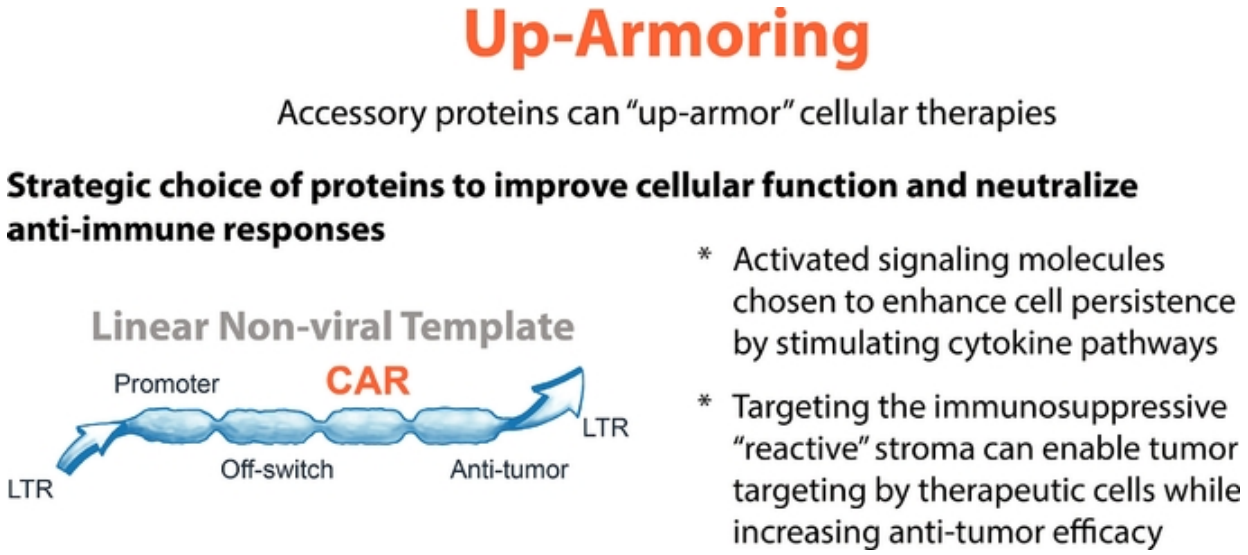


Figure 4. Following stable integration of the template into the target DNA locus, a short DNA duplication is present on each end.



SWITCHES

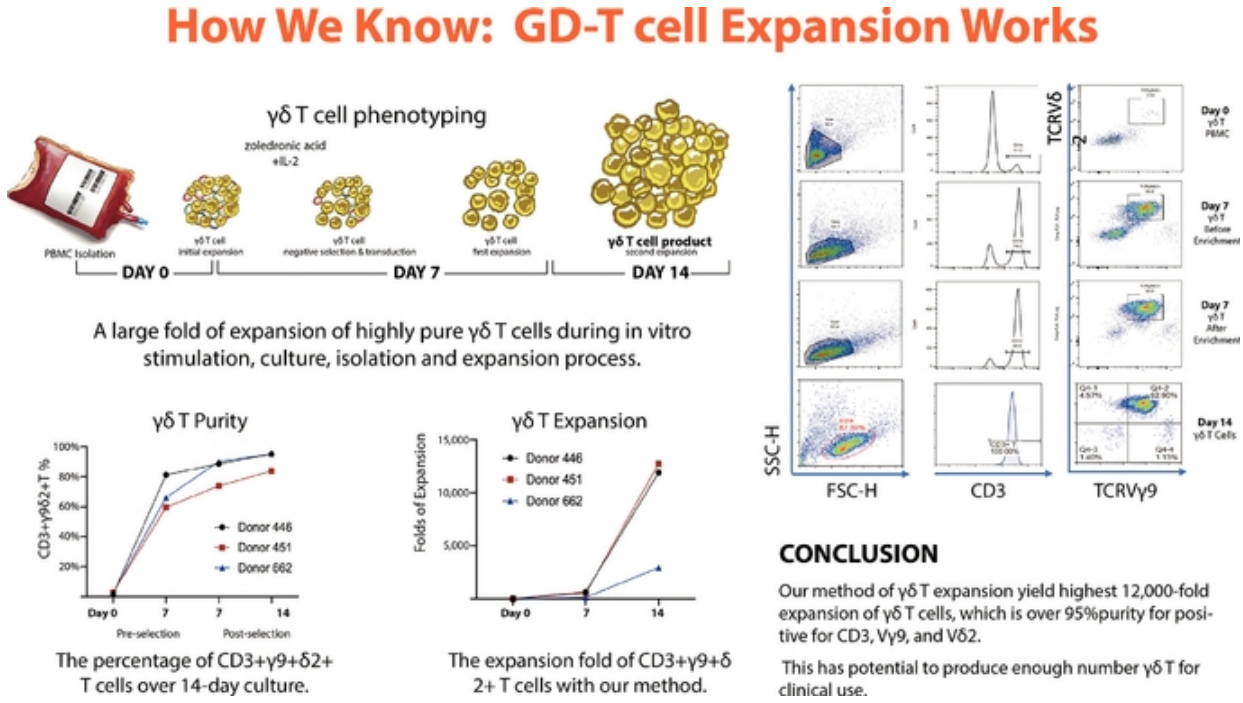
ACTIVATION Switch. A rapidly deployed activation switch can provide a survival and proliferation signal to the therapeutic cells to enhance their efficacy and persistence in vivo.

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.

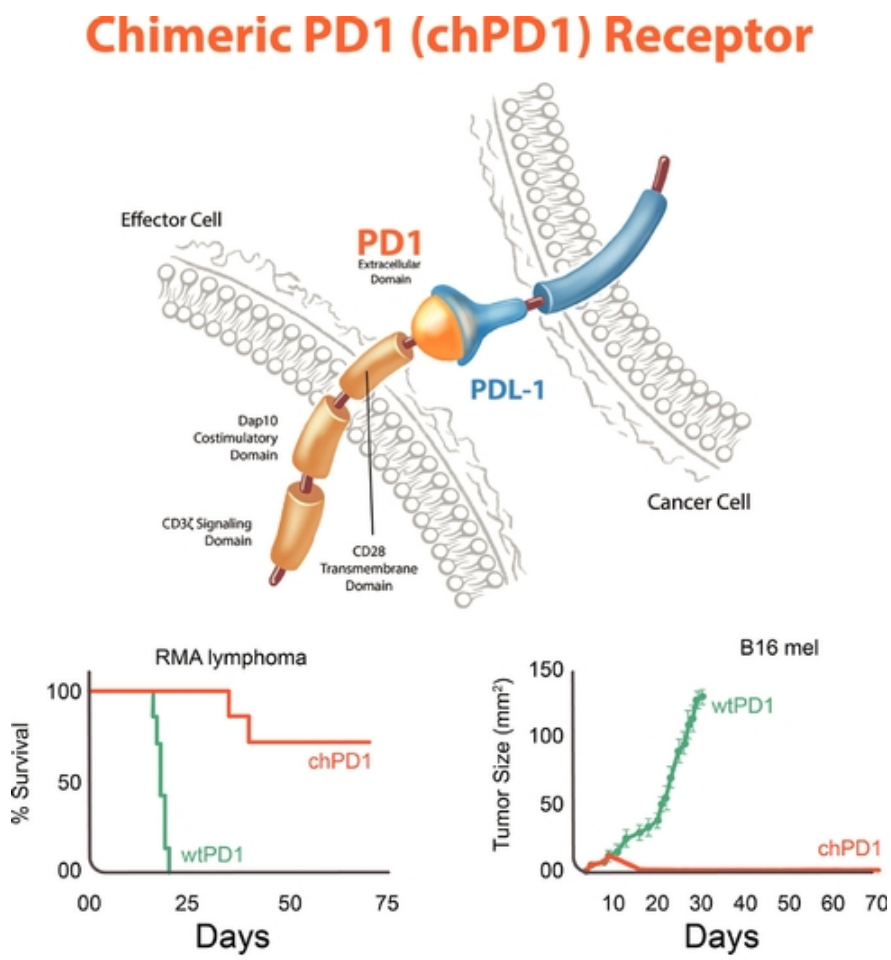
Manufacturing Allogeneic Effector Cells

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



PD-1: Avoiding Antigen Escape

To further boost the potency of our effector cells, we plan to explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, the chances for the tumor to escape treatment are greatly reduced.



chPD1 = chimeric PD1

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

Checkpoint inhibitors block PD-1 and PD-L1.

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

chPD1-expressing T cells can efficiently lyse both hematologic and solid tumors expressing PD-L1 and/or PD-L2, leading to greatly improved survival with minimal toxicity in animal models.

chPD1 Receptor signaling also leads to cytokine release that can have widespread anti-tumor effects in the tumor microenvironment.

Step 1. Collection

The starting material for our engineered T/NK cell products is white blood cells. For our allogenic products, the T/NK cells are collected from a healthy donor. These are collected using a standard blood bank procedure known as leukapheresis. The collected cells are then sent to a central processing facility, where the peripheral blood mononuclear cells, including T/NK cells, are isolated from the other sample components. The T/NK cells for our allogenic products are isolated and stored frozen, creating an inventory of starting healthy donor cells for manufacturing.

Step 2. Gene Editing

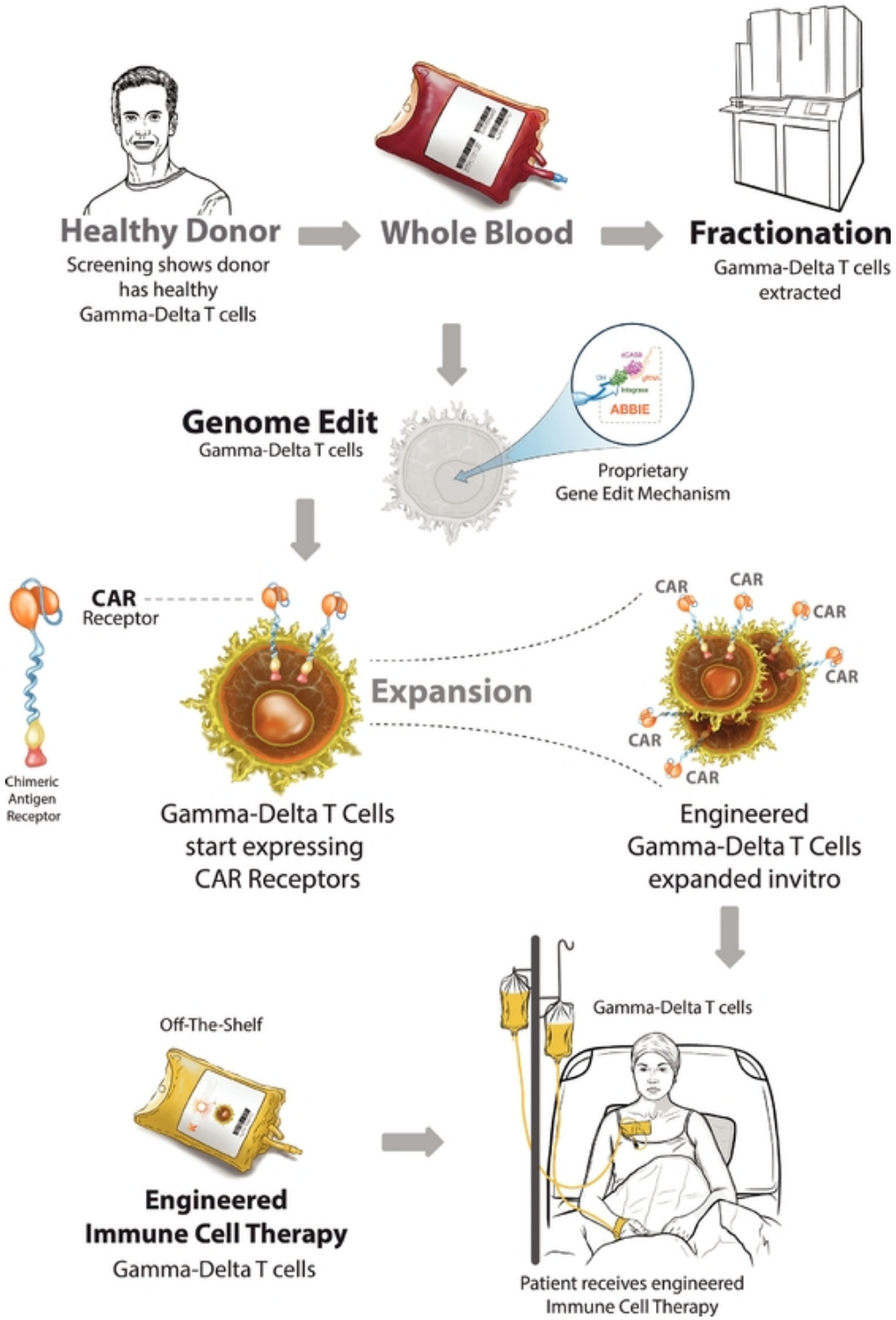
These cells are stimulated to proliferate, then transduced with a non-replicating retroviral vector to introduce the CAR gene into the patient's T/NK cells.

We are also currently developing ABBIE, which is a non-viral gene-editing mechanism to insert the target DNA template information into the T/NK cell genome. The CAR sequence will direct the expression of CAR proteins on the cell surface that allows the transduced T/NK 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 T/NK 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.



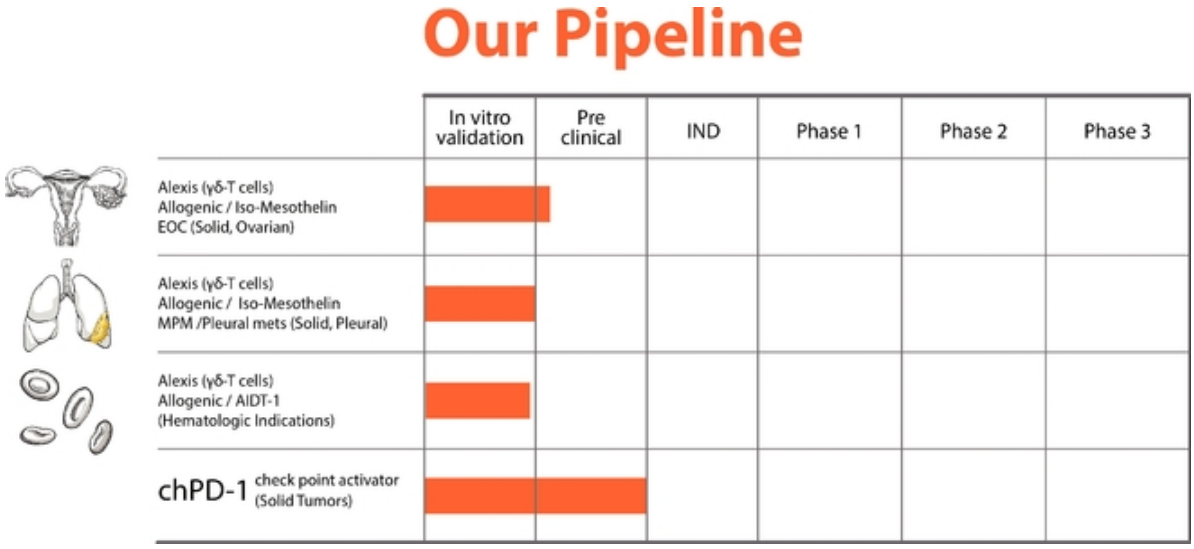
Note that we have not yet completed our ABBIE (gene editing) technology as shown in Step No. 5 above. Our clinical trial will be using the current industry standard retroviral vector.

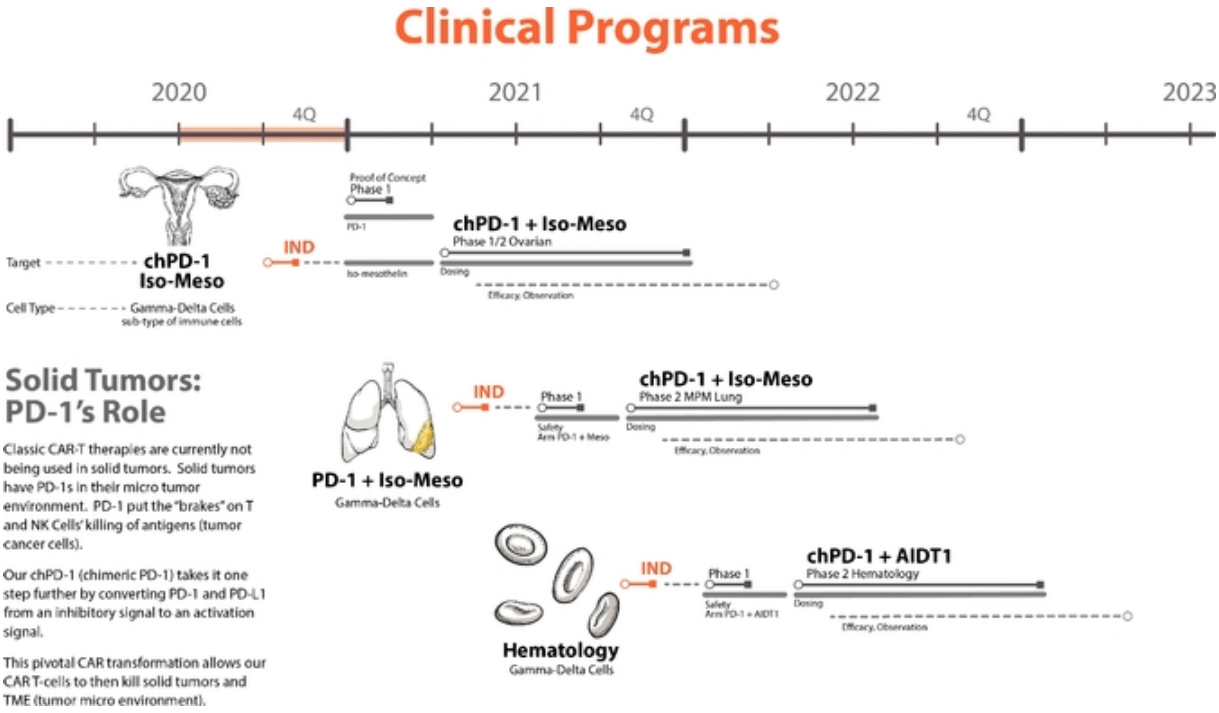
Our Product Pipeline and Development

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 or as off-the-shelf treatments for any patient with a particular cancer type. Each product candidate targets a selected antigen expressed on tumor cells and bears specific engineered attributes.

In the near term, we are progressing multiple product candidates directed at promising targets for blood cancers, including refractory large B cell lymphoma, and targets associated with solid tumors, such as malignant pleural mesothelioma (lung) and epithelial ovarian cancer.

