Table of Contents

As filed with the Securities and Exchange Commission on June 27, 2022.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

KIROMIC BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**46-4762913**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

7707 Fannin, Suite 140
Houston, TX 77054
(832) 968-4888

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Pietro Bersani, CPA.
Chief Executive Officer
7707 Fannin, Suite 140
Houston, TX 77054
(832) 968-4888

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Andrew Strong
Nicholas P. Griffin
Hogan Lovells US LLP
609 Main Street, Suite 4200
Houston, TX 77002
Tel.: (713) 632-1400

William N. Haddad, Esq.
Arif Soto, Esq.
Venable LLP
1270 Avenue of the Americas, 24th Floor
New York, NY, 10020
Tel.:(212) 503-9812

Approximate date of commencement of proposed sale to public:
From time to time after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement related to these securities filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell or a solicitation of an offer to buy these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED JUNE 27, 2022

Up to Shares of Common Stock
Warrants to Purchase Shares of Common Stock
Pre-Funded Warrants to Purchase up to Shares of Common Stock

Kiromic BioPharma, Inc.

This is a firm commitment public offering of up to shares of common stock (and/or pre-funded warrants in lieu thereof (the "pre-funded warrants")) of Kiromic BioPharma, Inc. and warrants to purchase up to shares of our common stock (the "common stock warrants"). The shares of common stock and common stock warrant will be sold together, with each share of common stock to be sold together with one common stock warrant. The combined purchase price for each share of common stock and accompanying common stock warrant is $.

Each common stock warrant will have an exercise price of $ per share, will become exercisable commencing on the date of issuance, and will expire on , 2027. The shares of common stock and accompanying common stock warrant are immediately separable and will be issued separately, but will be purchased together in this offering.

We are also offering to each purchaser whose purchase of shares of our common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the holder, 9.99)% of our outstanding shares of our common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded warrants to purchase shares of our common stock, in lieu of shares of common stock. Each pre-funded warrant will be exercisable for one share of our common stock.

Our common stock is listed on the Nasdaq Capital Market under the symbol "KRBP." On June 24, 2022, the last reported sale price of our common stock on the Nasdaq Capital Market was $0.36. There is currently no established trading market for the offered common stock warrants or pre-funded warrants.We are applying to list the Common Stock Warrants for trading on the Nasdaq Capital Market, but we cannot assure you that we will meet all of the required listing standards. Without an active trading market, the liquidity of the common stock warrants and pre-funded warrants will be limited.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 ("the JOBS Act") and, as such, 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 14. Neither the Securities and Exchange Commission (the "SEC") 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 and Accompanying Common Stock Warrant	Per Pre-Funded Warrant and Accompanying Common Stock Warrant	Total
Public offering price	$	$	$
Underwriting discounts and commissions[(1)]	$	$	$
Proceeds to us, before expenses	$	$	$

(1) Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1.0% of the offering price payable to the underwriters. We refer you to "Underwriting" beginning on page 118 for additional information regarding underwriters' compensation.

We have granted a 45-day option to the representative of the underwriters to purchase up to additional shares of common stock (and/or pre-funded warrants in lieu thereof) and common stock warrants to purchase up to shares of common stock, representing 15% of the shares of common stock (and/or pre-funded warrants in lieu thereof) and warrants sold in the offering, solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers on or about , 2022.

ThinkEquity

The date of this prospectus is , 2022

Table of Contents

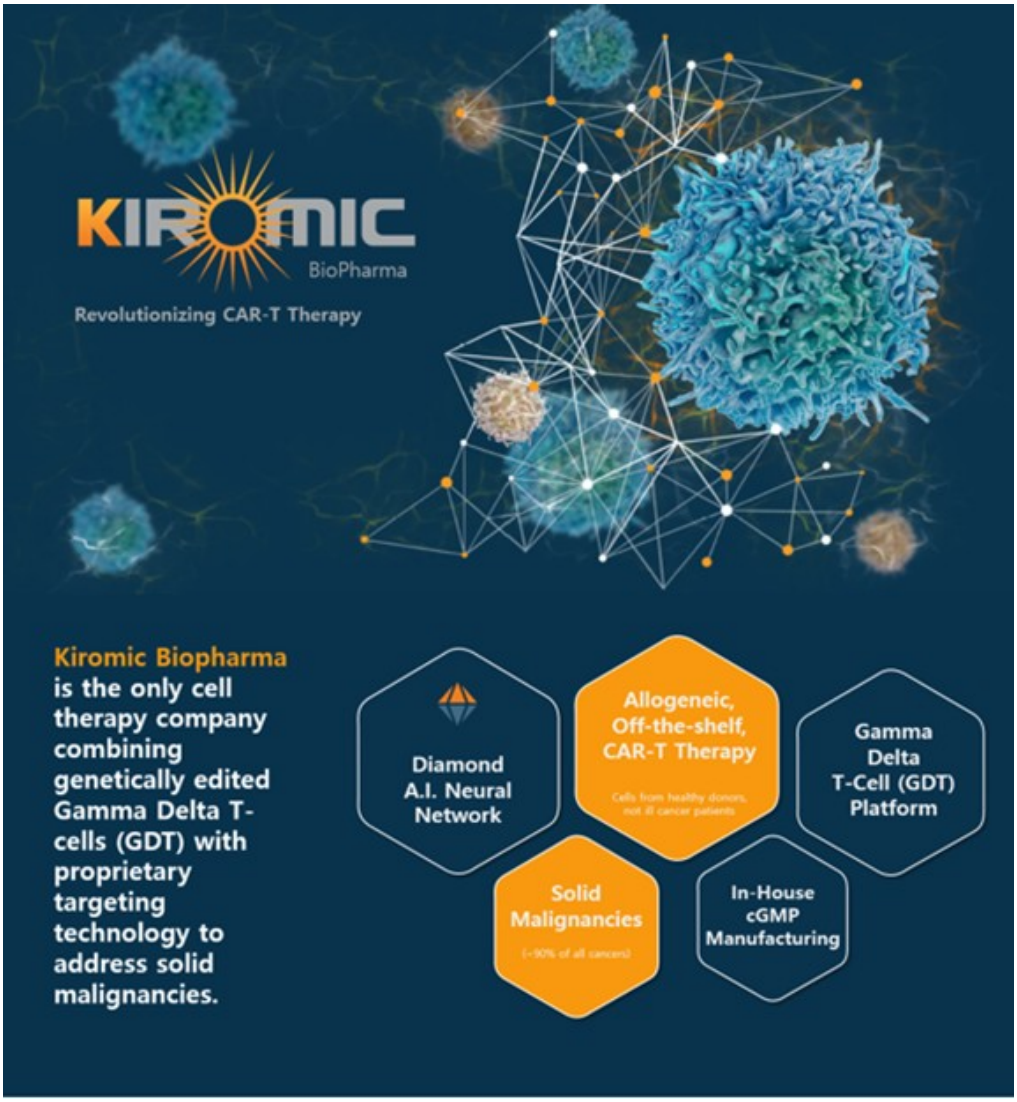


TABLE OF CONTENTS

Neither we nor the underwriter has authorized anyone to provide you any information that is different than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriter is not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States must inform themselves about, and observe any restrictions as to, this offering and the distribution of this prospectus applicable to that jurisdiction.