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 particular requirements*) are represented in the diagrams below:





ALEXIS Iso Mesothelin EOC

ALEXIS Iso Mesothelin is our allogenic CAR cell product candidate targeting Iso Mesothelin.

ALEXIS Iso Mesothelin represents an innovative approach for stage III to stage IV platinum resistant epithelial ovarian cancer and involves the use of CAR effector cells.

Target Indications

ALEXIS Iso Mesothelin targets epithelial ovarian cancer, or EOC. According to the American Cancer Society, approximately 21,750 individuals are diagnosed with EOC in the U.S. each year, and 300,000 worldwide.

EOC generally affects elderly women over 60 years old. Genetic mutations and/or a family history of ovarian/breast/colorectal cancer increase the risk of EOC. EOC can metastasize to abdominal peritoneum, which is extremely difficult to treat. The median life expectancy after local recurrence is approximately 15 months.

In total, the standard treatment can cost approximately $100,000. Ovarian cancer is a deadly disease with stage IV patients having a 5-year overall survival rate of only 30%.

Out of 21,750 U.S. patients who are initially diagnosed with EOC each year, we believe that up to 15,400 (70%) will potentially be eligible for our CAR cell therapy.

In 2018, this market size reached $1.2 billion according to Grand View Research (July 2019).

This market is expected to grow at 6.2% annually compounded from 2019 to 2026 according to Data Monitor Healthcare.

Development Plan

ALEXIS Iso Mesothelin will be studied in a Phase 1 clinical trial for EOC patients. We plan to submit an IND in Q4 2020. We will be the sponsor of the clinical trials, which will be conducted by industry-

standard CROs and the trials will be conducted by leading academic institutions and experienced research facilities in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open-label, single arm, multi-center, dose-escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with platinum resistant EOC.

The primary goal will be to assess safety and tolerability at increasing dose levels in order to estimate the maximum tolerated and efficacious dose.

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 our intended target (Iso Mesothelin).

To further boost the potency of our effector cells, we plan to also explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, we believe the chances for the tumor to escape treatment are greatly reduced.

Consequently, we plan to submit a Phase 1 IND for our PD-1 gamma delta reverse switch CAR T-cells for EOC in Q4 2020, followed by the submission of an IND for a Phase 1 combination PD-1/IsoMesothelin CAR clinical trial in Q3 2021.

ALEXIS Iso Mesothelin MPM

ALEXIS Iso Mesothelin MPM is our allogenic effector cell product candidate targeting Iso Mesothelin.

ALEXIS Iso Mesothelin MPM represents an innovative approach for malignant pleural mesothelioma and involves the use of CAR effector cells.

Target Indications

ALEXIS Iso Mesothelin MPM targets malignant pleural mesothelioma, or MPM. Mesothelioma is a disease in which malignant (cancer) cells form in the thin layer of tissue that covers organs typically in the chest or abdomen. Pleura refers to the thin layer of tissue that lines the chest cavity and covers the lungs. The tumors often spread over the surface of organs often without spreading into the organ. They may spread to nearby lymph nodes or in other parts of the body. Malignant mesothelioma may also form in the testicles or heart, but this is rare.

According to the American Cancer Society, approximately 3,000 individuals are diagnosed with MPM in the U.S. each year, and 43,000 deaths globally each year.

MPM rates are high in the military, particularly for those involved in ship building, construction, mechanics, and insulation/textile production and installation. Due to these higher rates, corporations have set aside approximately $30 billion each year to settle job-related asbestos MPM for their personnel.

The standard treatment for MPM involves chemotherapy that costs approximately $90,000, surgery that costs approximately $20,000 - $30,000, and radiation that costs approximately $10,000 - $50,000. In total, the standard treatment can cost up to $170,000. Approximately 80% of patients undergoing this treatment will eventually relapse. The average life expectancy after refractory is approximately 7 months.

Out of the 3,000 U.S. patients who are initially diagnosed with MPM each year, we believe that approximately 2,400 (80%) will eventually be eligible for our effector cell therapy.

Mesothelioma statistics show there are about 3,000 new cases of mesothelioma diagnosed in the United States each year. According to the most recent data, 57,657 mesothelioma cases were reported between 1999 and 2016. Between 1999 and 2017, there were more than 47,600 mesothelioma-related deaths. Pleural mesothelioma is the most common form, accounting for 80 - 90% of all cases. (Source: https://www.mesothelioma.com/mesothelioma/statistics/)

Driscoll et al. estimated that as many as 43,000 people worldwide die from the disease each year. It has also been estimated that there are around 10,000 mesothelioma cases annually in Australia, Japan, North America and western Europe combined. (Source: See Bulletin of the Delgermaa et. al, World Health Organization 2011;89:716-724C.)

This market is expected to grow at 7.60% annually compounded from 2020 to 2026 according to MarketWatch (April 2, 2020).

This market size is expected to reach $300 million by 2025 according to Persistent Market Research (July 2017).

Development Plan

ALEXIS Iso Mesothelin MPM will be studied in a Phase 1 clinical trial for pleural mesothelioma. We plan to submit an IND in 2021, and the subsequent clinical trial will be conducted by leading academic institutions and experienced research facilities in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open label, single arm, multi-center, dose escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with mesothelioma, who are relapsed/refractory to maximal surgical reduction and standard of care chemotherapy +/- radiation therapy.

The primary goal will be to assess safety and tolerability at increasing dose levels in order to estimate the maximum tolerated and efficacious dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure that all the patients meet all the corresponding inclusion and exclusion criteria and express our intended target IsoMesothelin.

To further boost the potency of our effector cells, we also plan to explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, we believe the chances for the tumor to escape treatment are greatly reduced.

Utilizing the data accrued from the prior Phase 1 combination PD-1/Iso-Mesothelin CAR T-cell trial for EOC, we plan to subsequently submit a Phase 1 combination IND for our PD-1/IsoMesothelin CAR T-cells for MPM in Q3 2021.

ALEXIS AIDT-1

ALEXIS AIDT-1 is our allogenic CAR cell product candidate targeting AIDT-1. This product is currently undergoing pre-IND studies. Following subsequent IND-enabling studies, we will be applying for an IND with the FDA in 2022.

ALEXIS AIDT-1 targets AIDT-1, an antigen expressed on the surface of B cells, including malignant B cells. The product represents an innovative approach for relapsed hematologic malignancies such as B cell acute lymphoblastic leukemia and for diffuse large B cell lymphoma and involves the use of adoptive T cells expressing CARs against AIDT-1. We expect our strategy to target B cell malignancies that have become refractory to currently available therapies.

Target Indications

ALEXIS AIDT-1 targets NHL (ie, diffuse large B cell lymphoma, or DLBCL). According to the American Cancer Society, approximately 25,000 - 30,000 individuals are diagnosed with DLBCL in the U.S. each year, and 200,000 worldwide. The growth rate for DLBCL is relatively stable.

The standard treatment is R-CHOP chemotherapy, which is a combination treatment consisting of five separate drugs: rituximab (Rituxan), cyclophosphamide, doxorubicin hydrochloride, vincristine (Oncovin), and prednisolone. R-CHOP chemotherapy costs approximately $100,000 per year. Average life expectancy following the failure of R-CHOP chemotherapy is approximately 6 months.

The failure rate for R-CHOP chemotherapy is 30 - 50%. Up to 50% of failures cannot get stem cell transplants and are potential candidates for CAR therapy. Standard CAR-T therapy costs between approximately $375,000 to $475,000.

Out of the 30,000 U.S. patients who are initially diagnosed with DLBCL each year, we believe that approximately 3,000 will eventually be eligible for our CAR-T cell therapy.

Worldwide number of patients for Non-Hodgkin's Lymphoma is estimated at 509,590. (Source: Global cancer statistics 2018: Globocan estimates of incidence & mortality world-wide for 36 cancers in 185 countries) with 77,240 cases in the U.S. in 2020 according to the American Cancer Society 2020).

The number of diagnosed hematologic cases is expected to grow at 10.5% annually compounded according to Data Monitor Healthcare (Source: See Hematologic Malignancies Market Size, Share & Trends Analysis Report by Type (Leukemia, Lymphoma, Multiple Myeloma), By Therapy (Chemotherapy, Radiotherapy, Immunotherapy), And Segment Forecasts, 2018 - 2025.)

The market size for hematologic cancers is expected to reach $4.6 billion by 2025 according to BIS Research (November 21, 2019).

Development Plan

ALEXIS AIDT-1 will be studied in a Phase 1 clinical trial for DLBCL, primary mediastinal B cell lymphoma, and transformed follicular lymphoma. We plan to submit an IND in 2022, and the clinical trial will be conducted by leading academic institutions and experienced research facilities in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open-label, single-arm, multi-center, dose escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with DLBCL, who are relapsed or refractory to prior treatment with an anti-CD20 monoclonal antibody therapy and an anthracycline containing chemotherapy and/or an autologous stem cell transplant.

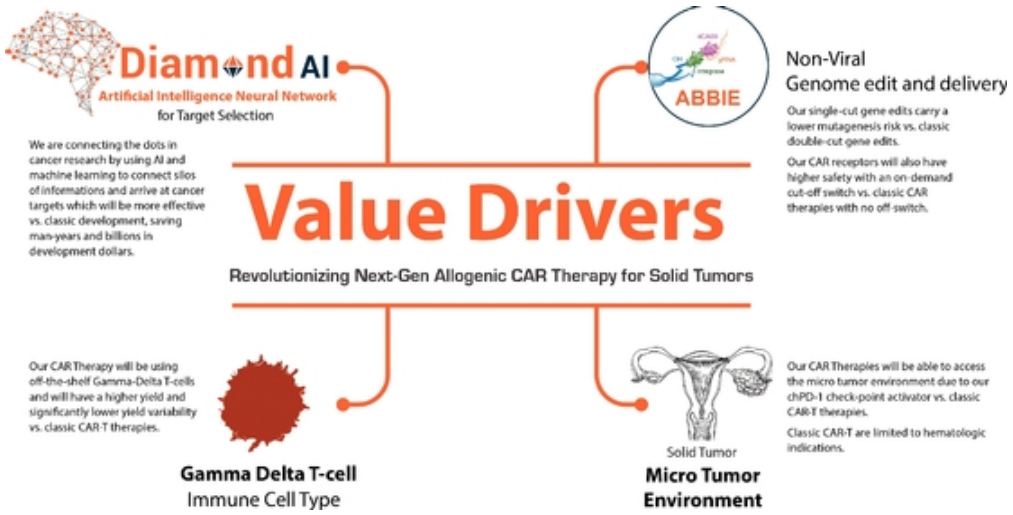
The primary endpoint will be to assess safety and tolerability at increasing dose levels in order to estimate the maximum tolerated and efficacious dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure than the patients are expressing our intended target (AIDT-1) and meet all corresponding inclusion and exclusion criteria.

To further boost the potency of our effector cells, we also plan to explore an additional targeting element that interferes with the inhibitory "checkpoint" protein, PD-1 found on most activated T cells

and other effector cells. By interacting with the PD-L1 and PD-L2 inhibitory ligands often found at high levels within the tumor microenvironment, PD-1 normally sends a suppressive signal to the cell to shut down its activity in a process known as exhaustion. However, using a "flipped" signaling receptor, we plan to turn PD-1 "inside-out," changing this inhibitory signal to a stimulatory signal. Thus, with two ways to activate the anti-tumor cells, we believe chances for the tumor to escape treatment are greatly reduced.

Utilizing the data accrued from the prior Phase 1 combination PD-1/Iso-Mesothelin CAR T-cell trial for EOC and MPM, we plan to subsequently submit a Phase 1 combination IND for our PD-1/IsoMesothelin CAR T-cells for a to be determined pre-clinically validated hematologic malignancy in Q3 2022.



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 platformbased 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 our intellectual property portfolio around our product candidates and our discovery programs, based on our own intellectual property 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 protection for our lead product candidates, ALEXIS AIDT-1, ALEXIS Isoform Mesothelin EOC and ALEXIS Isoform Mesothelin MPM, as well as our 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, preconditioning

methods, and dosing regimens; 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 October 6, 2020, our patent estate includes three issued U.S. patents and 21 pending patent applications (12 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)

Our tumor targets patent estate includes eight patents applications that we developed internally for target identification (1-8) and one patents applications (9) disclosing methods of use of identified targets, which we developed internally and in part following license agreements.

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 titled "Methods for Identifying and Using Diseases-Associated Antigens" is a United States utility patent application that is expected to expire on May 31, 2040. The claims in this patent application include composition of matter, use and process for a method treating a condition (e.g., cancer) with an appropriate immunotherapeutic agent and/or regimen. Also included are methods for the use of effective combinations of proteins encoded by hot-spot mutations and/or tumor-associated mRNA splice variants to optimize the targeting of a patient's condition (e.g., cancer) with immunotherapies.

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 titled, "OroVAX: AI Prediction of SARS-CoV-2 Immune Epitope Peptides for the Development of an Oral Vaccine." It is a United States Provisional Application that is expected to expire on May 8, 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.

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 titled, "Novel Nanoparticle—Based Vaccine Targeting Cancer/Testis Antigens (CTA) and its' Use in Solid and Hematological Malignancies" contains one utility application filed in Europe that is expected to expire on November 19, 2035, absent any extension of the patent right by a supplementary protection certificate (SPC). The claim in this patent application includes composition of matter, use and methods for a vaccine composition comprising of particles comprising nanoparticles, microparticles or a mixture thereof.

9. 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 titled, "PD1-Specific Chimeric Antigen Receptor as an Immunotherapy" has been exclusively in-licensed from Longwood University. It is The patent family contains one United States application and one PCT application for which we have entered and plan to

enter the national phase in a number of jurisdictions by May 26, 2020 that are expected to expire on September 26, 2038, absent any patent term adjustment or patent term extension. The claims in this patent application contains composition of matter claims for a 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 contain a method of treating cancer using the T lymphocyte genetically modified to express the CAR polypeptide.

Gamma-Delta T-cell Expansion

Gamma-Delta T-cell expansion represents our process for manufacturing allogeneic effector cells.

The Gamma-Delta T-cell expansion patent family titled "Mesothelin Isoform Binding Molecules and Uses Thereof" is a United States Provisional Application that is expected to expire on July 7, 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.

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 AIDT-1, ALEXIS ISOFORM Mesothelin EOC and ALEXIS ISOFORM Mesothelin MPM, as well as our other research-stage candidates.

The ABBIE patent family has been exclusively in-licensed from CGA 369, Inc. It is titled, "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 five utility applications in Europe, China, Japan, Korea, and the United States that are expected to expire on March 31, 2036, absent any patent term adjustment or patent term extension. The claims in this patent family contains composition of matter claims for nucleic acid constructs; organisms comprising nucleic acid constructs; fusion proteins; and nucleic acid vectors. The claims in this patent family also contain methods of inserting a DNA sequence into genomic DNA and inhibiting gene expression.

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 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. No payments have been made to date for this collaboration agreement.

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.

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. and Sangamo Therapeutics, Inc.

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.

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 is recently formed and the product was recently developed. 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,

handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

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.

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. When it goes into effect on January 1, 2020, the CCPA will require 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.

Employees

As of October 6, 2020, we had a total of 13 employees. We also utilize a number of consultants for financial reporting, clinical, regulatory, and 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.

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.

MANAGEMENT

Directors and Executive Officers

The following sets forth information about our directors, director nominees, and executive officers as of the date of this prospectus:

Name	Age	Position
Maurizio Chiriva Internati	51	Chairman, Chief Executive Officer and President
Tony Tontat	54	Chief Financial Officer, Chief Operating Officer and Director
Scott Dahlbeck	58	Chief Medical Officer
Gianluca Rotino	47	Chief Strategy and Innovation Officer and Director
Pietro Bersani	52	Director
Americo Cicchetti	50	Director
Michael Nagel	58	Director Nominee
Jerry Schneider	72	Director Nominee

Maurizio Chiriva Internati, DBSc, PhDs. Dr. Chiriva Internati has served as our Chairman and Chief Executive Officer since February 2018 and as our President since October 2019. Between December 2012 and September 2019, he served as Chief Scientific Officer. Between December 2012 and August 2018, he also served as our Director of Clinical Translation Research. Dr. Chiriva Internati has been an Associate Professor at the MD Anderson Cancer Center in Houston, Texas since August 2019. Prior to that, he served as an Associate Professor at Texas Tech University Health Sciences Center from September 2013 to June 2017. His research has led to the identification of novel cancer-testis antigens for the development of immunotherapeutic strategies against solid and non-solid tumors. This led to the development of the bioinformatic software Diamond CancerSplice, which is a key core platform of our company, leading to the discovery and prioritization of isoform antigens via insilico system.

Dr. Chiriva Internati earned a PhD in Immunology from the University of Nottingham, United Kingdom. He also earned a PhD in Morphological Science from the Università degli Studi di Milano, Italy, and a Doctoral Degree in Biological Sciences from the University of Milan, Italy. Dr. Chiriva-Internati was a Post-Doctoral Fellow in Immunology at the University of Arkansas for Medical Sciences, earned a certificate in Artificial Intelligence from MIT Sloan School of Management and earned a certificate in Financial Technology from Oxford Saïd Business School. Dr. Chiriva Internati was selected to serve on our board of directors due to his tenure with our company and his industry experience.

Tony Tontat. Mr. Tontat has served as our Chief Operating Officer since August 2019, as our Chief Financial Officer since October 2019 and as a member of our board of directors since January 2020. Prior to joining us, Mr. Tontat worked as a business and financial consultant and Financial Analyst since November 2011 for Exuma Blue Advisors, LLC, where he worked with many private and public companies. He primarily helped these companies raise funds at various stages of life cycle. He worked in financial teams to raise funds for public companies like Sorrento Therapeutics, Inc. and NantKwest. Prior to this, he worked as an investment analyst at healthcare- specialist hedge funds in New York and also worked as investment banker at HSBC Investment Bank in their New York and Paris offices. Mr. Tontat earned his BA in Economics from Harvard University. Mr. Tontat was selected to serve on our board of directors due to his financing experience.

Scott Dahlbeck, MD, PharmD. Dr. Dahlbeck has served as our Chief Medical Officer since October 2019. He previously served as our President from January 2013 to October 2019. Dr. Dahlbeck is an expert in prostate cancer research and treatment and has served as a Radiation Oncologist for several cancer centers, including as an Adjunct Assistant Professor in Internal Medicine, Pathology, and

Urology at the Texas Tech University Health Sciences Center. Dr. Dahlbeck has also patented, manufactured, and commercialized IP and has more than a decade of experience in medical and oncology commerce. Dr. Dahlbeck earned an MD from the University of Texas Health Science Center at Houston, completed residencies in family practice and radiation oncology, and earned a PharmD degree from the University of Nebraska Medical Center, College of Pharmacy.

Gianluca Rotino. Mr. Rotino has served as our Chief Strategy and Innovation Officer and as a member of our board of directors since January 2014. Prior to that, he served in various other senior positions, including Chief Business Officer and Executive VP of Corporate Development. Mr. Rotino is a seasoned business executive with experience in corporate strategy, business development, and capital fund raising. Mr. Rotino held positions as both CEO and Chairman of the Board for several Italian companies. His previous experience includes senior level managerial positions for companies in Italy in different fields, such as high tech, international development and corporate consulting. Mr. Rotino also worked in several law firm in Milan, Italy, where he specialized in mergers, acquisitions, intellectual property, and corporate law. Mr. Rotino earned his Business Development Degree in Pharma from the EBD Academy in London, UK, and a B.S. by EBD Group and Pharmaceutical Training International (PTI). He has also completed course work for drug discovery, development and commercialization provided by The University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences Drug Development. Mr. Rotino as earned his BA in Electronics at the Institute of Technology Feltrinelli in Milan. Mr. Rotino was selected to serve on our board of directors due to his tenure with our company and his corporate strategy, business development, and capital fund raising experience.

Pietro Bersani, CPA, JD. Mr. Bersani has served as a member of our board of directors since June 2020. Since April 2020, Mr. Bersani is a Partner with B2B CFO Partners, LLC, which provides strategic management advisory services to owners of privately held companies. During October 2016 and July 2018, he served as the President, and Chief Executive Officer at K.P. Diamond Eagle, Inc., a consulting firm specialized in development of innovative commercial and private aviation business models. He also held the same positions at K.P. Diamond Eagle, Inc. between November 2019 and March 2020. He later served as a Senior Director within Alvarez & Marsal's Private Equity Performance Improvement Practice, LLP between August 2018 and October 2019. Prior to those professional experiences, Mr. Bersani served as the Chief Financial Officer of Fuel Systems Solutions, Inc. between April 2011 and October 2016.

Mr. Bersani is a Certified Public Accountant and is also a Certified Public Auditor and a Chartered Certified Accountant in Italy where he developed a significant knowledge of US GAAP and IFRS. Mr. Bersani earned a BA and MA in Business Economics from L. Bocconi University, Italy. Mr. Bersani was designated by certain holders of our Series B Preferred Stock. Except for the foregoing, there is no arrangement or understanding between any director or executive officer and any other person pursuant to which he was or is to be selected as a director.

Americo Cicchetti, PhD. Dr. Cicchetti has served as a member of our board of directors since March 2020. Dr. Cicchetti has served as a Professor of Management at Università Cattolica del Sacro Cuore, Faculty of Economics, Rome since 2006. He is also currently the Director of the Graduate School of Health Economics and Management at Università Cattolica del Sacro Cuore.

In addition to his academic experience, Dr. Cicchetti was a member of the Price and Reimbursement Committee of the Italian National Drug Agency from 2009-2015.

He is a member of the European Network of Health Technology Assessment; Member of the Innovation Steering Group of the National HTA Program for Medical Devices (Ministry of Health, Italy); Member of the National Immunization Technical Advisory Group at the Ministry of Health, Italy since 2019; Member of the Health and Research Commission of the Rome Foundation since 2007; and a Member of the Board of Directors of the Health and Research Foundation since 2017.

Furthermore, Dr. Cicchetti is the Chief Executive Officer and Director for Molipharma, whose core business is the research and development of new drugs and diagnostics aimed at predicting, detecting and treating female oncological diseases. He also serves as an independent board member for Foundation Health and Research, and Leonida SICAF, a fixed capital investment company. He obtained his PhD in Management from University of Bologna, and his B.A. from University of Rome. Dr. Cicchetti was selected to serve on the board due to his industry experience.

Michael Nagel. Mr. Nagel has been nominated to serve on our board of directors. He has over 30 years of sales and marketing experience in the medical device industry. Since 2012, Mr. Nagel has served as the President and CEO of Vomaris Innovations, Inc, which specializes in wireless microcurrent-generating technologies that are focused on regeneration, healing, and recovery. Previously, Mr. Nagel served as the Chief Commercial Officer of Neomend, a biomaterial company that developed ProGel, a PMA approved surgical sealant for lung surgery. From 1997 to 2005, Mr. Nagel also served as Co-Founder and Vice President of Worldwide Sales and Marketing at Vascular Solutions (VASC).

In addition to Mr. Nagel's executive experience, he also serves as a director for Franklin Mountain Medical, LLC an early stage company in the structural heart market. Mr. Nagel holds both a B.A. in Business and a M.B.A. from the University of St. Thomas. Mr. Nagel was selected to serve on the board of directors due to his industry experience.

Jerry Schneider. Mr. Schneider has been nominated to serve on our board of directors. He has been an independent business and financial consultant since 2014. From 2004 to 2013, he was the Chief Financial Officer of Vistage International, a private equity-owned CEO peer-advisory membership company with over 20,000 global members. Prior to Vistage, Mr. Schneider spent seven years at Fresenius Medical Care—North America in Boston, a global dialysis service and products company owned by Fresenius Medical Care, a German publicly DAX traded company, where he served as Chief Financial Officer and later as Senior Vice President of Strategic Planning. Between 1994 and 1997, Mr. Schneider was the Executive Vice President and Chief Financial Officer of then NYSE publicly held GranCare, Inc. (GC), a healthcare company in the long-term care, assisted living and institutional pharmacy business. He currently serves on the board of directors and audit committee for Cognex, a provider of vision systems, software, sensors, and industrial barcode readers used in manufacturing automation since 2016. Cognex (CGNX) is publicly traded on the Nasdaq stock exchange. He serves on other for-profit and non-profit boards. Mr. Schneider received his Juris Doctor from Loyola Law School, and a B.S. in Accounting from the University of California at Berkeley. He has experience of being a "financial expert" appointed by the U.C. Regents which oversee the University of California's budget of over $30M. In addition to his business and financial experience, Mr. Schneider was selected to serve on the board of directors due to his being an audit committee "financial expert" under the SEC regulations.

Family Relationships

Mr. Rotino is Dr. Chiriva Internati's nephew. There are no other family relationships among any of our officers or directors.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our directors or executive officers were involved in any legal proceedings described in Item 401(f) of Regulation S-K in the past ten years.

Corporate Governance

Governance Structure

Currently, our Chief Executive Officer is also our Chairman. Our board believes that, at this time, having a combined Chief Executive Officer and Chairman is the appropriate leadership structure for our company. In making this determination, the board considered, among other matters, Dr. Chiriva Internati's tenure, having served with our company since 2012, and his industry experience. Among the benefits of a combined Chief Executive Officer/Chairman considered by the board is that such structure promotes clearer leadership and direction for our company and allows for a single, focused chain of command to execute our strategic initiatives and business plans.

The Board's Role in Risk Oversight

The board of directors oversees that the assets of our company are properly safeguarded, that the appropriate financial and other controls are maintained, and that our business is conducted wisely and in compliance with applicable laws and regulations and proper governance. Included in these responsibilities is the board's oversight of the various risks facing our company. In this regard, our board seeks to understand and oversee critical business risks. Our board does not view risk in isolation. Risks are considered in virtually every business decision and as part of our business strategy. Our board recognizes that it is neither possible nor prudent to eliminate all risk. Indeed, purposeful and appropriate risk-taking is essential for our company to be competitive on a global basis and to achieve its objectives.

While the board oversees risk management, company management is charged with managing risk. Management communicates routinely with the board and individual directors on the significant risks identified and how they are being managed. Directors are free to, and indeed often do, communicate directly with senior management.

Our board administers its risk oversight function as a whole by making risk oversight a matter of collective consideration. Once the board establishes committees, it is anticipated that much of the work will be delegated to such committees, which will meet regularly and report back to the full board. It is anticipated that the audit committee will oversee risks related to our financial statements, the financial reporting process, accounting and legal matters, that the compensation committee will evaluate the risks and rewards associated with our compensation philosophy and programs, and that the nominating and corporate governance committee will evaluate risk associated with management decisions and strategic direction.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his background, employment and affiliations, our board of directors has determined that Messrs. Bersani, Cicchetti, Nagel and Schneider do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of The Nasdaq Capital Market. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Person Transactions."

Committees of the Board of Directors

Our board has established an audit committee, a compensation and nominating and corporate governance committee, each with its own charter that has been approved by the board. Upon completion of this offering, we intend to make each committee's charter available on our website at www.kiromic.com.

Until such committees are established, our entire board of directors will undertake the functions that would otherwise be undertaken by the committees. In addition, our board of directors may, from time to time, designate one or more additional committees, which shall have the duties and powers granted to it by our board of directors.

Audit Committee

The members of our audit committee are Jerry Schneider, Michael Nagel, and Americo Cicchetti. Jerry Schneider serves as chairperson of the committee. All members of our audit committee meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable rules of Nasdaq Capital Market, or the Nasdaq rules. Our board of directors has determined that Jerry Schneider is an audit committee financial expert, as defined by the rules of the SEC, and satisfies the financial sophistication requirements of the Nasdaq rules.

The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company.

The audit committee will be responsible for, among other things: (i) retaining and overseeing our independent registered public accounting firm; (ii) assisting the board in its oversight of the integrity of our financial statements, the qualifications, independence and performance of our independent registered public accounting firm and our compliance with legal and regulatory requirements; (iii) reviewing and approving the plan and scope of the internal and external audit; (iv) pre-approving any audit and non-audit services provided by our independent registered public accounting firm; (v) approving the fees to be paid to our independent registered public accounting firm; (vi) reviewing with our chief executive officer and chief financial officer and independent registered public accounting firm the adequacy and effectiveness of our internal controls; (vii) reviewing hedging transactions; and (viii) reviewing and assessing annually the audit committee's performance and the adequacy of its charter.

Compensation Committee

The members of our compensation committee are Michael Nagel, Jerry Schneider, and Americo Cicchetti. Michael Nagel serves as the chairperson of the committee. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers.

The compensation committee will be responsible for, among other things: (i) reviewing and approving the remuneration of our executive officers; (ii) reviewing the compensation of our independent directors; (iii) making recommendations to the board regarding equity-based and incentive compensation plans, policies and programs; and (iv) reviewing and assessing annually the compensation committee's performance and the adequacy of its charter.

Nominating and Corporate Governance Committee

The members of our nominating and governance committee are Michael Nagel and Jerry Schneider. Michael Nagel serves as the chairperson of the committee. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees.

The nominating and corporate governance committee will be responsible for, among other things: (i) identifying and evaluating individuals qualified to become members of the board by reviewing nominees for election to the board submitted by stockholders and recommending to the board director nominees for each annual meeting of stockholders and for election to fill any vacancies on the board, (ii) advising the board with respect to board organization, desired qualifications of board members, the membership, function, operation, structure and composition of committees (including any committee authority to delegate to subcommittees), and self-evaluation and policies, (iii) advising on matters relating to corporate governance and monitoring developments in the law and practice of corporate governance, (iv) overseeing compliance with our code of ethics, and (v) approving any related party transactions.

The nominating and corporate governance committee's methods for identifying candidates for election to our board of directors (other than those proposed by our stockholders, as discussed below) will include the solicitation of ideas for possible candidates from a number of sources—members of our board of directors, our executives, individuals personally known to the members of our board of directors, and other research. The nominating and corporate governance committee may also, from time-to-time, retain one or more third-party search firms to identify suitable candidates.

In making director recommendations, the nominating and corporate governance committee may consider some or all of the following factors: (i) the candidate's judgment, skill, experience with other organizations of comparable purpose, complexity and size, and subject to similar legal restrictions and oversight; (ii) the interplay of the candidate's experience with the experience of other board members; (iii) the extent to which the candidate would be a desirable addition to the board and any committee thereof; (iv) whether or not the person has any relationships that might impair his or her independence; and (v) the candidate's ability to contribute to the effective management of our company, taking into account the needs of our company and such factors as the individual's experience, perspective, skills and knowledge of the industry in which we operate.

Code of Ethics

We have adopted a code of ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. Such code of ethics addresses, among other things, honesty and ethical conduct, conflicts of interest, compliance with laws, regulations and policies, including disclosure requirements under the federal securities laws, and reporting of violations of the code. Upon our listing on the Nasdaq Capital Market, our code of business conduct and ethics will be available under the Corporate Governance section of our website.

We are required to disclose any amendment to, or waiver from, a provision of our code of ethics applicable to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions. We intend to use our website as a method of disseminating this disclosure, as permitted by applicable SEC rules. Any such disclosure will be posted to our website within four business days following the date of any such amendment to, or waiver from, a provision of our code of ethics.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning all cash and non-cash compensation awarded to, earned by or paid to the named persons for services rendered in all capacities during the noted periods. No other executive officers received total annual salary and bonus compensation in excess of $100,000.

Name and Principal Position	Year	Salary ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Maurizio Chiriva Internati,	2019	280,000	—	—	280,000
Chief Executive Officer(1)	2018	280,000	—	—	280,000
Tony Tontat,	2019	—	—	67,500	67,500
Chief Operating Officer and Chief Financial Officer(2)	2018	—	454,064	22,500	476,564
Scott Dahlbeck,	2019	—	—	187,000	187,000
Chief Medical Officer(3)	2018	110,000	—	12,500	122,500

(1) Of the salaries owed to Dr. Chiriva Internati, $280,000 and $160,200 was paid in 2019 and 2018, respectively. The difference in 2018 were accrued and paid to Dr. Chiriva Internati as a lump sum in September of 2019.

(2) The amount included in option awards represents the aggregate grant date fair value for options granted to Mr. Tontat computed in accordance with FASB ASC Topic 718. All Other Compensation includes the consulting fees paid to Mr. Tontat under his consulting agreement.

(3) Dr. Dahlbeck's compensation structure was changed from salary to a consulting agreement in November 2018. Other compensation includes the consulting fees paid to Dr. Dahlbeck under his consulting agreement, and reimbursement for corporate housing expenses.

Employment Agreements

Maurizio Chiriva Internati

We entered into an employment agreement with Maurizio Chiriva Internati, our Chief Executive Officer that set forth the terms and conditions of his employment with us. The agreement will be effective upon the completion of the initial public offering. The employment agreement establishes an annual base salary of $504,000, which is subject to our discretionary review and adjustment in accordance with our policies, procedures and practices as they may exist from time to time.

Dr. Chiriva Internati will also receive annual stock compensation with a fair market value totaling $499,200. To account for this, on June 19, 2020, the Board of Directors granted Dr. Chiriva Internati 26,274 restricted stock units with a grant date fair value of $19.00 per share, with a quarterly vesting schedule over twelve months. In addition, Dr. Chiriva Internati's employment agreement entitled him to 355,262 restricted stock units which were granted by the Board of Directors on June 19, 2020 with a grant date fair value of $19.00 per share. The restricted stock units vest upon achievement of certain corporate milestones which were approved by the Board of Directors on June 19, 2020.

Dr. Chiriva Internati is also eligible to receive a target bonus at the rate of 40%-50% indexed to the achievement of corporate goals and achievements to be determined by the Board of Directors. Dr. Chiriva Internati is eligible to participate in all medical, personal leave and other employee benefit plans and programs for which he is eligible, subject to the terms and conditions of such plans and programs. We will also reimburse Dr. Chiriva Internati for any attorney's fees in connection with his

employment agreement up to $10,000. In the event of involuntary termination, Dr. Chiriva-Internati is eligible for 24 months of severance pay and immediate vesting of all stock options outstanding on the date of termination. Dr. Chiriva Internati's employment is "at will" and may be terminated by us or Mr. Rotino at any time and for any reason.

Tony Tontat

We entered into an employment agreement with Tony Tontat, our Chief Financial Officer and Chief Operating Officer that set forth the terms and conditions of his employment with us. The agreement will be effective upon the completion of the initial public offering. The employment agreement establishes an annual base salary of $300,000, which is subject to our discretionary review and adjustment in accordance with our policies, procedures and practices as they may exist from time to time.

Mr. Tontat will also receive annual stock compensation with a fair market value totaling $300,000. On June 19, 2020, the Board of Directors granted him 15,790 restricted stock units with a grant date fair value of $19.00 per share, with a quarterly vesting schedule over twelve months. In addition, Mr. Tontat's employment agreement entitled him to 139,213 restricted stock units which were granted by the Board of Directors on June 19, 2020. The restricted stock units vest upon achievement of certain corporate milestones which were approved by the Board of Directors on June 19, 2020. Finally, the Board of Directors issued Mr. Tontat 402,000 shares of common stock on June 19, 2020 in exchange for services rendered.

Mr. Tontat is also eligible to receive a target bonus at the rate of 40%-50% indexed to the achievement of corporate goals and achievements to be determined by the Board of Directors. Mr. Tontat is eligible to participate in all medical, personal leave and other employee benefit plans and programs for which he is eligible, subject to the terms and conditions of such plans and programs. We will also reimburse Mr. Tontat for any attorney's fees in connection with his employment agreement up to $10,000. In addition, in the event of involuntary termination, Mr. Tontat is eligible for 24 months of severance pay and immediate vesting of all stock options outstanding on the date of termination. Mr. Tontat's employment is "at will" and may be terminated by us or Mr. Tontat at any time and for any reason.

Scott Dahlbeck

On January 1, 2020, we entered into an employment agreement with Dr. Scott Dahlbeck, our Chief Medical Officer that set forth the terms and conditions his employment with us. The employment agreement establishes an annual base salary of $120,000, which is subject to our discretionary review and adjustment in accordance with our policies, procedures and practices as they may exist from time to time. Dr. Dahlbeck will also receive annual stock compensation with a fair market value totaling $245,000 based on stock grants approved by the Board of Directors. In addition, Dr. Dahlbeck's employment agreement entitled him to 14,311 stock options which was granted by the board of directors on June 8, 2020. Dr. Dahlbeck is also eligible to receive a target bonus at the rate of 35% indexed to the achievement of corporate goals and achievements to be determined by the Board of Directors. Dr. Dahlbeck is eligible to participate in all medical, personal leave and other employee benefit plans and programs for which he is eligible, subject to the terms and conditions of such plans and programs. We also reimburse Dr. Dahlbeck for corporate housing, and we reimbursed him for $0 and $4,200 in 2018 and 2019, respectively. Dr. Dahlbeck's employment is "at will" and may be terminated by us or Dr. Dahlbeck at any time and for any reason.

Gianluca Rotino

We entered into an employment agreement with Gianluca Rotino, our Chief Strategy and Innovation Officer that set forth the terms and conditions of his employment with us. The agreement will be

effective upon completion of the initial public offering. The employment agreement establishes an annual base salary of $300,000, which is subject to our discretionary review and adjustment in accordance with our policies, procedures and practices as they may exist from time to time.