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

Kiromic BioPharma, Inc. (together with its subsidiaries, "we," "us," "our" or the "Company") is an artificial intelligence ("AI") driven, end-to-end allogeneic cell therapy company, currently developing the multi-indication allogeneic T cell therapy that exploits the natural potency of the Gamma Delta T cell ("GDT") to target solid tumors.

Our end-to-end approach consists of target discovery and validation, product development, and current good manufacturing practices ("cGMP") compliant manufacturing, which we believe will allow us to leverage a new framework for the next generation of cell therapies. We also have new technologies in development that we believe will support our end-to-end approach.

From a target discovery standpoint, our proprietary target discovery engine is called "Diamond." The Diamond platform is a suite of data mining algorithms that can process large amounts of data, identify cancer-specific immunotherapy targets using proprietary AI models. We believe that Diamond accelerates the development of new drug technologies by applying the latest in machine learning methods to quickly locate rare cancer-specific targets in vast databases of billions of genomic datapoints and eliminate targets to likely to fail prior to costly laboratory validation and development.

From a development standpoint, we utilize innovative engineered and non-engineered GDT manufacturing technologies and are developing proprietary, virus-free gene editing tools, to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. Our Procel, Isocel, and Deltacel platforms consist of allogeneic cell therapy product candidates that are currently in the preclinical development stage. Our Procel product candidate consists of engineered GDTs that target PD-L1. Our Isocel product candidate consists of engineered GDTs that target Mesothelin Isoform 2 positive tumors ("Iso-Meso"). Our Deltacel product candidate consists of non-engineered GDTs that have been expanded, enriched, and activated *ex-vivo* through a proprietary process, and are used to treat solid tumors regardless of the specific tumor antigen expression.

We currently have one clinical trial candidate with the Procel product candidate platform titled Allogeneic Extrinsic Immune System PRO-1 ("ALEXIS-PRO-1"). We currently have one clinical trial candidate with the Isocel product candidate platform titled Allogeneic Extrinsic Immune System ISO-1 ("ALEXIS-ISO-1"). Our ALEXIS-PRO-1 clinical trial candidate is our allogeneic GDT therapy product candidate targeting PD-L1. Our ALEXIS-ISO-1 clinical trial candidate is our allogeneic GDT therapy product candidate targeting an isoform of Mesothelin that is preferentially present on tumor cells, namely Iso-Meso. The INDs for these trial candidates have been on a clinical hold since June 2021. We are currently working on addressing the United States Food and Drug Administration's (the "FDA's") comments. Accordingly, we expect the clinical hold on ALEXIS-PRO-1 will be lifted in the first half of 2023 allowing us to begin the activation process for the clinical trial by the end of the second quarter of 2023. For ALEXIS-ISO-1, we are targeting the activation process for the clinical trial to begin by the end of the last quarter of 2023.

We have also entered into a Sponsored Research Agreement (the "SRA") with The University of Texas MD Anderson Cancer Center ("MD Anderson") Principal Investigator to facilitate the development of our Deltacel, Procel, and Isocel product candidate platforms. We believe the SRA will generate sufficient in-vivo pre-clinical data to support three new GDT therapy IND submissions that we hope to submit, including INDs for: (1) Deltacel in combination with a standard anti-tumor modality ("IND #1"); (2) Procel in combination with a standard anti-tumor modality ("IND #2"); and (3) Isocel in combination with standard anti-tumor modality ("IND #3"). These three INDs have not been submitted to the FDA yet, and the trial candidates are described in further detail below. The beginning of the activation process for the clinical trials begins after the following two events: (1) the IND is considered effective (which would take place 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); and (2) commencing the review and approval process by an independent institutional review board ("IRB") or ethics committee at the first clinical trial site.

IND #1 will evaluate Deltacel GDTs in combination with a standard anti-tumor modality. We are planning to submit this IND during the second half of 2022, and believe clinical activation will begin by the end of the fourth quarter of 2022. IND #2 will explore a combination of ALEXIS-PRO-1 with a standard anti-tumor modality. We are planning to submit IND #2 during the first half of 2023, and believe clinical activation will begin by the end of the second quarter of 2023. IND #3 will evaluate a combination of ALEXIS-ISO-1 and a standard anti-tumor modality. We are planning to submit IND #3 during the second half of 2023, with clinical activation targeted to begin by the end of the fourth quarter of 2023.

From a manufacturing standpoint, we use in-house R&D laboratory facilities, an on-site animal facility for non-clinical studies, and cGMP production facilities for vector and cell manufacturing with a dedicated on-site quality control laboratory, which we believe will ensure rapid discovery, validation, development and a streamlined clinical product release. We believe that our allogeneic, off-the-shelf ("OTS") manufacturing process will result in short lead times and low costs, opening up opportunities for outpatient treatment.

Finally, our other technologies in development consist of:

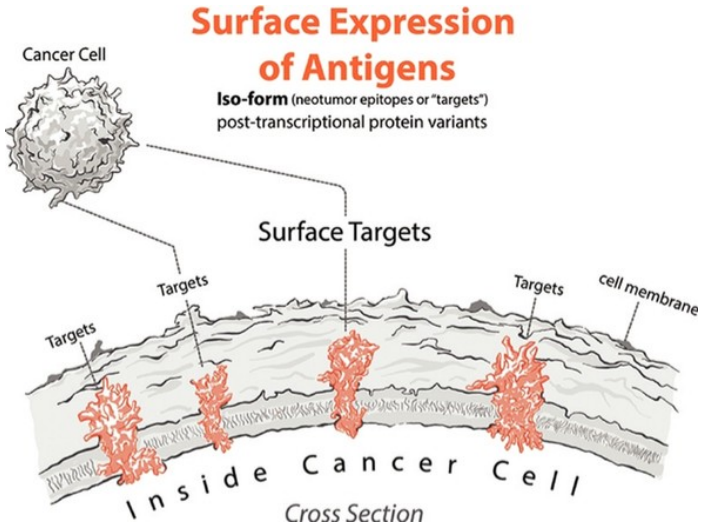
- An Invariant Natural Killer T cell ("iNKT") platform targeting PD-L1 and other tumor-preferred isoforms, similar to Iso-Meso. iNKT is considered as an unconventional T cell population with semi invariantly re-arranged T cell Receptor ("TCR"). They recognize many tumor-associated lipid antigens via their endogenous anti-tumor receptor, CD1d, which does not react against allogeneic cells, making iNKT ideally suitable for allogeneic cancer cell therapies. The innate ability of iNKTs to kill tumor cells combined with minimal graft versus host disease ("GvHD") risk provides an extremely attractive platform for developing OTS product. Although the relative percentage of iNKTs are very low in peripheral blood we believe that we have developed an efficient method of enriching, expanding, and engineering a pure population of iNKTs on a large scale, suitable for commercial manufacturing. We believe our iNKTs have exhibited the potential to efficiently kill tumor cells in-vitro and in an in-vivo pilot study. This year we will commence extensive IND application enabling studies.