Mr. Rotino will also receive annual stock compensation with a fair market value totaling $312,000. To account for this, on June 19, 2020, the Board of Directors granted Mr. Rotino 16,422 restricted stock units with a grant date fair value of $19.00 per share, with a quarterly vesting schedule over twelve months. In addition, Mr. Rotino's employment agreement entitled him to 139,213 restricted stock units which were granted by the Board of Directors on June 19, 2020 with a grant date fair value of $19.00 per share. The restricted stock units vest upon achievement of certain corporate milestones which were approved by the Board of Directors on June 19, 2020. Finally, the Board of Directors issued Mr. Rotino 320,000 shares of common stock on June 19, 2020 in exchange for past services rendered.

Mr. Rotino is also eligible to receive a target bonus at the rate of 40%-50% indexed to the achievement of corporate goals and achievements to be determined by the Board of Directors. Mr. Rotino is eligible to participate in all medical, personal leave and other employee benefit plans and programs for which he is eligible, subject to the terms and conditions of such plans and programs. We will also reimburse Mr. Rotino for any attorney's fees in connection with his employment agreement up to $10,000. In the event of involuntary termination, Mr. Rotino is eligible for 24 months of severance pay and immediate vesting of all stock options outstanding on the date of termination. Mr. Rotino's employment is "at will" and may be terminated by us or Mr. Rotino at any time and for any reason.

Outstanding Equity Awards at Fiscal Year-End

The following table includes certain information with respect to the value of all unexercised options and unvested shares of restricted stock previously awarded to the executive officers named above at the fiscal year ended December 31, 2019.

	OPTION AWARDS				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Maurizio Chiriva Internati	—	—	—	—	—
Tony Tontat	8,587	—	—	$ 6.64	11/10/2027
	28,621	—	28,620(1)	$ 11.88	03/13/2028
Scott Dahlbeck	—	—	—	—	—

(1) 25% of the options vested on the one year anniversary of the vesting start date (December 15, 2017). Another 25% of the options vested on the two year anniversary of the vesting start date with the remaining 28,621 options vesting annually until December 15, 2021. 14,311 options will vest on December 15, 2020 and 14,310 options will vest on December 15, 2021.

Director Compensation

No member of our board of directors received any compensation for his services as a director during the fiscal year ended December 31, 2019.

We entered into Director Services agreements with our independent directors that set forth the terms and conditions of their services to us. The agreements will take effect when we complete the initial

public offering. The Director Services agreement establishes cash compensation in the amount of $25,000 annually, paid on a quarterly basis. Independent directors will also be reimbursed $2,500 per day if travel is required. In addition, if the independent director is on a committee, they will be entitled to $750 per meeting.

The independent directors will also receive annual stock compensation with a fair market value totaling $50,000. On June 19, 2020, the Board of Directors granted all independent directors 3,948 stock options, vesting on a quarterly basis over the next 12 months, at an exercise price of $19.00 per share.

2017 Equity Incentive Plan

On January 20, 2017, our board of directors adopted our 2017 Equity Incentive Plan, or the Plan. The following is a summary of certain significant features of the Plan. The information which follows is subject to, and qualified in its entirety by reference to, the Plan document itself, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Awards that may be granted include incentive stock options as described in section 422(b) of the Internal Revenue Code of 1986, as amended, non-qualified stock options (i.e., options that are not incentive stock options), stock appreciation rights, or SARs, and awards of restricted stock or restricted stock units, or RSUs. These awards offer our employees, consultants and directors the possibility of future value, depending on the long-term price appreciation of our common stock and the award holder's continuing service with our company or one or more of its subsidiaries.

All of the permissible types of awards under the Plan are described in more detail as follows:

Purposes of Plan: The purpose of the Plan is to offer selected employees, consultants and directors the opportunity to acquire equity in our company.

Administration of the Plan: Administration of the Plan is entrusted to the board of directors, which may delegate its duties and responsibilities to one or more committees. Among other things, the board or committee has the authority to select persons who will receive awards, determine the types of awards and the number of shares to be covered by awards, and to establish the terms, conditions, restrictions and other provisions of awards.

Eligible Recipients: Persons eligible to receive awards under the Plan will be those employees, consultants and directors of our company and its subsidiaries who are selected by the board or committee.

Shares Available Under the Plan: The maximum number of shares of common stock that may be delivered to participants under the Plan is 1,708,615, subject to adjustment for certain corporate changes affecting the shares, such as stock splits. Shares subject to an award under the Plan for which the award is canceled, forfeited or expires again become available for grants under the Plan. Shares subject to an award that is settled in cash will not again be made available for grants under the Plan.

Stock Options:

General. Subject to the provisions of the Plan, the board or committee has the authority to determine all grants of stock options. That determination will include: (i) the number of shares subject to any option; (ii) the exercise price per share; (iii) the expiration date of the option; (iv) the manner, time and date of permitted exercise; (v) other restrictions, if any, on the option or the shares underlying the option; and (vi) any other terms and conditions as the compensation committee may determine.

Option Price. The exercise price for stock options will be determined at the time of grant. Normally, the exercise price will not be less than the fair market value on the date of grant, as determined in good faith by the board or committee. As a matter of tax law, the exercise price for any incentive stock

option awarded may not be less than the fair market value of the shares on the date of grant. However, incentive stock option grants to any person owning more than 10% of our voting stock must have an exercise price of not less than 110% of the fair market value on the grant date.

Exercise of Options. An option may be exercised only in accordance with the terms and conditions for the option agreement as established by the board or committee at the time of the grant. The option must be exercised by notice to us, accompanied by payment of the exercise price. Payments may be made in cash or, at the option of the board or committee, by actual or constructive delivery of shares of common stock to the holder of the option based upon the fair market value of the shares on the date of exercise.

Expiration or Termination. Options, if not previously exercised, will expire on the expiration date established by the board or committee at the time of grant; provided that such term cannot exceed ten years and that such term of an incentive stock option granted to a holder of more than 10% of our voting stock cannot exceed five years. Options will terminate before their expiration date if the holder's service with us terminates before the expiration date. The option may remain exercisable for specified periods after certain terminations of service, including terminations as a result of death, disability or retirement, with the precise period during which the option may be exercised to be established by the board or committee and reflected in the grant evidencing the award.

SARs. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The board or committee will determine the number of shares covered by SAR, the exercise price of each SAR and the conditions and limitations applicable to the exercise of each SAR. The term of a SAR may not be longer than ten years.

Restricted Stock and RSUs. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. The board or committee may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the board or committee, subject to the conditions and limitations contained in the Plan.

Other Material Provisions: Awards will be evidenced by a written agreement, in such form as may be approved by the board or committee. In the event of various changes to the capitalization of our company, such as stock splits, stock dividends and similar re-capitalizations, an appropriate adjustment will be made by the board or committee to the number of shares covered by outstanding awards or to the exercise price of such awards. The board or committee is also permitted to include in the written agreement provisions that provide for certain changes in the award in the event of a change of control of our company, including acceleration of vesting.

Except as otherwise determined by the board or committee at the date of grant, awards will not be transferable, other than by will or the laws of descent and distribution. Prior to any award distribution, we are permitted to deduct or withhold amounts sufficient to satisfy any employee withholding tax requirements. The board also has the authority, at any time, to discontinue the granting of awards. The board also has the authority to alter or amend the Plan or any outstanding award or may terminate the Plan as to further grants, provided that no amendment will, without the approval of our stockholders, increase the number of shares available under the Plan or change the persons eligible for awards under the Plan. No amendment that would adversely affect any outstanding award made under the Plan can be made without the consent of the holder of such award.

Except as set forth above, we do not have any ongoing plan or arrangement for the compensation of directors and executive officers.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our voting stock as of October 6, 2020, and as adjusted to reflect the sale of common stock offered by us and the selling stockholders in our initial public offering, for:

- each of our named executive officers directors, and director nominees;
- all of our named executive officers directors, and director nominees as a group; and
- each other stockholder known by us to be the beneficial owner of more than 5% of the outstanding shares of our voting stock.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares that they beneficially own, subject to applicable community property laws. Unless otherwise indicated in the footnotes below, based on the information provided to us by or on behalf of the selling stockholders, no selling stockholder is a broker-dealer or an affiliate of a broker-dealer.

Applicable percentage ownership is based on 6,082,999 shares of common stock outstanding at October 6, 2020 assuming the Preferred Stock Conversions. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options or other convertible securities held by that person or entity that are currently exercisable or releasable or that will become exercisable or releasable within 60 days of October 6, 2020. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. No holder of our Series A-1 Preferred Stock holds more than 5% of the outstanding shares of our voting stock before or after this offering. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o our company, 7707 Fannin, Suite 140, Houston, TX 77054.

	Number of Shares Beneficially Owned Prior to Offering (As Converted)	Percentage of Common Stock Beneficially Owned	
		Before Offering	After Offering
Name of the Beneficial Owner			
Maurizio Chiriva-Internati	1,375,272	22.61%	18.75%
Tony Tontat(1)	453,519	7.39%	5.82%
Scott Dahlbeck(2)	443,828	7.28%	6.05%
Gianluca Rotino(3)	467,806	7.51%	6.00%
Americo Cicchetti(4)	5,278	*	*
Michael Nagel(4)	2,639	*	*
Jerry Schneider(4)	2,639	*	*
Pietro Bersani(4)	3,959	*	*
All executive officers, directors and director nominees (8 persons named above)	2,754,940	45.03%	36.83%
Other 5% Stockholders:			
Angelo Minotti(5)	1,358,861	22.34%	18.53%
Jose A. Figueroa(6)	478,912	7.87%	6.53%
Jui-Lien Chou Ho(7)	402,109	6.51%	5.48%

* Less than 1%

(1) Contains 51,519 options to purchase common stock which are exercisable within 60 days.

(2) Contains 14,311 options to purchase common stock which are exercisable within 60 days.

(3) Contains 147,806 options to purchase common stock which are exercisable within 60 days.

(4) Contains options to purchase common stock which are exercisable within 60 days.

(5) Includes 169,060 shares of Series B Preferred Stock held directly, 125,021 shares of Series B Preferred Stock held by Encap (Global) Asset Management Limited and 62,824 shares of Series B Preferred Stock held by Interactive Engineering EOOD. Mr. Minotti is the Investment Officer of Encap (Global) Asset Management Limited and Interactive Engineering EOOD and has voting and investment control over the shares held by them. Mr. Minotti disclaims beneficial ownership of the shares held by Encap (Global) Asset Management Limited and Interactive Engineering EOOD except to the extent of his pecuniary interest, if any, in such shares. The address of Encap (Global) Asset Management Limited is 12-S Sebright Plaza, 6-23 Shell Street, North Point, Hong Kong. The address of Interactive Engineering EOOD is 3 Prof. Milko Bichev, Fl 1, District of Oborishet, 1504 Sofia, Region of Sofia, Municipality of Sofia, Bulgaria.

(6) The address of Jose A. Figueroa is 4504 South Professional Drive, Apt 10208, Edinburg, TX 78539.

(7) The address of Jui-Lien Chou Ho is 4009 19th Street, Ste D, Lubbock, TX 79410.

TRANSACTIONS WITH RELATED PERSONS

Transactions with Related Persons

Through June 30, 2020, we maintained two separate consulting agreements with our Chief Strategy and Innovation Officer (the "CSO"), and our Chief Financial Officer and Chief Operating Officer (the "CFO and COO").

Beginning in the year ended December 31, 2014, we entered into our first consulting agreement with the CSO. Pursuant to the amended agreement dated July 20, 2018, the CSO is 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 our Chief Executive Officer. The consulting agreement indicates that the CSO will provide a leadership role for our business development strategies. The consulting fees paid to the CSO totaled $540,700 and $25,300 in the six months ended June 30, 2020 and 2019, respectively. In addition, we issued the CSO 320,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations. We have entered into an employment agreement with the CSO that set forth the terms and conditions of his employment with us. The agreement will take effect when we complete the initial public offering. The employment agreement establishes an annual base salary of $300,000.

Beginning in the year ended December 31, 2018, we entered into our first consulting agreement with the CFO and COO. Initially, his title was "Consultant", and we changed his title to CFO and COO on October 25, 2019. The CFO and COO was elected as a director 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. The consulting fees paid to the CFO and COO totaled $100,000 and $7,500 in the six months ended June 30, 2020 and 2019, respectively. In addition, we issued the CFO and COO 402,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations. We have entered into an employment agreement with the CFO and COO that set forth the terms and conditions of his employment with us. The agreement will take effect when we complete the initial public offering. The employment agreement establishes an annual base salary of $300,000.

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

On April 3, 2020, we entered into the Joint Venture with Molipharma. Molipharma was founded in part by one of our directors, Americo Cicchetti. Mr. Cicchetti is also the Chief Executive Officer and Director of Molipharma.

DESCRIPTION OF SECURITIES

General

The following description summarizes important terms of the classes of our capital stock. This summary does not purport to be complete and is qualified in its entirety by the provisions of our current certificate of incorporation, as amended, and our current bylaws, which have been filed as exhibits to the registration statement of which this prospectus is a part.

We are authorized to issue 300,000,000 shares of common stock, par value $0.001 per share, and 60,000,000 shares of preferred stock, $0.0001 par value per share, of which 24,000,000 shares have been designated as Series A-1 Preferred Stock and 16,500,000 have been designated as Series B Preferred Stock.

As of the date of this prospectus, there are 4,989,269 shares of common stock, 21,822,301 shares of Series A-1 Preferred Stock and 16,391,397 shares of Series B Preferred Stock issued and outstanding.

Common Stock

Voting Rights. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Under our certificate of incorporation and bylaws, any corporate action to be taken by vote of stockholders other than for election of directors shall be authorized by the affirmative vote of the majority of votes cast. Directors are elected by a plurality of votes. Stockholders do not have cumulative voting rights.

Dividend Rights. Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation Rights. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Other Rights. Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock.

Preferred Stock

21,822,301 shares of Series A-1 Preferred Stock and 16,391,397 shares of Series B Preferred Stock will automatically convert into 624,594 and 469,136 shares of common stock, respectively, upon the closing of this offering (the "Preferred Stock Conversion"). The below is a summary of the terms of the Preferred Stock prior to the offering.

Ranking. With respect to rights on liquidation, winding up and dissolution, shares of Series A-1 Preferred Stock and Series B Preferred Stock rank *pari passu* to each other and senior to all shares of common stock.

Voting Rights. Shares of preferred stock vote together with the holders of common stock on an as-converted basis on all matters for which the holders of common stock vote at any meeting of stockholders or act by written consent, except as required by law. Notwithstanding the foregoing, so long as at least twenty-five percent (25%) of the Series B Preferred Stock collectively remains outstanding, we may not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or our

certificate of incorporation) the written consent or affirmative vote of the holders of at least sixty-seven percent (67%) of the then outstanding shares of Series B Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a single class on an as-converted basis, which approval shall not be unreasonably withheld, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(a) the amend, alter or repeal any provision of our certificate of incorporation or bylaws in a manner adverse to the rights of the Series B Preferred Stock;

(b) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Series B Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of our company, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series B Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock unless the same ranks junior to the Series B Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of our company, the payment of dividends and rights of redemption;

(c) reclassify, alter or amend any security that is junior to the Series B Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of our company, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or *pari passu* with the Series B Preferred Stock in respect of any such right, preference or privilege;

(d) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of our capital stock other than dividends or other distributions payable on the common stock solely in the form of additional shares of common stock or repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for us or any subsidiary in connection with the cessation of such employment or service at a price per share and other terms approved by the board;

(e) increase or decrease the authorized number of directors constituting the board of directors;

(f) liquidate, dissolve or wind-up the business and affairs of our company, effect any merger or consolidation or any other deemed liquidation event (as defined in the certificate of incorporation), consummate any public offering of common stock pursuant to an effective registration statement under the Securities Act, or consent to any of the foregoing;

(g) grant any lien or security interest in our assets, other than (i) purchase money liens or statutory liens of landlords, mechanics, materialmen, workmen, warehousemen and other similarly persons arising in the ordinary course of business, (ii) security interests in trade accounts receivable arising in the ordinary course of business, (iii) grants in connection with lines of credit with financial institutions or equipment leases or (iv) with the prior approval of the board, including the director that was designated by the holders of the Series B Preferred Stock;

(h) elect to change our company's status as a C corporation for United States federal tax purposes;

(i) change our principal business, enter into a new line of business or exit our line of business as it existed on September 7, 2019 other than with the prior approval of the board, including the director that was designated by the holders of the Series B Preferred Stock; or

(j) enter into or be party to any transaction with any director, officer or employee of our company or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such person other than (i) transactions resulting in payments to or by us in an amount less than $100,000 per year, (ii) transactions made in the ordinary course of business and pursuant to

reasonable requirements of our business and on fair and reasonable terms that receive the prior approval of the board or (iii) with the prior approval of the board, including the director that was designated by the holders of the Series B Preferred Stock;

Dividend Rights. Holders of preferred stock shall be entitled to receive dividends equal, on an as-converted to common stock basis, to and in the same form as dividends actually paid on shares of common stock when, as and if such dividends are paid on shares of common stock. No other dividends shall be paid on shares of preferred stock.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our company or deemed liquidation event, the holders of shares of preferred stock then outstanding shall be entitled to be paid out of the assets of our 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 of preferred stock equal to the applicable original issue price ($17.47 and $16.07 for the Series A-1 Preferred Stock and Series B Preferred Stock, respectively), plus all accrued and unpaid dividends, if applicable, whether or not declared together with any other dividends declared but unpaid thereon. If upon any such liquidation, dissolution or winding up or deemed liquidation event, the assets of our company available for distribution to its stockholders shall be insufficient to pay the holders of shares of preferred stock the full amount to which they shall be entitled, the holders of shares of preferred stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. After the payment of all preferential amounts required to be paid to the holders of shares of preferred stock, the remaining assets available for distribution to stockholders shall be distributed among the holders of the shares of preferred stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock immediately prior to such liquidation, dissolution or winding up or deemed liquidation event. A "deemed liquidation event" means, unless otherwise determined by the holders of at least a sixty-seven percent (67%) of the Series B Preferred Stock then outstanding (voting separately as a class): (a) a merger or consolidation in which our company or a subsidiary is a constituent party and we issue shares pursuant to such merger or consolidation, except any such merger or consolidation in which our shares of capital stock outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (i) the surviving or resulting corporation; or (ii) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or (b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by our company or any subsidiary of all or substantially all the assets of our company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries if substantially all of the assets of our company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary.

Conversion Rights. Each share of 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 a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate. All shares of Series A-1 preferred stock or Series B Preferred Stock shall also be automatically converted into shares of common stock at then effective conversion rate upon the vote or written consent of the holders of at least sixty-seven percent (67%) of the then outstanding shares of Series A-1 Preferred Stock or Series B Preferred Stock, as

applicable, voting or consenting, as the case may be, as a single class and on an as-converted basis. The conversion rate for the preferred stock is currently .0286 shares of common stock for each share of preferred stock, calculated by dividing the original issue price of such share ($0.50 and $0.46 for the Series A-1 Preferred Stock and Series B Preferred Stock, respectively) by the conversion price per share then in effect (currently $17.47 and $16.07 for the Series A-1 Preferred Stock and Series B Preferred Stock, respectively), which is subject to customary adjustments in the event of any stock splits, stock dividends, mergers or reorganizations. Subject to certain exceptions, the conversion price is also subject to adjustment in the event that we issue additional shares of common stock or shares convertible into common stock.

Other Rights. Holders of preferred stock have no preemptive or subscription rights and there are no redemption or sinking fund provisions applicable to the preferred stock.

Investors Rights Agreement

In connection with the Series B Preferred Stock financing, on September 7, 2019, we entered into an investors' rights agreement with the investors, pursuant to which we provided the investors with certain demand registration rights. Pursuant to the investors' rights agreement and subject to certain exceptions set forth therein, if at any time after the earlier of (i) five (5) years after the date of the agreement; or (ii) one hundred eighty (180) days after the effective date of a registration statement for our initial underwritten public offering of our common stock under the Securities Act (which we refer to as an IPO), we receive a request from holders of at least fifty percent (50%) of the securities held by the investors (which we refer to as the registrable securities) then outstanding if prior to an IPO or at least twenty percent (20%) of the registrable securities then outstanding if after an IPO, that we file a Form S-1 registration statement with respect to registrable securities with an anticipated aggregate offering price, net of certain selling expenses, of not less than $10,000,000, then we must (x) within ten (10) days after the date such request is given, give notice thereof to all holders other than the initiating holders; and (y) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the initiating holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders. In addition, if we propose to register any of our securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in certain excluded registrations), we must, at such time, promptly give each holder notice of such registration. Upon the request of each holder given within twenty (20) days after such notice is given by us, we must cause to be registered all of the registrable securities that each such holder has requested to be included in such registration. The registrable securities are being registered in the registration statement of which this prospectus forms a part.

In addition, we agreed that we would not, without the prior written consent of the holders of not less than sixty- seven percent (67%) of the registrable securities then outstanding, enter into any agreement with any other holder or prospective holder of any securities of that would allow such holder or prospective holder (i) to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the registrable securities of the Series B investors that are included, or (ii) to initiate a demand for registration of any securities held by such holder or prospective holder; provided that this limitation shall not apply to any additional Series B investor who becomes a party to the investors' rights agreement.

Warrants

As of the date of the prospectus, there are no warrants outstanding.

Options

As of the date of this prospectus, there are options for the purchase of 618,510 shares of common stock outstanding under our 2017 Equity Incentive Plan with a weighted average exercise price of $11.58 per share.

Restricted Stock Units

As of the date of this prospectus, there are 946,245 shares of common stock issuable upon the vesting of restricted stock units with a weighted-average grant date fair value of $14.21 per share.

Transfer Agent and Registrar

We have appointed VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598, telephone 212-828-8436, as the transfer agent for our common stock.

Anti-Takeover Effects of Provisions of Delaware State Law

Our Fourth Amended and Restated Certificate of Incorporation and our Second Amended and Restated Bylaws, both to be in effect immediately following this offering, or our certificate of incorporation and our bylaws, include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our board of directors or management team, including the following:

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.

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have 7,332,999 shares of common stock issued and outstanding. All of the shares sold in this offering will be freely transferable without restriction under the Securities Act unless purchased by one of our affiliates as that term is defined in Rule 144 under the Securities Act, which generally includes directors, executive officers and 10% stockholders. Sales of substantial amounts of our shares in the public market could adversely affect prevailing market prices of our shares.

All outstanding shares prior to this offering are "restricted securities" as that term is defined in Rule 144 and may be sold only if they are sold pursuant to an effective registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act such as those provided in Rules 144 and 701 promulgated under the Securities Act, which rules are summarized below. Restricted shares may also be sold outside of the United States in accordance with Regulation S under the Securities Act. This prospectus may not be used in connection with any resale of our shares acquired in this offering by our affiliates.

Rule 144

In general, under Rule 144 of the Securities Act, a person or entity that has beneficially owned our common stock for at least six months and is not our "affiliate" will be entitled to sell our common stock, subject only to the availability of current public information about us, and will be entitled to sell shares held for at least one year without any restriction. A person or entity that is our "affiliate" and has beneficially owned our common stock for at least six months will be able to sell, within a rolling three month period, the number of shares that does not exceed the greater of the following:

(i) 1% of the then outstanding common stock, which immediately after this offering will equal approximately 73,330 shares if the maximum number of shares being offered by us are sold and all shares of Preferred Stock are converted to common stock; and

(ii) the average weekly trading volume of our common stock on the Nasdaq Capital Market during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by affiliates under Rule 144 must be made through unsolicited brokers' transactions. They are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees, directors or consultants who purchases our common stock from us pursuant to a compensatory stock or option plan or other written agreement relating to compensation is eligible to resell such common stock 90 days after we become a reporting company under the Exchange Act in reliance on Rule 144, but without compliance with some of the restrictions, such as the holding period, contained in Rule 144. However, the Rule 701 shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE COMPANY'S COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of the Company's common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. No ruling on the U.S. federal, state, or local tax considerations relevant to the Company's operations or to the purchase, ownership or disposition of its shares, has been requested from the IRS or other tax authority. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences described below.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions, regulated investment companies or real estate investment trusts;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of the Company's capital stock (except to the extent specifically set forth below);
- US expatriates and certain former citizens or long-term residents of the United States;
- partnerships or entities classified as partnerships for U.S. federal income tax purposes or other pass- through entities (and investors therein);
- persons who hold the Company's common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive the Company's common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who do not hold the Company's common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code; or
- persons deemed to sell the Company's common stock under the constructive sale provisions of the Internal Revenue Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds the Company's common stock, the tax treatment of a partner generally will depend on the status

of the partner and upon the activities of the partnership. Accordingly, partnerships that hold the Company's common stock, and partners in such partnerships, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of the Company's common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder (other than a partnership) if you are any holder other than:

- an individual citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more "U.S. persons" (within the meaning of Section 7701(a)(30) of the Internal Revenue Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person

Distributions

As described in "Dividend Policy," the Company has never declared or paid cash dividends on its common stock and does not anticipate paying any dividends on its common stock in the foreseeable future. However, if the Company does make distributions on its common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from the Company's current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both the Company's current and its accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in the Company's common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "—Gain on Disposition of common stock."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to a non-U.S. holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, a non-U.S. holder must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E, or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of the Company's common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to the Company or its paying agent, either directly or through other intermediaries.

Dividends received by a non-U.S. holder that are effectively connected with such non-U.S. holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by a non-U.S. holder in the United States) are generally exempt from the withholding tax described above. In order to obtain this exemption, a non-U.S. holder must

provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if a non-U.S. holder is a corporate non-U.S. holder, dividends received by such non-U.S. holder that are effectively connected with such non-U.S. holder's conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of the Company's common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by such non-U.S. holder in the United States);
- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by such non-U.S. holder in the United States);
- the non-U.S. holder's are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or
- the Company's common stock constitutes a United States real property interest by reason of its status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period preceding the non-U.S. holder's disposition of the Company's common stock, or (ii) the non-U.S. holder's holding period for its common stock.

The Company believes that it is not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether it is a USRPHC depends on the fair market value of its U.S. real property relative to the fair market value of its other business assets, there can be no assurance that the Company will not become a USRPHC in the future. Even if it becomes a USRPHC, however, as long as the Company's common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if the non-U.S. holder's actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of (i) the five-year period preceding the non-U.S. holder's disposition of the Company's common stock, or (ii) the non-U.S. holder's holding period for the Company's common stock.

Gains described in the first bullet point above, generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. An individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, the Company must report annually to the IRS, regardless of whether any tax was withheld, the amount of dividends paid to a non-U.S. holder, the non-U.S. holder's name and address and the amount of tax withheld, if any. A similar report will be sent to the non-U.S. holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in the non-U.S. holder's country of residence.

Payments of dividends or of proceeds on the disposition of stock made to a non-U.S. holder may be subject to information reporting and backup withholding at a current rate of 24% unless such non-U.S. holder establishes an exemption, for example, by properly certifying such non-U.S. holder's non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E, or another appropriate version of IRS Form W-8.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act, or FATCA, imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of the Company's common stock paid to "foreign financial institutions" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of the Company's common stock paid to a "non-financial foreign entity" (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of the Company's common stock on or after January 1, 2019. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in the Company's common stock.

Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of the Company's common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

ThinkEquity, a division of Fordham Financial Management, Inc. ("ThinkEquity") is acting as representative of the underwriters of this offering. We have entered into an underwriting agreement dated October 15, 2020 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase from us, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of common shares listed next to its name in the following table:

Underwriter	Number of Shares
ThinkEquity, a division of Fordham Financial Management, Inc	919,000
Paulson Investment Company, LLC	331,000
Total	1,250,000

The underwriters are committed to purchase all shares offered by us other than those covered by the over- allotment option described below, if any are purchased. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

The underwriters are offering the shares subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters propose to offer the shares offered by us to the public at the public offering price set forth on the cover of the prospectus. After the shares are released for sale to the public, the underwriters may change the offering price and other selling terms at various times.

Over-Allotment Option

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the representative to purchase a maximum of 187,500 additional shares of common stock (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the representative exercises all or part of this option, it will purchase shares covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be $12.00 and the total net proceeds, before expenses, to us will be $14,747,800.

Discount

The following table shows the public offering price, underwriting discounts and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	$ 12.00	$ 15,000,000	$ 17,250,000
Underwriting discount (7.5%)	$ 0.90	$ 1,125,000	$ 1,293,800
Proceeds, before expense, to us	$ 11.10	$ 13,875,000	$ 15,956,200

We have agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering (excluding proceeds received from exercise of the underwriters' over-allotment option).

We have paid an expense deposit of $35,000 to the representative for out-of-pocket-accountable expenses, which will be returned to us to the extent such out-of-pocket accountable expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

In addition, we have agreed to reimburse the representative for fees and expenses of legal counsel to the underwriters in an amount not to exceed $100,000, fees and expenses related to the use of book building, prospectus tracking and compliance software for the offering in the amount of $29,500, up to $15,000 for background checks of our officers and directors, $10,000 for data services and communications expenses, $3,000 for the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, and the out-of-pocket fees and expenses of the representative for marketing and roadshows for the offering not to exceed $20,000.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately $1,036,000.

Representative's Warrants

We have agreed to issue to the representative warrants to purchase up to a total of 62,500 shares of our common stock (the "Representative's Warrants"). The Representative's Warrants will be exercisable at a per share exercise price equal to 125% of the public offering price per share of the shares of common stock sold in this offering. The Representative's Warrants are exercisable at any time, from time to time, in whole or in part, during the four and one half year period commencing six months from the effective date of the registration statement related to this offering.

The Representative's Warrants and the shares of common stock underlying the Representative's Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to FINRA Rule 5110(g)(1). The Representative or permitted assignees under such rule may not sell, transfer, assign, pledge, or hypothecate the Representative's Warrants or the securities underlying the Representative's Warrants, nor will the representative engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Representative's Warrants or the underlying shares of common stock for a period of 180 days from the effective date of the registration statement. Additionally, the Representative's Warrants may not be sold, transferred, assigned, pledged, or hypothecated for a 180-day period following the effective date of the registration statement, except to any underwriter and selected dealer participating in the offering and their bona fide officers or partners. The Representative's Warrants will provide for adjustment in the number and price of the Representative's Warrants and the shares of common stock underlying the Representative's Warrants in the event of recapitalization, merger, stock split, or other structural transaction, or a future financing undertaken by us.

Discretionary Accounts

The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

Pursuant to certain "lock-up" agreements, we, our executive officers and directors and our stockholders, have agreed not to, without the prior written consent of the representative, offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole

or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, for a period of 12 months from the date of this prospectus, in the case of our directors and officers, and 6 months from the date of this prospectus, in the case of our other stockholders.

Right of First Refusal.

Subject to certain limited exceptions, until twelve (12) months after the closing of this initial public offering, ThinkEquity has a right of first refusal to act as sole investment banker, sole book-runner and/or sole placement agent, at ThinkEquity's sole discretion, for each and every future public and private equity and debt offering, including all equity-linked offerings, by us or any of our successors or subsidiaries during such 12-month period on terms customary to the representative.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities that underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over- allotted by the underwriters is not greater than the number of securities that they may purchase in the over- allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of

securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the Nasdaq Capital Market or on the OTCQB in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the securities and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

Certain of the underwriters and their affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they may receive customary fees and commissions. However, we have not yet had, and have no present arrangements with any of the underwriters for any further services.

Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport

to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area and the United Kingdom

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State") and the United Kingdom, from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State and the United Kingdom except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State and the United Kingdom:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societ-$$-Aga e la Borsa, "CONSOB" pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no.58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 1197l") as amended ("Qualified Investors"); and

- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980)

(Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company. In

the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering

LEGAL MATTERS

The validity of the shares of our common stock offered hereby will be passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, New York, New York. Venable, LLP, New York, New York has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

EXPERTS

The financial statements as of December 31, 2019 and 2018, and for each of the two years in the period ended December 31, 2019, included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement, of which this prospectus is a part, on Form S-1 with the SEC relating to this offering. This prospectus does not contain all of the information in the registration statement and the exhibits included with the registration statement. For further information pertaining to us and the common stock to be sold in this offering, you should refer to the registration statement and its exhibits. References in this prospectus to any of our contracts, agreements or other documents are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contracts, agreements or documents. You may read and copy the registration statement, the related exhibits and other material we file with the SEC at the SEC's public reference room in Washington, D.C. at 100 F Street, Room 1580, N.E., Washington, D.C. 20549. You can also request copies of those documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file with the SEC. The website address is http://www.sec.gov.

Upon the effectiveness of the registration statement, we will be subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be inspected and copied at the locations set forth above. We also anticipate making these documents publicly available, free of charge, on our website as soon as reasonably practicable after filing such documents with the SEC. Information on, or accessible through, our website is not part of this prospectus.

FINANCIAL STATEMENTS

KIROMIC BIOPHARMA, INC. AND SUBSIDIARY

AUDITED CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

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

April 6, 2020 (June 25, 2020, as to the effects of the reverse stock split described in notes 2 and 12)

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

Kiromic BioPharma, Inc. and Subsidiary

Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,929,100	$ 384,300
Unbilled receivables from granting agency	—	24,300
Inventories	22,200	16,300
Prepaid expenses and other current assets	89,100	135,300
Total current assets	2,040,400	560,200
Property and equipment, net	587,900	298,000
Other assets	24,400	17,800
Total Assets	$ 2,652,700	$ 876,000
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 452,400	$ 219,100
Accrued expenses and other current liabilities	221,300	372,600
Deferred rent, current portion	—	19,000
Total current liabilities	673,700	610,700
Total Liabilities	673,700	610,700
Commitments and contingencies (Note 7)		
Stockholders' Equity:		
Series A-1 Preferred Stock, $0.0001 par value: 24,000,000 shares authorized as of December 31, 2019 and 2018; 21,822,301 and 20,886,782 shares issued and outstanding as of December 31, 2019 and 2018, respectively	9,134,700	8,727,400
Series B Preferred Stock, $0.0001 par value: 14,130,435 shares authorized as of December 31, 2019; 9,869,659 shares issued and outstanding as of December 31, 2019	1,306,900	—
Preferred Stock, $0.0001 par value: 21,869,565 shares authorized as of December 31, 2019; 0 shares issued and outstanding as of December 31, 2019	—	—
Common stock: 300,000,000 shares authorized as of December 31, 2019 and 2018, respectively; 2,863,812 and 2,862,093 shares issued and outstanding as of December 31, 2019 and 2018, respectively	—	—
Additional paid-in capital	13,965,000	10,237,600
Accumulated deficit	(22,427,600)	(18,699,700)
Total Stockholders' Equity	1,979,000	265,300
Total Liabilities and Stockholders' Equity	$ 2,652,700	$ 876,000

See accompanying notes to the consolidated financial statements

Kiromic BioPharma, Inc. and Subsidiary

Consolidated Statements of Operations

	Years Ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 1,201,700	$ 1,424,900
General and administrative	2,503,700	1,757,700
Total operating expenses	3,705,400	3,182,600
Loss from operations	(3,705,400)	(3,182,600)
Other expense		
Interest expense	(22,500)	(633,100)
Other expense	(22,500)	(633,100)
Loss before income taxes	(3,727,900)	(3,815,700)
Income taxes	—	—
Net loss	$ (3,727,900)	$ (3,815,700)
Net loss per common share, basic and diluted	$ (1.39)	$ (1.33)
Weighted average common shares outstanding, basic and diluted	2,862,809	2,862,093
Pro forma net loss per common share, basic and diluted (unaudited)	$ (1.06)	
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)	3,532,917	

See accompanying notes to the consolidated financial statements

Kiromic BioPharma, Inc. and Subsidiary

Consolidated Statements of Changes in Stockholders' Equity

	Series A-1 Preferred Stock		Series B Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at January 1, 2018	—	$ —	—	$ —	2,862,093	$ —	$ 9,604,600	$ (14,884,000)	$(5,279,400)
Issuance of Series A-1 Preferred Stock	2,007,000	900,000	—	—	—	—	—	—	900,000
Conversion of convertible promissory notes and accrued interest into Series A-1 Preferred Stock	18,879,782	7,827,400	—	—	—	—	—	—	7,827,400
Stock compensation expense	—	—	—	—	—	—	633,000	—	633,000
Net loss	—	—	—	—	—	—	—	(3,815,700)	(3,815,700)
Balance at December 31, 2018	20,886,782	8,727,400	—	—	2,862,093	—	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	2,863,812	$ —	$13,965,000	$ (22,427,600)	$ 1,979,000

See accompanying notes to the consolidated financial statements

Kiromic BioPharma, Inc. and Subsidiary

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (3,727,900)	$ (3,815,700)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	87,500	80,900
Stock compensation expense	522,900	633,000
Non-cash interest	20,500	633,100
Changes in operating assets and liabilities:		
Unbilled receivables from granting agency	24,300	(18,900)
Inventories	(5,900)	—
Prepaid expenses and other current assets	46,200	212,500
Other assets	(6,600)	(3,000)
Accounts payable	293,400	(4,400)
Accrued expenses and other current liabilities	(151,300)	149,400
Interest payable	—	(363,400)
Deferred rent	(19,000)	(25,400)
Convertible promissory notes derivative liability	2,000	369,000
Net cash used for operating activities	(2,913,900)	(2,152,900)
Cash flows from investing activities:		
Purchases of property and equipment	(302,700)	(137,300)
Net cash used for investing activities	(302,700)	(137,300)
Cash flows from financing activities:		
Proceeds from sale of convertible promissory notes	250,000	725,000
Exercise of stock options	11,400	—
Proceeds from Series A-1 Preferred Stock issuance	—	900,000
Proceeds from Series B Preferred Stock issuance	4,500,000	—
Net cash provided by financing activities	4,761,400	1,625,000
Net change in cash and cash equivalents	1,544,800	(665,200)
Cash and cash equivalents:		
Beginning of year	384,300	1,049,500
End of year	$ 1,929,100	$ 384,300
Supplemental disclosures of non-cash investing and financing activities:		
Conversion of accounts payable into convertible promissory notes	$ 134,800	$ —
Accretion and settlement of Series B Preferred Stock dividend	$ 40,000	$ —
Accruals for property, plant, and equipment	$ 74,700	$ —
Conversion of convertible promissory notes and accrued interest to Series A-1 Preferred Stock	$ 407,300	$ 7,827,400

See accompanying notes to the consolidated financial statements

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements

As of and for the Years Ended December 31, 2019 and 2018

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 focused on discovering, developing, and commercializing novel immune-oncology and small molecule therapy applications through its robust product pipeline, which are in the pre initial new drug ("pre-IND") validation stages of the US Food and Drug Administration clinical trial process. 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 is recently formed and the product was recently developed. This business has not generated any revenues.