- ABBIE, which is a novel cell engineering system to manufacture GMP-grade off the shelf cell therapies without the use of a viral vector, thus making our products safer and easier to manufacture.

Target Discovery: Diamond (Identify, Screen, Prioritize)

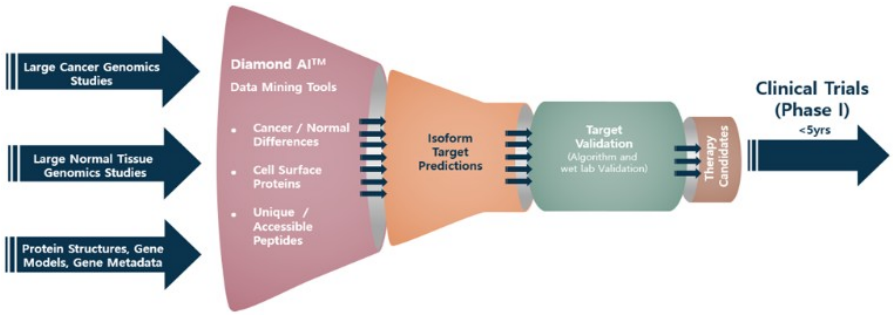
Diamond addresses one of the main challenges in developing a robust clinical pipeline: *target identification*.

Successful development of precision immunotherapies requires identifying a distinguishing feature of tumor cells (generally referred to as a "target"). The target must be common on tumor cells but not on normal cells. It also must be accessible and able to trigger an effective immune response. It is both critical and extremely difficult to find good immunotherapy targets.



Diamond is an integrated suite of data mining and AI algorithms that can identify and validate novel cancer immunological targets. The targets it identifies are segments of cell surface proteins (peptides) that are specific to tumor cells and that can be bound by immune T cells or B cells. Diamond generates a prioritized list of cancer immunological targets. These targets can be used to create therapies such as antibody therapies, T cell therapies, Chimeric Antigen Receptor T cell ("CAR-T cell") therapies and vaccine therapies.

Diamond also has a large and growing database of genomics, proteomics, cytometry, demographics, 3D structures, and gene models and annotations. The data base has approximately 2 billion data points and is an integrated collection of large public consortium datasets and Kiromic proprietary study data. The data covers 38 types of cancer and 47 types of normal human tissue with hundreds of samples and millions of datapoints for each.



Development: Using Engineered and Non-Engineered Allogeneic GDT Based Therapies

After identifying targets on solid tumors through Diamond, we seek to use those targets to train immune cells. The trained immune cells generate a therapeutic immune response in patients. These peptides, known as tumor-specific iso-antigens ("TSIAs"), generate an immunological response and therefore eradicate cancer cells.

Our Approach

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

We are currently in the process of completing the Nonclinical Research and Quality sections of the IND amendments for our ALEXIS-PRO-1 and ALEXIS-ISO-1, for first in-human OTS gamma delta chimeric PD-L1 GDTs, and chimeric antigen receptor ("CAR") (Iso-Meso) GDT therapy product, respectively. Our target indications will be metastatic and progressive locally advanced solid malignancies which have no curative options. These biomarkers have been validated in-vitro and in-vivo, with preclinical animal models.

We are also in the process of compiling preclinical data that we plan to use to submit three new INDs. The first new IND being for the Deltacel product candidate platform, for a first in-human, OTS, using non-engineered GDTs that are combined with a standard anti-tumor modality. The two other INDs, being for the Procel and Isocel product candidate platforms, for a first in-human, OTS, using engineered GDTs that are combined with a standard anti-tumor modality.

Next Generation Allogeneic Therapy Summary

We believe that our next generation allogeneic approach will allow us to do the following:

1. Address a Growing Market: Solid tumors represent approximately 90% of new cases according to the American Cancer Society, we believe that our therapies can address a significant contingency of these cases. Further, we believe that the overall global CAR-T cell therapy market could expand to over $33 billion by 2027.

2. Thwarting Antigen Escape by Targeting PD-L1: Similarly, since many solid tumors have a wide expression of PD-L1, we believe that our ALEXIS-PRO-1 and IND #2 trial candidates can effectively treat most solid cancers.

3. Exploitation of GDT's Natural Potency: Further, by using GDTs, we believe that our trial candidates can achieve superior efficacy.

Manufacturing Allogeneic OTS Therapies

Our proprietary manufacturing approach utilizes unique in-house processes that we believe maximize yield and deliver engineered and non-engineered T cells that are significantly more potent compared to the competition. The discussion below shows our unique process compared to traditional processes.

For our allogeneic products, T cells are collected from a healthy donor. The collected cells are then sent to our central processing facility, where the peripheral blood mononuclear cells, including GDTs, are isolated.

For our Procel and Isosel product candidates, these T cells are engineered by stimulating the cells to proliferate, then transduced with a non-replicating retroviral vector. These engineered cells are then propagated in cell culture bags until sufficient cells are available. The process is often referred to as "retroviral transduction". The engineered GDTs are then washed and frozen at the cell processing site.

For our Deltacel product candidate, which consists of non-engineered GDTs that have been expanded and enriched ex-vivo and activated through a proprietary process used to treat solid tumors, there is no retroviral transduction required because it is a non-viral approach.

This inventory will be securely stored and then shipped to oncology centers as needed.

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

For all of our ALEXIS and Deltacel trial candidates, we believe that all materials and components utilized in the production of the cell line, retroviral vector (for Procel and Isocel only) and final T cell product will be readily available from qualified suppliers in line with the clinical timelines discussed previously.

In addition, we believe we have sufficient space at our headquarters in Houston, Texas, to support clinical grade operations.

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.

Benefits

We believe that the manufacturing of our therapies with these process and infrastructure results in the following key benefits:

1. No Lead Time – OTS therapies are ready on demand. They are produced in advance of patient visits and are cryogenically frozen. Conversely, autologous therapies have approximately three to five weeks of lead time.

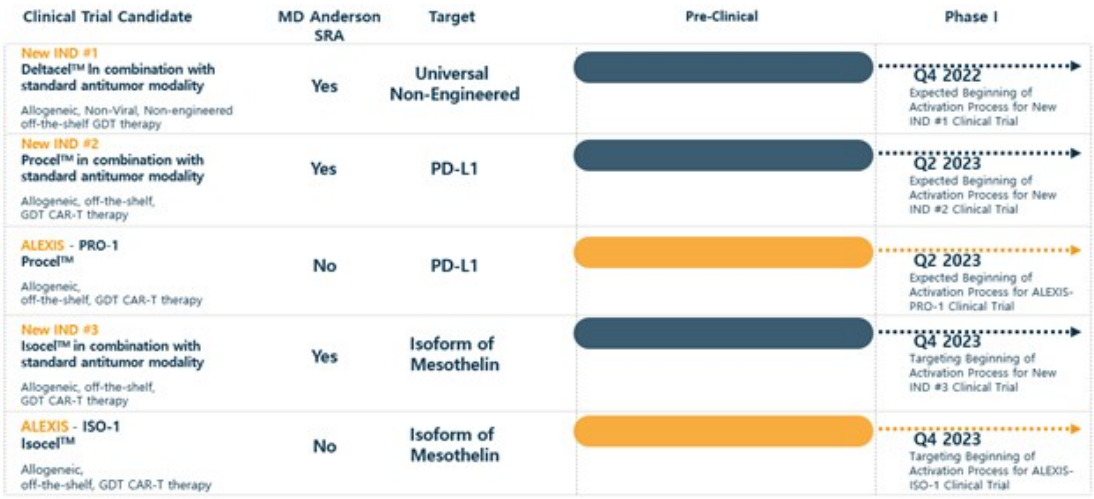
2. Outpatient Treatment – This means reduced hospitalization and other treatment related costs. Current hospitals struggle to break even if CAR-T cell therapies are administered in the inpatient setting.

3. Lower Production Costs – We have In-house cGMP manufacturing (full control and vertical integration of the manufacturing process) for vector production and cell therapy production.

Our Product Pipeline and Development

Using our proprietary technologies, we are researching and developing multiple product candidates for the treatment of solid tumors. Our product candidates are allogeneic engineered and non-engineered GDTs to be used for specific patients as OTS treatments for patients with solid tumors.

Our product pipeline and clinical program projected timelines as of the date of this prospectus are represented in the diagrams below:



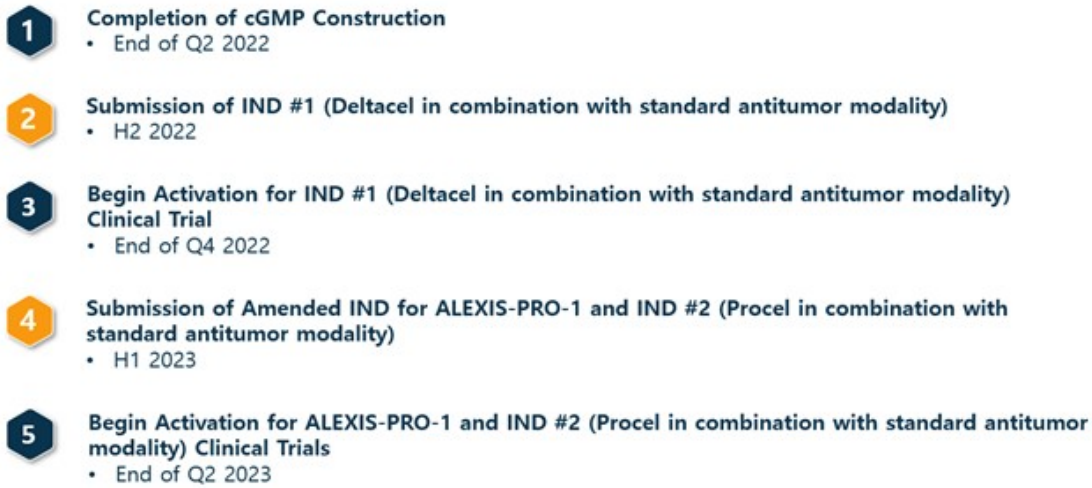
Clinical Program

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

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

The field of immunotherapy is currently expanding with a variety of approaches and we believe that our suite of GDT therapies is uniquely positioned to make an impact in this setting based upon our promising preclinical in-vitro and in-vivo studies which have revealed strong and specific tumor cytotoxicity with minimal adverse effects.

As previously discussed, our INDs for ALEXIS-PRO-1 and ALEXIS-ISO-1 are currently on a clinical hold. We hope to be able to submit IND #1, IND #2, and IND #3 in the future using the in-vivo preclinical data that will be generated under the SRA with MD Anderson. Below is a graphic outlining what we believe are our upcoming clinical milestones and expected timing for achieving each milestone based on our current expectations.



SUMMARY OF RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in the section title "Risk Factors," that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in the section titled "Risk Factors," alone or in combination with other events or circumstances, may adversely affect our ability to effect a business combination, and may have an adverse effect on our business, cash flows, financial condition and results of operations. In that event, the trading price of our securities could decline, and you could lose all or part of your investment. Such risks include, but are not limited to:

Risks Related to Our Financial Position

- We have incurred losses since inception, may never achieve or sustain profitability and will need substantial additional funding and cannot be certain that additional capital will be available.
- If we are unable to raise substantial additional capital, we may be forced to delay, reduce or eliminate our research programs, product development activities and commercialization efforts.
- Our financial situation creates doubt whether we will continue as a going concern.
- We identified material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future.

Risks Related to our Business

- We have a limited operating history and we have never commercialized a product.
- We must maintain quality controls and compliance with manufacturing standards.
- Our future success depends on our ability to retain our key executives and qualified personnel.
- We may experience difficulties in managing our growth, which could disrupt our operations.
- We had ineffective disclosure controls and procedures as of December 31, 2021, and earlier periods and we may be subject to securities laws claims regarding past disclosures.
- We face risks associated with increased political uncertainty and our business may be adversely affected by the ongoing coronavirus ("COVID-19") pandemic.
- We may become involved in litigation from time to time (including litigation related or arising from our Internal Review) that may adversely affect our business and results of operations.

Risks Related to our Product Candidates

- Our immunotherapy approach 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 face substantial competition and other existing or future technologies may provide significant advantages over our technologies.
- We may expend resources pursuing programs or products that may be less successful than others.
- If we experience delays or difficulties in patient enrollment or in the commencement and completion of clinical trials, our development efforts and the receipt of regulatory approvals could be delayed or prevented.
- We may be required to perform additional or unanticipated clinical trials. If our immunotherapy candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value.
- Results from preclinical studies and early-stage clinical trials may not be predictive and preliminary interim or "top-line" data that we announce may change as more data become available.
- Our product candidates are complex and difficult to manufacture.
- 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.
- The market opportunities for our product candidates may be smaller than we estimate.