Going Concern—The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

The Company has incurred losses, negative cash flows from operations, and has not generated any revenues since its inception. In addition to incurring losses from operations, the Company has primarily financed its operations with the proceeds from equity and debt financing arrangements. The Company's long-term success is dependent upon its ability to successfully develop, commercialize and market its products, earn revenue, obtain additional capital when needed, and, ultimately, to achieve profitable operations. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. The Company does not have sufficient cash on hand or available liquidity that can be utilized to fund future operations for at least twelve months following the date the financial statements were available to be issued. Thus, there are conditions and events that raise substantial doubt regarding the Company's ability to continue as a going concern.

The Company is seeking significant additional capital funding to develop our platform and Pre-IND product lines, additional hiring of scientific professionals and 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. Management has the ability to eliminate certain forecasted discretionary costs that would not be in violation of the intended use of proceeds outlined in the Series B Preferred Stock purchase agreements. The Company has concluded that management's plans are probable of being achieved to have the necessary funding to meet its working capital needs to continue operations for at least twelve months following the date the consolidated financial statements were available to be issued. As a result, the Company has concluded that management's plans are probable of being implemented and alleviate substantial doubt about the Company's ability to continue as a going concern.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

1. ORGANIZATION (Continued)

The financial statements do not include any adjustments related 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, NIH, the primary agency of the US 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 which 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. Starting in 2020, 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 ("GAAP"). All intercompany balances were eliminated upon consolidation. Operating results for the year ended December 31, 2019 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 our outstanding common stock. On June 17, 2020, the Company completed a 1-for-3.494 reverse stock split of our outstanding common stock. As a result of these stock splits, the Company's issued and outstanding common stock decreased from 100,060,000 shares to 2,863,812 shares. Accordingly, unless otherwise noted, all share and per share information has been restated to retroactively show the effect of this stock split.

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, 2019 and 2018, 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.

Unbilled Receivables from Granting Agency—Unbilled receivables include certain cost reimbursements owed to the Company resulting from a biomedical research grant from the NIH. Direct costs subject to reimbursement are recorded only after actual expenses have been incurred while indirect costs are calculated using the percentage-of-completion accounting method. Unbilled receivables represent qualified cost reimbursements for which reimbursement which have not yet been requested from or

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

billed to the NIH due to the timing of the accounting invoicing cycle. The Company estimates the amount of probable credit losses from its existing unbilled receivables in the form of an allowance for doubtful accounts. The Company determines the allowance for doubtful accounts based upon an aging of unbilled receivables, historical experience, and management judgment. Unbilled receivable balances are reviewed individually for collectability. For the years ended December 31, 2019 and 2018, the Company has not experienced any credit-related losses.

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, 2019 and 2018, no such adjustments have been recorded.

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

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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	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 $20,000 and $121,500 for the years ended December 31, 2019 and 2018, 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 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 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,* ("ASC 740") 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

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2019 and 2018.

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 ("CROs") in connection with preclinical studies and contract manufacturing organizations ("CMOs") 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, 2019 and 2018, the Company recognized $298,000 and $258,000, 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—The Company has 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 ("Next Financing Close"). The embedded derivative liability is 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 is valued using a probability weighted expected return model. See Note 6.

Upon repurchase of convertible promissory notes, ASC 470, *Debt with conversion and other options*, ("ASC 470") 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 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 and Disclosures* ("ASC 820"). 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, 2019 and 2018.

The Company's liabilities that were measured at fair value on a non-recurring and recurring basis converted into Series A-1 Stock as of December 31, 2019 and December 31, 2018. 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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

	December 31, 2019	December 31, 2018
Convertible promissory notes		
Beginning balance	$ —	$ 5,737,000
Amounts allocated to the embedded derivative liability at inception (at fair value)	(21,000)	(8,000)
Conversions from accounts payable into convertible promissory notes	134,800	—
Proceeds from issuances of convertible promissory notes	250,000	725,000
Conversions into Series A-1 Stock	(363,800)	(6,454,000)
Ending balance	$ —	$ —
Rollforward of Level 3 Liabilities Measured at Fair Value on a Recurring Basis:		
Convertible promissory note embedded derivative liability Beginning balance	$ —	$ 369,000
Realized and unrealized gains and losses	2,000	167,000
Fair value of embedded derivative liability at inception	21,000	8,000
Amounts derecognized upon conversion of the related convertible promissory notes	(23,000)	(544,000)
Ending balance	$ —	$ —

Nonvested Stock Options—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 include annual, monthly, and fully vested. Annual vesting conditions are for 4 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.

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 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.

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*.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 as a privately held company, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience as a future publicly traded company. The Company has consequently 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. The Company plans to continue to use the SAB 110 simplified method until it has sufficient trading history as a publicly traded company.

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. The fair value of the common stock underlying the Company's stock-based compensation grants has historically been determined by the Company's board of directors, with input from management and third-party valuations. The Company believes that the board of directors has the relevant experience and expertise to determine the fair value of the Company's common stock. Given the absence of a public trading market of the Company's 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 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 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;

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

For valuations after the completion of an initial public offering, 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.

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

Reclassifications—Certain reclassifications have been made to the 2018 financial statements in order to conform to the 2019 presentation. Specifically, inventory balances have now been separately presented from prepaid expenses and other current assets. There were no changes to previously reported shareholders' equity or net loss as a result of the reclassifications.

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 October 16, 2019, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2021. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

In March 2016, FASB issued ASU 2016-09, *Stock Compensation—Improvements to Employee Share-Based Payment Accounting*. On January 1, 2018, the Company adopted the amendments to ASC 718, which simplify accounting for share based payment transactions. As part of the amendment, the Company has elected to recognize the actual forfeitures by reducing the employee share-based compensation expense in the same period as the forfeitures occur. The adoption did not result in a material impact on the Company's financial statements and related disclosures.

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

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 October 16, 2019, 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, 2018, the Company adopted ASU 2018-07, *Improvements to Non-employee Share-Based Payment Accounting* (Topic 718). This standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. FASB clarified that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606—Revenue from Contracts with Customers. Since the Company has not generated any revenue to date, this adoption did not result in a material impact on the Company's consolidated financial statements and related disclosures.

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, 2019 and 2018, respectively.

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, the common shares underlying the Series B Preferred Stock, convertible promissory notes, and convertible preferred stock have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average common shares

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

3. NET LOSS PER COMMON SHARE (Continued)

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 earnings per share :

	Years Ended December 31,	
	2019	2018
Net loss per common share, basic and diluted		
Net loss	$ (3,727,900)	$ (3,815,700)
Less: Accretion and settlement of Series B Preferred Stock dividend	(40,000)	—
Less: Series B Preferred Stock discount amortization	(210,600)	—
Net loss attributable to common shareholders, basic and diluted	$ (3,978,500)	$ (3,815,700)
Weighted average common shares outstanding, basic and diluted	2,862,809	2,862,093
Net loss per common share, basic and diluted	$ (1.39)	$ (1.33)

For the years ended December 31, 2019 and 2018, potentially dilutive securities excluded from the computations of diluted weighted-average common shares outstanding were (in shares):

	2019	2018
Options to purchase	75,405	61,785
Series A-1 Preferred Stock	624,594	597,816
Series B Preferred Stock	282,478	—
Warrants underlying Series B Preferred Stock	839,784	—
Total	1,822,261	659,601

Unaudited Pro Forma Net Loss Per Common Share

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, resulting in at least $20,000,000 of net proceeds to the Company, all shares of Series A-1 Preferred Stock and Series B Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate. In addition, the warrants to purchase shares of common stock underlying Series B Preferred Stock were not considered in the calculation due to duration of the warrant vesting schedule in relation to Series B Preferred Stock issuance dates. No warrants would be exercisable based on the issuance date of the Series B Preferred Stock. The vesting schedule of the warrants is as follows:

- 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

3. NET LOSS PER COMMON SHARE (Continued)

The unaudited pro forma basic and diluted net loss per common share for the year ended December 31, 2019 has been prepared to give effect to adjustments arising upon the completion of such public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per common share does not include any pro forma adjustments to net loss.

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per common share for the year ended December 31, 2019 has been prepared to give effect, upon such a public offering, to the automatic conversion of all outstanding shares of Series A-1 Preferred Stock and Series B Preferred Stock into common stock as if the proposed public offering had occurred January 1, 2019 for any shares issued and outstanding on December 31, 2018 and on the date of issuance for any shares issued during the year ended December 31, 2019.

Pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31, 2019
Numerator:	
Net loss	$ (3,727,900)
Pro forma net loss—basic and diluted	$ (3,727,900)
Denominator:	
Weighted-average common stock outstanding—basic and diluted	2,862,809
Pro forma adjustment to reflect automatic conversion of Series A-1 Preferred Stock to common stock upon the completion of the proposed initial public offering	608,014
Pro forma adjustment to reflect automatic conversion of Series B Preferred Stock to common stock upon the completion of the proposed initial public offering	62,094
Pro forma weighted-average common stock outstanding—basic and diluted	3,532,917
Pro forma net loss per common share—basic and diluted	$ (1.06)

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31:

	2019	2018
Equipment	$ 488,800	$ 158,000
Leasehold improvements	302,700	282,600
Office furniture, fixtures, and equipment	16,600	10,100
Software	141,500	121,500
	949,600	572,200
Less: Accumulated depreciation	(361,700)	(274,200)
Total	$ 587,900	$ 298,000

Depreciation expense was $87,500 and $80,900 for the years ended December 31, 2019 and 2018, respectively. Depreciation expense is recorded within 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:

	2019	2018
Accrued consulting and outside services	$ 221,300	$ 221,300
Accrued compensation	—	145,000
Accrued other	—	6,300
Total	$ 221,300	$ 372,600

6. 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 years ended December 31, 2019 and

6. CONVERTIBLE PROMISSORY NOTES (Continued)

2018. The net present value of the conversion discount related embedded derivative was measured using a discount rate of 25% as of December 31, 2019 and 50% as of December 31, 2018. Below is a table that outlines the initial value of issuances and the bifurcated embedded derivative liability during the years ended December 31:

	2019	2018
Convertible promissory notes- issuances	$ 250,000	$ 725,000
Conversion of accounts payable into convertible promissory notes	134,800	—
Total issuances and conversions into convertible promissory notes	384,800	725,000
Embedded derivative liability		
Initial fair value upon issuance of convertible promissory notes	21,000	271,000
Change in fair value	2,000	273,000
Converted embedded derivative liability into Series A-1 Preferred Stock	(23,000)	(544,000)
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 8 for further details. No additional convertible promissory notes were issued for the year ended December 31, 2019 following the conversion on August 15, 2019.

On December 20, 2018, the Company closed the capital raise of Series A-1 Preferred Stock, which qualified as the Next Financing Close. In accordance with the convertible promissory notes, all of the convertible promissory notes were converted into Series A-1 Preferred Stock. See Note 8 for further details. No additional convertible promissory notes were issued for the year ended December 31, 2018 following the conversion on December 20, 2018.

7. 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. The Company may extend this lease for up to two years. The total lease payments per month will be $21,353 beginning January 1, 2020. The Company records rent expense on a straight-line basis over the term of the respective leases.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

7. COMMITMENTS AND CONTINGENCIES (Continued)

As of December 31, 2019, future minimum commitments under facility lease agreements were as follows:

	Amount
2020	256,200
2021	85,400
Total	$ 341,600

Annual rent expense for the facility lease agreements was $129,100 and $156,700 for the years ended December 31, 2019 and 2018, 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, 2019 and 2018, 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, based on information presently known, the Company is not involved in any matters that would have a material effect on the Company's financial position.

8. STOCKHOLDERS' EQUITY

Third Amended and Restated Certificate of Incorporation

On December 16, 2019, the Company amended and restated its certificate of incorporation,

The amendments to the Charter are the following:

(i) Change the name of the Company to "Kiromic BioPharma, Inc.",

(ii) 1-for-10 reverse split of the Company's outstanding shares of Common Stock. Shares of common stock have been retrospectively revised to reflect the reverse split,

(iii) Increase the Company's authorized Preferred Stock to 60,000,000 shares,

(iv) Change the par value of the Preferred Stock, from $0.01 to $0.0001 per share

Following the amendments to the Charter, the Company had 21,869,565 remaining shares of Preferred Stock authorized for issuance. The total authorized 60,000,000 Preferred Stock shares was reduced by 24,000,000 shares designated as Series A-1 Preferred Stock and 14,130,435 shares designated as Series B Preferred Stock.

Common Stock—From inception in December 2012 through May 2016, the Company raised proceeds from capital contributions for common stock at a $0.001 par value, net of redemptions, totaling

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

8. STOCKHOLDERS' EQUITY (Continued)

$6,214,800. When the Company converted from Kiromic, LLC to Kiromic, Inc., the shares converted from two classes to a single class of common stock. At the time of conversion, the par value on the two classes of common stock eliminated, and the par value of common stock transferred entirely into additional paid-in capital. Other than from proceeds for the exercise of vested stock options, there were no additional raises from common stock that occurred in the years ended December 31, 2019 or 2018.

The Company authorized shares of 300,000,000 as of December 31, 2019 and 2018, respectively. The certificate of incorporation authorizing 600,000,000 shares was dated May 27, 2016. The Company amended its certificate of incorporation on December 20, 2018 to reduce the number of authorized shares. As of December 31, 2019 and 2018, the Company issued 2,863,812 and 2,862,093 shares of common stock, respectively.

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 a stock option plan. On September 25, 2019, the board of directors approved an additional 286,205 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 stock splits, the total number of authorized shares was updated to 858,615.

There were 258,813 shares and 51,892 shares available for issuance as of December 31, 2019 and 2018, respectively (see Note 9). In the year ended December 31, 2019, option grantees exercised their option to purchase 1,719 shares of common stock for $6.64 per share for proceeds of $11,400. No options were exercised in 2018.

Series A-1 Preferred Stock—Between June 8, 2018 and August 14, 2018, the Company entered into agreements to issue preferred stock and received advances of $900,000. The advances received under the agreements were recorded as liabilities until the preferred stock was issued and bore interest at a rate of 6.5%. The agreements were amended on September 10, 2018, when, in exchange for additional preferred stock to be issued, the advances no longer bore interest. On December 20, 2018, 2,032,749 shares of Series A-1 Preferred Stock were issued for the $912,800, representing the advances received and accrued interest through September 10, 2018.

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 (see above) 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

8. STOCKHOLDERS' EQUITY (Continued)

With respect rights on liquidation, winding up and dissolution, shares of 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 resulting in at least $20,000,000 of net proceeds to the Company, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate.

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 0.3 shares of common stock for each share of Series B Preferred Stock purchased at a price of $0.001 per share of common stock ("Warrants"). See below for further details.

Until the effective date of the Charter, 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 shall initially be equal to the Series B Preferred Stock Original Issue 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 shall thereafter 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

8. STOCKHOLDERS' EQUITY (Continued)

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 the Charter 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. Below is a table that outlines the initial value of issuances allocated to Series B Preferred Stock and the Series B Preferred Stock discount amortized during the year ended December 31, 2019:

	December 31, 2019
Series B Preferred Stock proceeds	$ 4,500,000
Series B Preferred Stock discount	(3,443,700)
Series B Preferred Stock discount amortization	210,600
Accretion and settlement of Series B Preferred Stock dividend	40,000
Series B Preferred Stock ending balance	$ 1,266,900

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 (see below) 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 resulting in at least $20,000,000 of net proceeds to the Company, 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 December 20, 2018, the Company's certificate of incorporation was amended to authorize 24,000,000 shares Series A-1 Preferred Stock. This amendment qualified as the Next Financing Close with respect to the convertible promissory notes. Therefore, the

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

8. STOCKHOLDERS' EQUITY (Continued)

outstanding principal and accrued interest was converted into Series A-1 Preferred Stock. At the time of conversion, outstanding principal and accrued interest of the convertible promissory notes totaled $7,541,600. Per the convertible promissory notes, the conversion price was $0.40. Accordingly, 18,854,033 shares were issued to convert the outstanding principal and accrued interest into Series A-1 Preferred Stock.

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.

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 ("Warrants"). The Warrants become exercisable in accordance with the schedule set forth below following completion by the Company of an initial public offering 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. These warrants are equity classified and the fair value of $3,233,000 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 years ended December 31, 2019:

	December 31, 2019
Risk-free interest rate	1.54% - 1.88%
Expected volatility	71.95% - 72.20%
Expected life (years)	10.00
Expected dividend yield	0%

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

9. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan

In January 2017, the Company's board of directors approved the adoption of the Plan. The Plan permits the Company to grant up to 858,615 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. Stock options granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over an agreed service period.

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:

	2019	2018
Risk-free interest rate	1.60% - 2.92%	2.24% - 2.92%
Expected volatility	72.29% - 78.16%	74.54% - 78.16%
Expected life (years)	4.93 - 6.07	4.93 - 6.01
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 Company's common shares, 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:

	2019		2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	520,517	$ 8.64	351,996	$ 6.64
Granted	209,505	17.29	250,121	11.37
Exercised	(1,719)	6.64		—
Cancelled and forfeited	(130,220)	11.56	(81,600)	8.38
Balance at December 31	598,083	$ 11.04	520,517	$ 8.64
Options exercisable at December 31:	368,527	$ 7.72	341,056	$ 7.22
Weighted average grant date fair value for options granted during the year:		$ 10.82		$ 6.31

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

9. STOCK-BASED COMPENSATION (Continued)

The following table summarizes additional information about stock options outstanding and exercisable at December 31, 2019 and 2018 under the Plan: The intrinsic value of options exercised during the year ended December 31, 2019 was $17,600.

	Options Outstanding				Options Exercisable		
Year Ended 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
2018	520,517	9.16	$ 8.64	$ 1,687,000	341,056	$ 7.22	$ 1,589,500
2019	598,083	8.07	$ 11.04	$ 19,163,700	368,527	$ 7.72	$ 13,031,000

Total stock compensation expense recognized for all stock-based compensation awards recognized in the consolidated statements of operations for the years ended December 31, 2019 and 2018, is as follows:

	2019	2018
Research and development	$ 332,000	$ 303,000
General and administrative	190,900	330,000
Total	$ 522,900	$ 633,000

As of December 31, 2019, total unrecognized stock compensation expense is $2,354,097, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 3.5 years.

10. INCOME TAXES

For the years ended December 31, 2019 and 2018, 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, 2019 and 2018.

	2019	2018
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

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

10. INCOME TAXES (Continued)

associated with these deferred tax assets as of December 31, 2019 and 2018 due to the significant uncertainty about the realization of the deferred tax asset until the Company can operate profitably.

The Tax Cuts and Jobs Act was enacted on December 22, 2017, and has several key provisions that significantly changed US tax law by, including lowering US corporate income tax rate to 21%, creating a new limitation on deductible interest expense, and changing rules related to use and limitations of net operating loss carryforwards for tax years beginning after December 31, 2017.

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

	2019	2018
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 2,605,400	$ 1,941,000
Stock compensation expense	597,400	487,600
Intangible assets	27,800	36,100
Total gross deferred tax assets	3,230,600	2,464,700
Valuation allowance	(3,198,100)	(2,455,100)
Property and equipment	(32,500)	(9,600)
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2019 and 2018, the Company has a US net operating loss ("NOL") carryforward of $12,406,800 and $9,242,900, 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, 2019 and 2018, 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, 2019, the Company is not currently under audit by any income tax authority.

11. RELATED PARTY TRANSACTIONS

Through December 31, 2019, the Company maintained three separate consulting agreements with the Company's Chief Strategy and Innovation Officer (the "CSO"), the Chief Financial Officer and Chief Operating Officer (the "CFO and COO"), and the Chief Medical Officer (the "CMO").

Beginning in the year ended December 31, 2014, the Company entered into its first consulting agreement with the CSO. Pursuant to the amended agreement dated July 20, 2018, the CSO is 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 CSO will provide a leadership role for the Company's business development

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

11. RELATED PARTY TRANSACTIONS (Continued)

strategies. The consulting fees paid to the CSO totaled $207,800 and $119,100 in the years ended December 31, 2019 and 2018, respectively.

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 is entitled to a consulting fee of $2,500 per month amended to $10,000 per month. The consulting fees paid to the CFO totaled $67,500 and $22,500 in the years ended December 31, 2019 and 2018, respectively.

Beginning in the year ended December 31, 2018, the Company entered into its first consulting agreement with the CMO. Pursuant to the amended agreement on August 1, 2019, the CMO is entitled to a consulting fee of $400 per hour. The consulting agreement indicates that the CMO will direct the development of clinical strategies and plans to integrate the Company's compounds into standard medical practice. The consulting fees paid to the CMO totaled $182,800 and $12,500 in the years ended December 31, 2019 and 2018, respectively.

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the consolidated balance sheet date through April 6, 2020, the date at which the consolidated financial statements were available to be issued and through June 25, 2020 as it relates to the reverse stock split, and determined that other than the events mentioned below, no events or transactions occurred that are required to be disclosed.

Preferred Share Issuance

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 sale of the Series B Preferred Stock, each investor was issued warrants to purchase three 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"). The Warrants become exercisable in accordance with the schedule set forth below following completion by the Company of an initial public offering 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.

Kiromic BioPharma, Inc. and Subsidiary

Notes to Consolidated Financial Statements (Continued)

As of and for the Years Ended December 31, 2019 and 2018

12. SUBSEQUENT EVENTS (Continued)

The Series B Preferred Stock conversion price shall initially be equal to the Series B Preferred Original Issue Price of $16.07 per share divided by the rate at which shares of Series B Preferred Stock may be converted into shares of common stock.

Capital Expenditures

On January 6, 2020, the Board of Directors approved construction of the Company's Good Manufacturing Practices ("GMP") and Vivarium facility. The GMP and Vivarium are being built on the expansion to the Houston lease, which has approximately 4,100 square feet. The initial approved cost of the facilities totaled $598,900.

On March 17, 2020, the Board of Directors approved additional capital expenditures for two clean rooms and office re-modeling within the Vivarium. The cost of these additions totaled $238,200.

Joint Venture Agreement

On April 3, 2020, the Company 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"). Molipharma was founded in part by one of our directors, Americo Cicchetti. Mr. Cicchetti is also the Chief Executive Officer and Director of Molipharma.

With respect to Oncology, the Company 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 the Company. Molipharma agreed to undertake to financially support the research program for COVID-19 and the Company 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.

Reverse Stock Split

On June 17, 2020, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock, non-voting common stock and convertible preferred stock, each on a 1-for-3.494 basis (Reverse Stock Split). The Reverse Stock Split also applied to any outstanding securities or rights convertible into, or exchangeable or exercisable for, common stock, non-voting common stock or convertible preferred stock. The par value of the common stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, non-voting common stock, restricted stock, options to purchase common stock, share data, per share data, convertible preferred stock and related information contained in the financial statements and related footnotes have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on June 17, 2020.

Kiromic BioPharma, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,683,500	$ 1,929,100
Inventories	22,200	22,200
Prepaid expenses and other current assets	824,800	89,100
Total current assets	2,530,500	2,040,400
Property and equipment, net	1,326,700	587,900
Other assets	24,400	24,400
Total Assets	$ 3,881,600	$ 2,652,700
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 1,261,600	$ 452,400
Accrued expenses and other current liabilities	409,100	221,300
Loan payable	115,600	—
Total current liabilities	1,786,300	673,700
Total Liabilities	1,786,300	673,700
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Series A-1 Preferred Stock, $0.0001 par value: 24,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 21,822,301 shares issued and outstanding as of June 30, 2020 and December 31, 2019	9,134,700	9,134,700
Series B Preferred Stock, $0.0001 par value: 16,500,000 and 14,130,435 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 16,391,397 and 9,869,659 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	2,331,300	1,306,900
Preferred Stock, $0.0001 par value: 19,500,000 and 21,869,565 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock: 300,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 4,989,269 and 2,863,812 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	26,276,500	13,965,000
Accumulated deficit	(35,647,200)	(22,427,600)
Total Stockholders' Equity	2,095,300	1,979,000
Total Liabilities and Stockholders' Equity	$ 3,881,600	$ 2,652,700

See accompanying notes to the condensed consolidated financial statements

Kiromic BioPharma, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 1,272,300	$ 125,900	$ 2,300,400	$ 329,400
General and administrative	10,094,600	143,100	10,919,200	326,900
Total operating expenses	11,366,900	269,000	13,219,600	656,300
Loss from operations	(11,366,900)	(269,000)	(13,219,600)	(656,300)
Other income (expense)				
Interest expense	—	(11,400)	—	(15,000)
Other income (expense), net	—	(11,400)	—	(15,000)
Net loss before income taxes	(11,366,900)	(280,400)	(13,219,600)	(671,300)
Income tax benefits (expense)	—	—	—	—
Net loss	$ (11,366,900)	$ (280,400)	$ (13,219,600)	$ (671,300)
Net loss per share, basic and diluted	$ (3.80)	$ (0.10)	$ (4.52)	$ (0.23)
Weighted average common shares outstanding, basic and diluted	3,077,085	2,862,093	3,077,085	2,862,093
Pro forma net loss per common share, basic and diluted	$ (2.93)		$ (3.41)	
Pro forma weighted-average common shares outstanding, basic and diluted	3,879,718		3,879,718	

See accompanying notes to the condensed consolidated financial statements

Kiromic BioPharma, Inc.

Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(unaudited)

	Three and Six Months Ended June 30, 2020								
	Series A-1 Preferred Stock		Series B Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at January 1, 2020	21,822,301	$ 9,134,700	9,869,659	$ 1,306,900	2,863,812	$ —	$ 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	—	—	—	368,400	—	—	(368,400)	—	—
Warrants underlying Series B Preferred Stock issuance	—	—	—	—	—	—	2,668,300	—	2,668,300
Stock compensation expense	—	—	—	—	—	—	456,000	—	456,000
Net loss	—	—	—	—	—	—	—	(1,852,700)	(1,852,700)
Balance at March 31, 2020	21,822,301	$ 9,134,700	16,391,397	$ 2,007,000	2,863,812	$ —	$ 16,720,900	$ (24,280,300)	$ 3,582,300
Series B Preferred Stock discount amortization	—	—	—	324,300	—	—	(324,300)	—	—
Exercise of warrants	—	—	—	—	1,399,921	—	4,900	—	4,900
Common stock issuance to employees and non-employees	—	—	—	—	725,536	—	9,432,000	—	9,432,000
Stock compensation expense	—	—	—	—	—	—	443,000	—	443,000
Net loss	—	—	—	—	—	—	—	(11,366,900)	(11,366,900)
Balance at June 30, 2020	21,822,301	$ 9,134,700	16,391,397	$ 2,331,300	4,989,269	$ —	$ 26,276,500	$ (35,647,200)	$ 2,095,300

	Three and Six Months Ended June 30, 2019						
	Series A-1 Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	20,886,782	$ 8,727,400	2,862,093	$ —	$ 10,237,600	$ (18,699,700)	$ 265,300
Stock compensation expense	—	—	—	—	104,000	—	104,000
Net loss	—	—	—	—	—	(390,900)	(390,900)
Balance at March 31, 2019	20,886,782	$ 8,727,400	2,862,093	$ —	$ 10,341,600	$ (19,090,600)	$ (21,600)
Stock compensation expense	—	—	—	—	105,000	—	105,000
Net loss	—	—	—	—	—	(280,400)	(280,400)
Balance at June 30, 2019	20,886,782	$ 8,727,400	2,862,093	—	10,446,600	(19,371,000)	(197,000)

See accompanying notes to the condensed consolidated financial statements

Kiromic BioPharma, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (13,219,600)	$ (671,300)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	68,500	43,000
Stock compensation expense	10,331,000	209,000
Changes in operating assets and liabilities:		
Unbilled receivables from granting agency	—	(25,300)
Inventories	—	(5,900)
Prepaid expenses and other current assets	(141,500)	11,400
Accounts payable	291,000	(98,200)
Accrued expenses and other current liabilities	66,800	6,100
Interest payable	—	14,000
Deferred rent	—	(19,000)
Convertible promissory notes derivative liability	—	135,800
Net cash used for operating activities	(2,603,800)	(400,400)
Cash flows from investing activities:		
Purchases of property and equipment	(762,300)	(20,000)
Net cash used for investing activities	(762,300)	(20,000)
Cash flows from financing activities:		
Proceeds from sale of convertible promissory notes	—	250,000
Proceeds from warrant exercise	4,900	—
Proceeds from loan payable	115,600	—
Proceeds from Series B Preferred Stock issuance	3,000,000	—
Net cash provided by financing activities	3,120,500	250,000
Net change in cash and cash equivalents	(245,600)	(170,400)
Cash and cash equivalents:		
Beginning of year	1,929,100	384,300
End of period	$ 1,683,500	$ 213,900
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	$ 45,000	$ 74,700
Accruals for deferred initial public offering costs	$ 594,200	$ —
Conversion of accounts payable into convertible promissory notes	$ —	$ 134,800
Warrants underlying Series B Preferred Stock issuance	$ 2,668,300	$ —

See accompanying notes to the condensed consolidated financial statements

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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 focused on discovering, developing, and commercializing novel immune-oncology and small molecule therapy applications through its robust product pipeline, which are in the pre initial new drug ("pre-IND") validation stages of the US Food and Drug Administration clinical trial process. 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 is recently formed and the product was recently developed. This business has not generated any revenues.

Going Concern—

These condensed consolidated financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its 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 flow from operations of $2,603,800 for the six months ended June 30, 2020, and an accumulated deficit of $35,647,200 as of June 30, 2020. The Company does not have sufficient cash on hand or available liquidity to meet its obligations through the 12 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.

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. Given its projected operating requirements and its existing cash and cash equivalents, the Company plans to complete an additional financing transaction in the second half of 2020 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. 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.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

1. ORGANIZATION (Continued)

The condensed 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 ("NIH"), the primary agency of the US 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. Starting in 2020, 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 condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information (Accounting Standards Codification ("ASC") 270, Interim Reporting) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information necessary for a full presentation of financial position, results of operations, and cash flows in conformity GAAP. Operating results for interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented.

All intercompany balances were eliminated upon consolidation.

On December 17, 2019, we completed a 1-for-10 reverse stock split of our outstanding common stock. On June 17, 2020, the Company completed a 1-for-3.494 reverse stock split of our 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.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Cash and Cash Equivalents—As of June 30, 2020 and December 31, 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.

Unbilled Receivables from Granting Agency—Unbilled receivables include certain cost reimbursements owed to the Company resulting from a biomedical research grant from the NIH. Direct costs subject to reimbursement are recorded only after actual expenses have been incurred while indirect costs are calculated using the percentage-of-completion accounting method. Unbilled receivables represent qualified cost reimbursements for which reimbursement have not yet been requested from or billed to the NIH due to the timing of the accounting invoicing cycle. The Company estimates the amount of probable credit losses from its existing unbilled receivables in the form of an allowance for doubtful accounts. The Company determines the allowance for doubtful accounts based upon an aging of unbilled receivables, historical experience, and management judgment. Unbilled receivable balances are reviewed individually for collectability. For the three and six months ended June 30, 2020 and 2019, the Company has not experienced any credit-related losses.

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 condensed 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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 June 30, 2020 and December 31, 2019, no such adjustments have been recorded.

Deferred Initial Public Offering Costs—In the three months ended June 30, 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, which are deferred in other current assets in accordance with ASC 505-10-25 in the condensed consolidated balance sheets. Initial public offering costs consist of legal, accounting, and other costs directly related to the Company's efforts to raise capital. As of June 30, 2020, $696,700 of deferred costs related to the initial public offering were classified as other current assets on the condensed consolidated balance sheets, respectively.

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	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 $0 and $20,000 for the six months ended June 30, 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.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 condensed 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 condensed 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 condensed 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*, ("ASC 740") 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 condensed consolidated statements of operations. No such interest or penalties were recognized during the three and six months ended June 30, 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 ("CROs") in connection with preclinical studies and contract manufacturing organizations ("CMOs") 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 three months ended June 30, 2020 and 2019, the Company recognized $0 and $86,700, respectively, as reductions to research and development expense within the

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

condensed consolidated statements of operations pursuant to its grant from the NIH. During the six months ended June 30, 2020 and 2019, the Company recognized $0 and $188,300, respectively, as reductions to research and development expense within the condensed consolidated statements of operations pursuant to its grant from the NIH.

Convertible Promissory Notes Derivative Liability—The Company has 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 ("Next Financing Close"). The embedded derivative liability is initially recorded at fair value, with gains and losses arising from changes in fair value recognized in interest expense in the condensed consolidated statements of operations at each period end while such instruments are outstanding. The embedded derivative liability is valued using a probability weighted expected return model. See Note 7.

Upon repurchase of convertible promissory notes, ASC 470, *Debt with conversion and other options*, ("ASC 470") 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 condensed 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, 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 and Disclosures* ("ASC 820"). 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.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

There were no changes in the fair value hierarchy levels during the six months ended June 30, 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 Stock as of June 30, 2020 and 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:

	June 30, 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—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 include annual, monthly, and fully vested. 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.

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 the straight-line method over the requisite service period. The fair value of

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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 as a privately held company, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience as a future publicly traded company. The Company has consequently 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. The Company plans to continue to use the SAB 110 simplified method until it has sufficient trading history as a publicly traded company.

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. The fair value of the common stock underlying the Company's stock-based compensation grants has historically been determined by the Company's board of directors, with input from management and third-party valuations. The Company believes that the board of directors has the relevant experience and expertise to determine the fair value of the Company's common stock. Given the absence of a public trading market of the Company's 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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 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.

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

Subsequent Events—The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the condensed consolidated financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

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 June 3, 2020, the FASB changed the effective date of this standard 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,

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 October 16, 2019, 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.

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, the common shares underlying the Series B Preferred Stock, convertible promissory notes, and convertible 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 earnings per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (11,366,900)	$ (280,400)	$ (13,219,600)	$ (671,300)
Less: Series B Preferred Stock discount amortization	(324,300)	—	(692,700)	—
Net loss attributable to common shareholders, basic and diluted	$ (11,691,200)	$ (280,400)	$ (13,912,300)	$ (671,300)
Weighted average common shares outstanding, basic and diluted	3,077,085	2,862,093	3,077,085	2,862,093
Net loss per common share, basic and diluted	$ (3.80)	$ (0.10)	$ (4.52)	$ (0.23)

For the six months ended June 30, 2020 and 2019, potentially dilutive securities excluded from the computations of diluted weighted-average common shares outstanding were (in shares):

	June 30, 2020	June 30, 2019
Options to purchase	—	196,774
Convertible promissory notes	—	50,227
Series A-1 Preferred Stock	624,594	597,816
Series B Preferred Stock	469,136	—
Total	1,093,730	844,817

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

3. NET LOSS PER COMMON SHARE (Continued)

Pro Forma Net Loss Per Common Share

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, resulting in at least $20,000,000 of net proceeds to the Company, all shares of Series A-1 Preferred Stock and Series B Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate.

The pro forma basic and diluted net loss per common share for the three and six months ended June 30, 2020 has been prepared to give effect to adjustments arising upon the completion of such public offering. The pro forma net loss attributable to common stockholders used in the calculation of pro forma basic and diluted net loss per common share does not include any pro forma adjustments to net loss.

The pro forma basic and diluted weighted-average common shares outstanding used in the calculation of pro forma basic and diluted net loss per common share for the three and six months ended June 30, 2020 has been prepared to give effect, upon such a public offering, to the automatic conversion of all outstanding shares of Series A-1 Preferred Stock and Series B Preferred Stock into common stock as if the proposed public offering had occurred January 1, 2019 for any shares issued and outstanding on December 31, 2019 and on the date of issuance for any shares issued during the six months ended June 30, 2020.

Pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Numerator:		
Net loss	$ (11,366,900)	$ (13,219,600)
Pro forma net loss—basic and diluted	$ (11,366,900)	$ (13,219,600)
Denominator:		
Weighted-average common stock outstanding—basic and diluted	3,077,085	3,077,085
Pro forma adjustment to reflect automatic conversion of Series A-1 Preferred Stock to common stock upon the completion of the proposed initial public offering	613,503	613,503
Pro forma adjustment to reflect automatic conversion of Series B Preferred Stock to common stock upon the completion of the proposed initial public offering	189,130	189,130
Pro forma weighted-average common stock outstanding—basic and diluted	3,879,718	3,879,718
Pro forma net loss per common share—basic and diluted	$ (2.93)	$ (3.41)

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at June 30, 2020 and December 31, 2019:

	June 30, 2020	December 31, 2019
Equipment	$ 563,600	$ 488,800
Leasehold improvements	307,100	302,700
Office furniture, fixtures, and equipment	16,600	16,600
Software	141,500	141,500
Construction in progress	728,100	—
	1,756,900	949,600
Less: Accumulated depreciation	(430,200)	(361,700)
Total	$ 1,326,700	$ 587,900

Depreciation expense was $34,700 and $21,200 for the three months ended June 30, 2020 and 2019, and $68,500 and $43,000 for the six months ended June 30, 2020 and 2019, respectively. Depreciation expense is allocated between research and development and general and administrative operating expenses on the condensed consolidated statements of operations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at June 30, 2020 and December 31, 2019:

	June 30, 2020	December 31, 2019
Accrued consulting and outside services	$ 400,900	$ 221,300
Accrued other	8,200	—
Total	$ 409,100	$ 221,300

6. LOAN PAYABLE

On May 1, 2020, the Company received a loan in the principal amount of $115,100 (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, we are using the proceeds from this loan to primarily help maintain our 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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

6. LOAN PAYABLE (Continued)

regarding, among other things, the maintenance of employment and compensation levels. We intend to use the SBA Loan for qualifying expenses and to apply for forgiveness of the SBA Loan in accordance with the terms of the CARES Act.

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 our financial condition or business operations that may materially affect our ability to pay the SBA Loan.

As the legal form of the Note is a debt obligation, the Company is accounting for it as debt under ASC 470, *Debt*, and recorded an initial liability of $115,100 in the condensed consolidated balance sheet upon receipt of the loan proceeds. The Company is accruing interest over the term of the loan and is not imputing 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 condensed consolidated statement of operations.

7. 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 six months ended June 30, 2019. The net present value of the conversion discount related embedded derivative was measured using a discount rate of 25% in the six months ended June 30, 2019. There have been no convertible promissory note issuances in the six months ended June 30, 2020. Below is a table that outlines the

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. CONVERTIBLE PROMISSORY NOTES (Continued)

initial value of issuances and the bifurcated embedded derivative liability during the six months ended June 30, 2020 and 2019:

	June 30, 2020	June 30, 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	—	1,000
Embedded derivative liability balance at June 30	$ —	$ 22,000

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 9 for further details. No additional convertible promissory notes were issued for the six months ended June 30, 2020 following the conversion on August 15, 2019.

8. 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. The Company may extend this lease for up to two years. The total lease payments per month will be $21,353 beginning January 1, 2020. The Company records rent expense on a straight-line basis over the term of the respective leases.

As of June 30, 2020, future minimum commitments under facility lease agreements were as follows:

	Amount
2020	$ 128,100
2021	85,400
Total	$ 213,500

Rent expense for the facility lease agreements was $127,100 and $58,000 during the six months ended June 30, 2020 and 2019, and $67,100 and $20,800 during the three months ended June 30, 2020 and 2019, respectively. Rent expense is included as an allocation between research and development and general and administrative expense in the condensed 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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. COMMITMENTS AND CONTINGENCIES (Continued)

underlying assets. As of June 30, 2020 and December 31, 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, based on information presently known, the Company is not involved in any matters that would have a material effect on the Company's financial position.

9. STOCKHOLDERS' EQUITY (DEFICIT)

Third Amended and Restated Certificate of Incorporation and Amendments

On December 16, 2019, the Company amended and restated its certificate of incorporation ("the Charter").

The amendments to the Charter are the following:

(i) Change the name of the Company to "Kiromic BioPharma, Inc.",

(ii) 1-for-10 reverse split of the Company's outstanding shares of common stock. Shares of common stock have been retrospectively revised to reflect the reverse split,

(iii) Increase the Company's authorized Preferred Stock to 60,000,000 shares,

(iv) Change the par value of the Preferred Stock, from $0.01 to $0.0001 per share

Following the amendments to the Charter, the Company had 19,500,000 remaining shares of Preferred Stock authorized for issuance. The total authorized 60,000,000 Preferred Stock shares was reduced by 24,000,000 shares designated as Series A-1 Preferred Stock and 16,500,000 shares designated as Series B Preferred Stock as of June 30, 2020.

Following the amendments to the Charter, the Company had 21,869,565 remaining shares of Preferred Stock authorized for issuance. The total authorized 60,000,000 Preferred Stock shares was reduced by 24,000,000 shares designated as Series A-1 Preferred Stock and 14,130,435 shares designated as Series B Preferred Stock as of December 31, 2019.

On June 17, 2020, the Company filed an amendment to the Charter to effect a reverse split of shares of the Company's common stock, nonvoting common stock and convertible preferred stock, each on a 1-for-3.494 basis. This reverse split was also applied to any outstanding securities or rights convertible into, or exchangeable or exercisable for, common stock, non-voting common stock or convertible preferred stock. The par value of the common stock was not adjusted as a result of the reverse stock split. All references to common stock, non-voting common stock, restricted stock, options to purchase common stock, share data, per share data, convertible preferred stock and related information contained in the financial statements and related footnotes have been retrospectively adjusted to reflect the effect of this reverse split. This reverse split was effected on June 17, 2020.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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9. STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

Common Stock—From inception in December 2012 through May 2016, the Company raised proceeds from capital contributions for common stock at a $0.001 par value, net of redemptions, totaling $6,214,800. When the Company converted from Kiromic, LLC to Kiromic, Inc., the shares converted from two classes to a single class of common stock. At the time of conversion, the par value on the two classes of common stock eliminated, and the par value of common stock transferred entirely into additional paid-in capital. There were no additional raises from common stock that occurred in the six months ended June 30, 2020 or 2019.

The Company authorized shares of 300,000,000 as of June 30, 2020 and December 31, 2019, respectively. 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 0 and 839,952 warrants outstanding as of June 30, 2020 and December 31, 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 Chief Financial Officer and Chief Operating Officer ("CFO and COO") and Chief Strategy and Innovation Officer ("CSO"), 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 a stock option 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 379,563 shares and 258,813 shares available for issuance as of June 30, 2020 and December 31, 2019, respectively.

Series A-1 Preferred Stock—Between June 8, 2018 and August 14, 2018, the Company entered into agreements to issue preferred stock and received advances of $900,000. The advances received under the agreements were recorded as liabilities until the preferred stock was issued and bore interest at a rate of 6.5%. The agreements were amended on September 10, 2018, when, in exchange for additional preferred stock to be issued, the advances no longer bore interest. On December 20, 2018, 2,032,749 shares of Series A-1 Preferred Stock were issued for the $912,800, representing the advances received and accrued interest through September 10, 2018.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

9. STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

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 (see above) 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 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 resulting in at least $20,000,000 of net proceeds to the Company, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate.

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 effective date of the Charter, 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 shall initially be equal to the Series B Preferred Stock Original Issue 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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

9. STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

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 shall thereafter 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 the Charter 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.

Below is a table that outlines the initial value of issuances allocated to Series B Preferred Stock and the Series B Preferred Stock discount amortized during the three months and six months ended June 30:

	2020	2019
Series B Preferred Stock		
Balance at January 1,	$ 1,306,900	$ —
Series B Preferred Stock proceeds	3,000,000	—
Series B Preferred Stock discount	(2,668,300)	—
Series B Preferred Stock discount amortization	368,400	—
Balance at March 31	$ 2,007,000	$ —
Series B Preferred Stock discount amortization	324,300	—
Balance at June 30	$ 2,331,300	$ —

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

9. STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

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 (see below) 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 resulting in at least $20,000,000 of net proceeds to the Company, 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 December 20, 2018, the Company's certificate of incorporation was amended to authorize 24,000,000 shares Series A-1 Preferred Stock. This amendment qualified as the Next Financing Close with respect to the convertible promissory notes. Therefore, the outstanding principal and accrued interest was converted into Series A-1 Preferred Stock. At the time of conversion, outstanding principal and accrued interest of the convertible promissory notes totaled $7,541,600. Per the convertible promissory notes, the conversion price was $0.40. Accordingly, 18,854,033 shares were issued to convert the outstanding principal and accrued interest into Series A-1 Preferred Stock.

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.

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. The warrants become exercisable in accordance with the schedule set forth below following completion by the

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

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9. STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

Company of an initial public offering 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. As of June 30, 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.

The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions for the six months ended June 30, 2020 and 2019:

	June 30, 2020	June 30, 2019
Risk-free interest rate	1.54% - 1.88%	—%
Expected volatility	71.95% - 72.71%	—%
Expected life (years)	10.00	—
Expected dividend yield	0%	—%

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 outstanding as of June 30, 2020.

10. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan—Stock Options

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. Stock options granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over an agreed service period.

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

10. STOCK-BASED COMPENSATION (Continued)

The Black-Scholes option-pricing model was used to estimate the fair value of stock options with the following weighted-average assumptions for the six months ended June 30:

	2020	2019
Risk-free interest rate	0.23% - 2.92%	2.06% - 2.92%
Expected volatility	72.29% - 82.15%	74.54% - 78.16%
Expected life (years)	4.93 - 6.07	4.93 - 6.01
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 Company's common shares, 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 June 30 under the Plan:

	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	598,083	$ 11.11	520,517	$ 8.64
Granted	65,424	19.15	—	—
Exercised	—	—	—	—
Cancelled and forfeited	(45,508)	14.25	—	—
Balance at June 30	617,999	$ 11.84	520,517	$ 8.64
Options exercisable at June 30:	382,204	$ 8.50	363,321	$ 7.43
Weighted average grant date fair value for options granted during the year:		$ 20.54		$ —

The following table summarizes additional information about stock options outstanding and exercisable at June 30, 2020 and 2019 under the Plan:

	Options Outstanding				Options Exercisable		
Three Months Ended June 30,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2019	520,517	8.43	$ 8.64	$ 1,687,000	363,321	$ 7.43	$ 3,392,266
2020	617,999	8.03	$ 11.84	$ 2,008,892	382,204	$ 8.50	$ 1,718,959

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

10. STOCK-BASED COMPENSATION (Continued)

Total stock compensation expense recognized for all stock-based compensation awards recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2020 and 2019, is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 386,000	$ 43,000	$ 811,000	$ 85,000
General and administrative	57,000	62,000	88,000	124,000
Total	$ 443,000	$ 105,000	$ 899,000	$ 209,000

As of June 30, 2020, total unrecognized stock compensation expense is $2,393,972, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 2.89 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. Because there was no public market for Company's common shares, 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 June 30 under the Plan:

	2020	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	—	$ —
Granted	709,334	19.00
Vested	—	—
Cancelled and forfeited	—	—
Nonvested RSUs at June 30	709,334	$ 19.00

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

10. STOCK-BASED COMPENSATION (Continued)

During the six months ended June 30, 2020, 709,334 RSUs were granted. During the six months ended June 30, 2020, no RSUs vested. No RSUs were granted or vested in the six months ended June 30, 2019.

11. INCOME TAXES

The Company's effective tax rate from continuing operations was 0% for both the three and six months ended June 30, 2020, and 0% for the three and six months ended June 30, 2019. The Company recorded no income tax provision for the three and six months ended June 30, 2020 and 2019, respectively.

The provision for income taxes during the interim reporting periods is calculated by applying an estimate of the annual effective tax rate ("AETR") for the full fiscal year to "ordinary" income or loss for the reporting period. Each quarter, the estimate of the annual effective tax rate is updated, and if the estimated effective tax rate changes, a cumulative adjustment is made. There is a potential for volatility of the effective tax rate due to several factors, including changes in the mix of the pre-tax income and the jurisdictions to which it relates, changes in tax laws, business reorganizations and settlements with taxing authorities.

The income tax rates vary from the US federal statutory rate of 21% primarily due to the full valuation allowance on the Company's deferred tax assets. The Company has recorded the full valuation allowance based on an evaluation of both positive and negative evidence, including latest forecasts and cumulative losses in recent years. The Company has concluded that it was more likely than not that none of its deferred tax assets would be realized.

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

12. RELATED PARTY TRANSACTIONS

Through June 30, 2020, the Company maintained two separate consulting agreements with the Company's CSO and the Company's CFO and COO.

Beginning in the year ended December 31, 2014, the Company entered into its first consulting agreement with the CSO. Pursuant to the amended agreement dated July 20, 2018, the CSO is 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 CSO will provide a leadership role for the Company's business development strategies. The consulting fees paid to the CSO totaled $540,700 and $25,300 in the six months ended June 30, 2020 and 2019, respectively. In addition, the Company issued the CSO 320,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations. See Note 9.

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

Kiromic BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(unaudited)

12. RELATED PARTY TRANSACTIONS (Continued)

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 $100,000 and $7,500 in the six months ended June 30, 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 9.

On June 8, 2020, the Company issued the Chief Medical Officer and another employee 3,106 and 430 shares of common stock. The shares were issued in exchange for services rendered and no cash considerations. See Note 9.

13. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the condensed consolidated balance sheet date through August 24, 2020, the date at which the consolidated financial statements were available to be issued, and other than the events mentioned below, determined that no events or transactions occurred that are required to be disclosed.

2017 Stock Incentive Plan Terminations, Cancellations, and Grants

On August 20, 2020, the board of directors canceled and terminated 709,334 RSUs and 15,792 stock options, granted during the quarter ended June 30, 2020. Thereafter, on August 20, 2020, the Board of Directors granted 946,245 RSUs and 21,112 stock options to the same individuals with a grant date fair value of $14.21 per share. 3,959 and 0 of the stock option and RSU grants were considered vested on the grant date, respectively.

Capital Expenditures

On August 20, 2020, the Board of Directors approved capital expenditures for good manufacturing practices facility laboratory equipment totaling $531,400.

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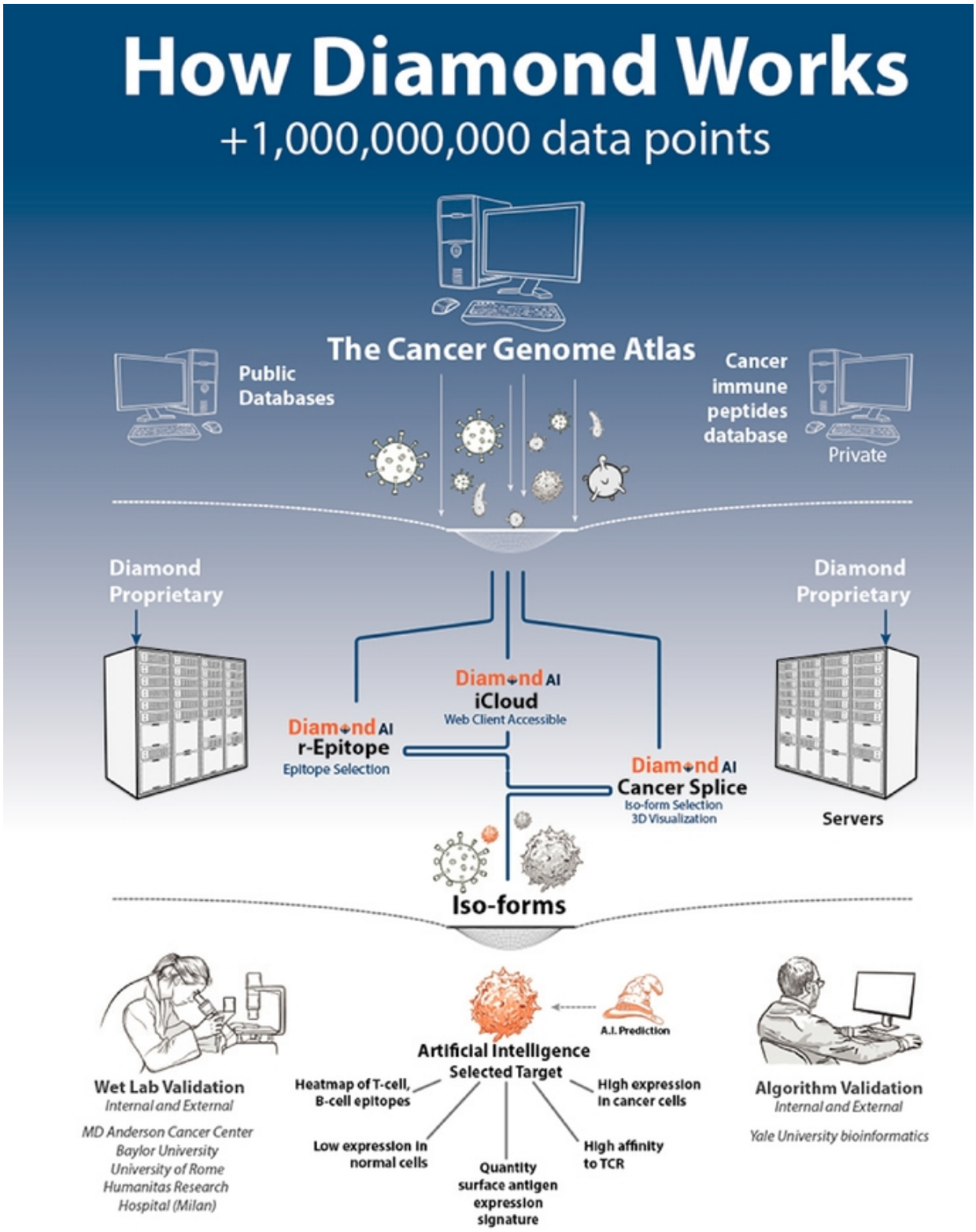

1,250,000 Shares of Common Stock

Kiromic BioPharma, Inc.

PROSPECTUS

Sole Book-Running Manager

ThinkEquity
a division of Fordham Financial Management, Inc.

Co-Manager
Paulson Investment Company, LLC

October 15, 2020

Through and including November 9, 2020 (the 25th day after the date of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.