Risks Related to Government Regulation

- The FDA regulatory approval process is lengthy and time-consuming, we may continue to experience significant delays, and our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.
- We may find it difficult to enroll patients in our clinical trials.
- 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 regulatory landscape that will govern our product candidates is uncertain.
- The FDA may disagree with our plans, and we may fail to obtain regulatory approval of our product candidates and we may be unable to obtain orphan drug designation or to maintain the associated benefits.
- Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory obligations and continued regulatory review.

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.
- Our relationships with healthcare professionals, clinical investigators, Contract Research Organizations ("CROs"), and third-party payors 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.

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.
- 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 could lose license rights that are important to our business if we fail to comply with our obligations in the agreements under which we license such intellectual property.
- We may not be able to protect our intellectual property rights throughout the world.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or trade secrets of third parties.

Risks Related to the Securities in this Offering

- Our common stock may be volatile or may decline regardless of our operating performance and an active trading market for our common stock may not be sustained. You may not be able to sell your shares at or above the public offering price, or at all.
- We do not expect to pay dividends in the foreseeable future.
- If you purchase shares of common stock in this offering, you will suffer immediate dilution in the book value of your shares.
- If a trading market for our Common Stock Warrants or Pre-Funded Warrants (each as defined below) does not develop, you may not be able to sell such warrants quickly or at or above the price you paid.
- If we do not maintain a current and effective prospectus related to this offering, public holders of the Common Stock Warrants and Pre-Funded Warrants will only be able to exercise such warrants on a "cashless basis."
- Holder of our warrants will have no rights as a common stockholder until they exercise such warrants and upon exercise of the Pre-Funded Warrants, we will not receive any meaningful amount of additional funds.
- Significant holders or beneficial holders of shares of our common stock may not be permitted to exercise the Pre-Funded Warrants that they hold.
- We may issue additional debt and equity securities, which could materially adversely affect the market price of our common stock.
- Failure to meet the continued listing requirements of The Nasdaq Stock Market, LLC ("Nasdaq") could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.
- We have broad discretion in how we use the net proceeds from this offering.

CORPORATE INFORMATION

We were first organized as a corporation in the State of Texas on August 6, 2006 under the name "Kiromic, Inc." On May 27, 2016, we converted to a corporation in the State of Delaware under the name "Kiromic, Inc" and on December 16, 2019, we changed our name to "Kiromic BioPharma, Inc." 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.

Kiromic, Kiromic BioPharma, Diamond, Deltacel, Procel, Isocel, and our logo are some of our trademarks used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and tradenames.

IMPLICATIONS OF BEING AN EMERGING GROWTH COMPANY AND A SMALLER REPORTING COMPANY

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to only disclose two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; and
- an exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

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

THE OFFERING	
Common stock offered by us	shares
Warrants offered by us	Warrants to purchase up to shares of our common stock (the "Common Stock Warrants"). Each Common Stock Warrant will have an exercise price of $ per share, will be exercisable commencing on the date of issuance and will expire on , 2027. The shares of common stock and Common Stock Warrants will be sold together, with each share of common stock to be sold together in a fixed combination with a Common Stock Warrant to purchase shares of common stock. For additional information regarding the Common Stock Warrants, see "Description of Securities" beginning on page 106 of this prospectus.
Pre-Funded Warrants offered by us	We are also offering, in lieu of shares of our common stock to certain investors, pre-funded warrants to purchase shares of common stock (the "Pre-Funded Warrants") that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock. Each Pre-Funded Warrant will be exercisable for one share of common stock. This offering also relates to the shares of common stock issuable upon exercise of any Pre-Funded Warrant sold in this offering. The Pre-Funded Warrants will be exercisable immediately and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. For each Pre-Funded Warrant that we sell, the number of shares of common stock that we are offering will be decreased on a one-for-one basis.
Over-allotment option	We have granted the underwriters an option for a period of 45 days from the date of this prospectus to purchase up to an additional shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants, representing 15% of shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants sold in the public offering solely to cover over-allotments, if any. The purchase price to be paid per additional share of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants shall be equal to the public offering price, less the underwriting discount.
Shares of common stock outstanding before this offering	shares
Shares of common stock to be outstanding after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares to cover over-allotments, if any) in each case, assuming we sell only shares of common stock and no Pre-Funded Warrants and that none of the Common Stock Warrants offered hereunder are exercised. To the extent Pre-Funded Warrants are sold it will reduce the number of shares of common stock on a one for one basis.

Use of proceeds	We estimate that we will receive net proceeds of approximately $ (or approximately $ if the underwriters exercise their over-allotment option in full) from the sale of shares of our common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants by us in this offering. We plan to use the net proceeds of this offering primarily for (i) submission and the clinical trial activation of IND #1, which is our Deltacel product candidate in combination with a standard anti-tumor modality, (ii) IND resubmission of the IND for ALEXIS-PRO-1 and the corresponding trial activation, (iii) intellectual property protection and reinforcement, (iv) IND applications and IND enabling trials for our other product candidates, (v) working capital and (vi) general corporate purposes, including but not limited to legal fees associated with pending matters. The details of our plans are set forth in the "Use of Proceeds" section. We also intend to use net proceeds and our existing cash and cash equivalents, (i) for research and development activities related to our pre-clinical and discovery programs (ii) for personnel expenses, working capital and other general corporate purposes, and (iii) to acquire or invest in complementary businesses, products, or technologies, or to obtain the right to use such complementary technologies.
Risk factors	You should carefully read the section entitled "Risk Factors" on page 14 for a discussion of factors that you should consider before deciding to invest in shares of our common stock.
Lock-up	We and our executive officers and directors, have agreed not to, without the prior written consent of the representative, offer, issue, sell, contract to sell, assign, transfer, pledge, 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 six (6) months from the date of this prospectus, in the case of our directors and officers.
National securities exchange listing	Our common stock is listed on The Nasdaq Capital Market under the symbol "KRBP." We are applying to list the Common Stock Warrants for trading on the Nasdaq Capital Market, but we cannot assure you that we will meet all of the required listing standards. We do not intend to list the Pre-Funded Warrants on the Nasdaq Capital Market or any other national securities exchange or nationally recognized trading system.

The number of shares of common stock to be outstanding after this offering is based on 15,839,112 shares of common stock outstanding as of June 24, 2022, and excludes as of June 24, 2022:

- 338,872 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of $8.49 per share;
- 225,018 shares of our common stock issuable upon the vesting of outstanding restricted stock units, with a weighted-average grant date fair value of $10.37 per share;

- 62,500 shares of our common stock underlying outstanding warrants that were issued in October 2020 with an exercise price of $15.00 per share;
- 400,000 shares of our common stock underlying outstanding warrants that were issued in July 2021 with an exercise price of $6.25 per share;
- 1,884,082 shares of our common stock reserved for future issuance under our Omnibus 2021 Equity Incentive Plan;
- shares of our common stock underlying the Common Stock Warrants being offered hereunder; and
- shares of our common stock underlying the warrants being issued to the representative of the underwriters in connection with this offering,with an exercise price of .

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

- the sale and issuance by us of shares of common stock being offered here under (and no sale of any Pre-Funded Warrants);
- no exercise of the underwriters' option to purchase up to an additional shares of common stock to cover over-allotments, if any; and
- no exercise of the Common Stock Warrants.

SUMMARY FINANCIAL INFORMATION

The following tables present summary financial data for our business. We derived the statements of operations data for the years ended December 31, 2021 and 2020 from our audited consolidated financial statements appearing elsewhere in this prospectus. We derived the statements of operations data for the three months ended March 31, 2022 and 2021 and the balance sheet data as of March 31, 2022 from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus. These unaudited condensed consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and, in management's opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair statement of such financial data. Our historical results are not necessarily indicative of the results that may be expected in any future period. You should read the following data together with our audited consolidated financial statements and the unaudited condensed consolidated financial statements and the related notes, as well as the information included in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" which appears elsewhere in this prospectus.

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.

Consolidated Statements of Operations Data

	Years Ended December 31,		Three Months Ended March 31,	
Statement of Operations	**2021**	**2020**	**2022**	**2021**
Operating expenses:				
Research and development	$ 11,367,800	$ 5,052,900	$ 2,925,800	$ 1,885,600
General and administrative	13,937,900	14,144,000	4,439,200	2,071,000
Impairment Expense	430,000	—	—	—
Total operating expenses	25,735,700	19,196,900	7,365,000	3,956,600
Loss from operations	(25,735,700)	(19,196,900)	(7,365,000)	(3,956,600)
Other income (expense)				
Gain on loan extinguishment	105,800	—	—	105,800
Other income	53,400	—	—	—
Interest expense	(12,200)	(3,300)	(2,800)	(3,700)
Total other income (expense)	147,000	(3,300)	(2,800)	102,100
Net loss	$ (25,588,700)	$ (19,200,200)	$ (7,367,800)	$ (3,854,500)
Net loss per share, basic and diluted	$ (2.26)	$ (4.42)	$ (0.48)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	11,417,083	4,505,867	15,542,444	7,332,999

Consolidated Balance Sheet Data

The table below presents our balance sheet data as of March 31, 2022:

	March 31, 2022	
	As Reported	**As Adjusted**
Balance sheet data		
Cash and cash equivalents	$ 15,123,100	$ 37,644,100
Working capital	12,625,800	35,146,800
Total assets	25,889,800	48,410,800
Total stockholders' equity	20,032,100	42,553,100

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of shares of common stock in this offering at an offering price of $ per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position

We have incurred losses since inception and we expect to incur significant net losses in the foreseeable future.

We generated negative cash flows from operations and have incurred net operating losses each year since we started business. For the year ended December 31, 2021, we incurred net losses of $25,588,700 and our net cash used in operating activities was $20,321,500. For the three months ended March 31, 2022, we incurred net losses of $7,367,800 and our net cash used in operating activities was $7,578,900. As of March 31, 2022, our accumulated deficit was $74,584,300. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next twelve months. As our focus on development of our product candidates has increased, losses have resulted primarily from expenses associated with research and development and clinical trial-related activities, as well as general and administrative expenses. While we have implemented and continue to implement cost reduction measures where possible, we nonetheless expect to continue operating in a loss position on a consolidated basis and expect that recurring operating expenses will be at higher levels for the year ending December 31, 2022. Further, we anticipate that our expenses will increase substantially if and as we:

- continue our current research and development programs, including conducting laboratory, and preclinical 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 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.

Our ability to generate sufficient revenue from any of our products, product candidates or technologies to achieve profitability will depend on a number of factors including, but not limited to, the success of our research and development programs, our ability to achieve regulatory approvals, 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.

We may never achieve or sustain profitability.

We do not know when or whether we will become profitable. We have no products approved for commercial sale and have not generated revenue from operations. To become and remain profitable, we must succeed in developing, obtaining regulatory approval for and commercializing one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing commercialization capabilities for any approved products and achieving market acceptance for any approved products. We may never succeed in these activities. Even if we succeed in these activities, we may never generate revenue in an amount sufficient to achieve profitability.

Because of the numerous risks and uncertainties associated with biotechnology product development and commercialization, we are unable to accurately predict whether and when we will achieve profitability. If we are required by the FDA, the European Medicines Agency (the "EMA") or any comparable regulatory authority to perform preclinical studies or clinical trials in addition to those we currently expect to conduct, or if there are any delays or complications in completing preclinical studies of our product candidates or, if preclinical studies are successful, in submitting an IND or Clinical Trial Application to the FDA and comparable regulatory authorities, and if clinical trials are successful, in submitting a Biologic License Application ("BLA") or Marketing Authorization Application to the FDA and comparable regulatory authorities, manufacturing clinical trial supplies and completing clinical trials, our expenses could increase substantially and our ability to achieve profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain profitability in subsequent periods. After we achieve profitability, if ever, we expect to continue to engage in substantial research and development activities and to incur substantial expenses to develop and commercialize additional product candidates. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our revenues, expenses and profitability.

Our failure to achieve or sustain profitability would depress our market value and could impair our ability to execute our business plan, raise capital, develop additional product candidates or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

We will need substantial additional funding to develop our product candidates and conduct our future operations and to repay our outstanding debt obligations. We cannot be certain that additional capital will be available on terms acceptable to us, or at all

We have an ongoing need to raise additional cash from outside sources to continue funding our operations, including our continuing substantial research and development expenses. We do not currently believe that our cash balance will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to our development programs, and any delays in, adverse events and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our product candidates to market and the cost of such arrangements at the time;
- the cost of manufacturing our product candidates, including compliance with GMP applicable to our product candidates;
- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;

- competing technological and market developments; and
- our ability to introduce and sell new products.

The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical and preclinical development efforts.

We have secured capital historically from equity offerings. To obtain additional capital, we may pursue debt and/or equity offering programs, strategic corporate partnerships, state and federal development programs, licensing arrangements, and sales of assets. We cannot be certain that additional capital will be available on terms acceptable to us, or at all.

Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, preferred stock, convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on debt or other securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted.

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.

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

The Company has not generated any revenues to date. For the three months ended March 31, 2022 and 2021, we had a net loss of $7,367,800 and $3,854,500, respectively. There can be no assurances that we will be able to achieve a level of revenues adequate to generate sufficient cash flow from operations or obtain funding from additional financing through private placements, public offerings and/or bank financing necessary to support our working capital requirements. No assurance can be given that additional financing will be available, or if available, will be on acceptable terms. These conditions raise substantial doubt about our ability to continue as a going concern.

We have identified certain material weaknesses in our internal control over financial reporting and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

In the course of preparing our financial statements, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses related to: (1) lack of internal control processes and procedures regarding the financial close and reporting process, procure to pay process, and human resources and payroll process; (2) those controls being designed without the

appropriate segregation of duties; (3) lack of full time accounting and finance personnel; and (4) internal communication deficiencies surrounding our failure to timely disclose that the Company had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing the Company's IND applications that the Company submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 clinical trial candidates, respectively, on clinical holds (the "June 16 and 17, 2021 FDA Communications"). In order to remediate these material weaknesses, we have hired and plan to continue to hire and engage additional accounting, finance, and system implementation specialists and we have formed a Disclosure Committee comprised of certain members of the Company's management. We have implemented, and plan to continue to implement, new controls, new processes and technologies to implement formalized internal controls framework and procedures.

We believe we have taken the necessary actions to substantially address each of the material weaknesses discussed above, and we plan to take additional steps to improve our accounting function. However, we may not be able to fully remediate these material weaknesses until it can be confirmed that such remedial measures have been operating effectively for a sufficient period of time. Further, we cannot assure you that any such actions will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, deficiencies or material weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until after we are no longer an "emerging growth company" as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that are filed with the SEC. The existence of material weaknesses in internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq.

Risks Related to our Business

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 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.

As a company, we have never commercialized a product. We currently have no active sales force or commercial infrastructure. We may lack the necessary expertise, personnel and resources to successfully commercialize our product candidates.

We currently have no active sales force or commercial infrastructure. As a company, we have never commercialized a product for any indication. Even if we receive regulatory approval for one or more of our product candidates from the FDA or comparable regulatory authorities, we will need to develop robust internal sales, marketing and distribution capabilities to commercialize such products, which will be expensive and time-consuming, or enter into collaborations with third parties to perform these services.

There are costs and risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We must also compete with other biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

Alternatively, we may wish to establish collaborations with third parties to maximize the potential of our product candidates jurisdictions in which a product candidate has been approved. The biotechnology industry is characterized by intense competition. Therefore, we may not be successful in entering into such commercialization arrangements with third parties on favorable terms, or at all. In addition, we may have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

There can be no assurance that we will be able to develop the necessary commercial infrastructure and capabilities to successfully commercialize our product candidates or be able to establish or maintain relationships with third parties necessary to perform these services. As a result, we may not successfully commercialize any product in any jurisdiction.

We must maintain quality controls and compliance with manufacturing standards.

The manufacture of our product candidates is, and the manufacture of any future drug and/or cell-related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of drug products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's cGMP, Quality System Regulations ("QSRs"), as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no assurance that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek remedial action.

Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre- market approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that after such occurrences we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or the loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

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 Pietro Bersani, our Chief Executive Officer, Scott Dahlbeck, our Chief of Staff, Mike Ryan, our Chief Bioinformatics Research Computing Officer, and Daniel Clark, our Chief Financial Officer.

Although we have employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. 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. If we are not able to effectively manage this expansion, that may impact our future financial performance, our ability to develop and commercialize product candidates alone or with collaborators, and our ability to compete effectively. In addition, we may have difficulty identifying, hiring and integrating new personnel if we are unable to effectively manage expansion.

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

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

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

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

respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies make our shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation. In addition, as an emerging growth company, we are required to provide only two years of audited financial statements and two years of selected financial data in our initial registration statement, compared to three and five years, respectively, for comparable data reported by other public companies.

We could be an emerging growth company for up to five years from our initial public offering ("IPO"), although circumstances could cause us to lose that status earlier, including if the market value of our shares held by non-affiliates equals or exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time or if we have total annual gross revenues of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 (our fiscal year end); or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile. When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort towards ensuring compliance with them, and we cannot predict or estimate the amount or timing of such additional costs.

We may be subject to securities laws claims regarding past disclosures.

We may be subject to additional claims for rescission (under which a successful claimant would have the right to receive the total amount paid for his or her shares, plus interest and less any income earned on the shares, in exchange for surrender of the shares), damages (under which a successful claimant would have the right to receive the total amount paid for his or her shares, plus interest and less any income earned on the shares, in exchange for surrender of the shares) or other securities law claims resulting from our failure to timely disclose the June 16 and 17, 2021 FDA Communications.

On July 2, 2021, we consummated a public offering of $40 million of our common stock. Neither the Registration Statement on Form S-1 with respect to this offering that was filed on June 25, 2021 nor the final prospectus dated June 29, 2021 with respect to this offering contained any disclosure with respect to the June 16 and 17, 2021 FDA Communications. Our Form S-1 and final prospectus for the offering stated the following with respect to our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates: "These products are in the pre-IND stage of the FDA clinical trial process. We are currently going through the IND enabling trials process for these product candidates and we expect that first in human dosing in Phase I of clinical trials will commence in the third quarter of 2021." Anyone who purchased shares of our common stock in the offering and anyone who purchased or sold shares of our common stock in the public market after June 16, 2021 could claim that they were misled by our failure to disclose the clinical hold on studies under the INDs for these product candidates and that they suffered damages. On March 7, 2022, certain shareholders who had purchased shares of our common stock in the Company's public offering that closed on July 2, 2021 filed a complaint against the Company and certain our current and former officers and directors for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock in the offering. The plaintiffs seek unspecified damages; rescission to the extent they still hold Kiromic securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. We expect to vigorously defend against this action. We have evaluated that it is reasonably possible that the claims from entities related to Sabby Management LLC (the "Sabby Entities") and Empery Asset Management, LP(the "Empery Entities") may result in an estimated loss ranging between $0 and $8,100,000. Similarly, we have

evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, we are unable to estimate any possible range of loss attributed to other unasserted claims at this time. Even if we are successful in defending against this litigation or any other unasserted claims, securities litigation is costly to defend and would likely divert management's attention away from the business.

In addition to the above, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of stockholders of the Company. These press releases were in response to an approximately 15% decline in the Company's stock price on July 16, 2021, the date we had first announced we had received comments from the FDA on our ALEXIS-PRO-1 and ALEXIS-ISO-1 INDs. If claims are ultimately made pursuant to these investigations or otherwise, we intend to defend ourselves vigorously, but are unable to predict the outcome of any such litigation. Even if we are successful, securities litigation is costly to defend and would likely divert management's attention away from the business.

The existence of pending and potential securities law claims may adversely affect our ability to raise capital.

We had ineffective disclosure controls and procedures as of March 31, 2022 and earlier periods, which could result in our potential exposure to litigation and could adversely affect or ability to raise capital in the future.

We have determined that our disclosure controls and procedures were not effective as of March 31, 2022. Our disclosure controls and procedures were ineffective due to the existence of material weaknesses in internal control over financial reporting, including a material weakness resulting from internal communication deficiencies surrounding our failure to timely disclose the June 16 and 17, 2021 FDA Communications as previously described. We had previously determined that our disclosure controls and procedures were not effective as of December 31, 2021 due to the existence of material weaknesses in our internal control over financial reporting. We made the same determination in earlier periods as well. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

In January 2022, a Committee of our board of directors (the "Board") has made several recommendations to improve the effectiveness of the Company's disclosure controls and procedures, which recommendations were accepted and adopted by the Board. The recommendations that have been adopted include among other things: (i) the appointment of an Interim CEO who has received training in appropriate disclosure controls and procedures and who will be responsible for supervising our disclosure controls and procedures, (ii) the establishment of a Disclosure Committee of our management, and (iii) the appointment of two additional independent directors to the Board. However, the fact that we experienced ineffective disclosure controls could result in further potential exposure to litigation and could adversely affect our ability to raise funds in the future.

Matters relating to or arising from our Internal Review, including regulatory investigations and proceedings, litigation matters, and potential additional expenses, may adversely affect our business and results of operations. We may also become involved in litigation from time to time that may materially adversely affect us.

Matters relating to or arising from our Internal Review, including potential regulatory investigations and proceedings, current and potential litigation matters, and potential additional expenses, may adversely affect our business and results of operations. See "Management's Discussion and Analysis of Financial Condition and Results of Operation — Recent Developments — Results from our Internal Review" for more information.

From time to time, we have also become and may in the future be involved in legal proceedings relating to various matters, including intellectual property, commercial, employment, former employees (including any claims brought by Dr. Chiriva arising from his termination) class action, whistleblower and other litigation and claims, as well as governmental and other regulatory investigations and proceedings. Litigation and governmental and regulatory investigations and proceedings are time-consuming, and may divert management's attention and resources, cause us to incur significant expenses or liability or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we believe that we have meritorious claims or defenses. Because litigation and governmental and regulatory investigations and proceedings are inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business.

Risks Related to our Product Candidates

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 TSIA's 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 that 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 face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing, or commercializing products before, or more successfully, than we do.

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of our product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability, and safety. In many cases, the products that we intend to commercialize, if successfully commercialized, will compete with existing market-leading products.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products.

Large and established companies compete in the same market as our product candidates. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies.

The genome editing field is relatively new and evolving rapidly, and other existing or future technologies may provide significant advantages over our product candidates of our Diamond 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 ("TALENs"), and clustered regularly interspaced short palindromic repeats associated protein-9 nuclease ("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.

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.

If we experience delays or difficulties in patient enrollment for clinical trials, our research and development efforts and the receipt of necessary regulatory approvals could be significantly delayed or prevented.

Commencement and successful and timely completion of clinical trials require us to enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or comparable regulatory authorities. Any delay or difficulty in patient enrollment could significantly delay or otherwise hinder our research and development efforts and delay or prevent receipt of necessary regulatory approvals. Despite diligent planning of our clinical trials and analysis of their feasibility regarding patient recruitment, we may experience difficulties, delays or inability in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the severity and incidence of the disease under investigation;
- the eligibility criteria for the study in question, including any misjudgment of, and resultant adjustment to, the appropriate ranges applicable to the exclusion and inclusion criteria;
- the size of the study population required for analysis of the trial's primary endpoints;

- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the number of clinical trial sites and the proximity of prospective patients to those sites;
- the design of the trial and the complexity for patients and clinical sites;
- the nature, severity and frequency of adverse side effects associated with our product candidates;
- the screening procedures and the rate of patients failing screening procedures;
- the ability to provide appropriate screening assays;
- the risk that patients' general health conditions do not allow the conduct of study/screening procedures (for example, tumor biopsy);
- the ability to manufacture patient products appropriately (for example, at a sufficient high dose, or with sufficiently active T cells);
- the efforts to facilitate timely enrollment in clinical trials and the effectiveness of recruiting publicity;
- the patient referral practices of physicians within the same hospital as well as within other hospitals or private practices;
- competing clinical trials for similar therapies, other new therapeutics, new combination treatments, new medicinal products;
- approval of new indications for existing therapies or approval of new therapies in general or changes in standard of care;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved or become standard of care for the indications we are investigating;
- the ability to obtain and maintain patient consents; and
- inability of clinical sites to enroll patients as healthcare capacities are required to cope with natural disasters, epidemics or other health system emergencies, such as the COVID-19 pandemic.

Further, challenges in recruiting and enrolling suitable patients to participate in clinical trials could increase costs, affect the timing and outcome of our planned clinical trials and result in delays to our current development plan for our product candidates.

Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.

We cannot guarantee that clinical trials of our product candidates will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of the clinical trial process, and other events may cause us to temporarily or permanently stop a clinical trial. Events that may prevent successful or timely commencement and completion of clinical development include:

- negative preclinical data;
- delays in receiving the required regulatory clearance from the appropriate regulatory authorities to commence clinical trials or amend clinical trial protocols, including any objections to our INDs or protocol amendments from regulatory authorities;
- delays in reaching, or a failure to reach, a consensus with regulatory authorities on study design;
- delays in reaching, or a failure to reach, an agreement on acceptable terms with prospective independent clinical investigators, CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different investigators, CROs and clinical trial sites;

- difficulties in obtaining required IRB or ethics committee approval at each clinical trial site;
- challenges in recruiting and enrolling suitable patients that meet the study criteria to participate in clinical trials;
- the inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- imposition of a clinical hold by regulatory authorities or IRBs for any reason, including safety concerns and non-compliance with regulatory requirements;
- failure by independent clinical investigators, CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practices (GCPs) or applicable regulatory guidelines in other jurisdictions;
- the inability to manufacture adequate quantities of a product candidate or other materials necessary in accordance with cGMPs and current good tissue practices ("cGTPs") to conduct clinical trials;
- lower than anticipated patient retention rates;
- difficulties in maintaining contact with patients after treatment, resulting in incomplete data;
- ambiguous or negative interim results;
- our independent clinical investigators, CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a clinical trial;
- unforeseen safety issues, including occurrence of adverse events associated with the product candidate that are viewed to outweigh the product candidate's potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- lack of adequate funding to continue the clinical trial; or
- delays and disruptions as a result of the COVID-19 pandemic.

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 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 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 U.S. 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 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.

Results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage or other clinical trials.

Positive and promising results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage clinical trials or from clinical trials of the same product candidates. The primary objectives of our current Phase 1 clinical trials are to establish safety and tolerability and to determine the recommended Phase 2 dose. Results from those and future early-stage clinical trials may not be representative of results from later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Late-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. In particular, we expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as for our cellular therapy product candidates, than for "OTS" products, like many other drugs. Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. There can be no assurance that we will not face similar setbacks. Therefore, despite positive results observed in early-stage clinical trials, our product candidates may fail to demonstrate sufficient efficacy in our pivotal or confirmatory clinical trials.

Preliminary interim or "top-line" data that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may announce or publish preliminary interim or "top-line" data from clinical trials. Positive preliminary data may not be predictive of such trial's subsequent or overall results. Preliminary data are subject to the risk that one or more of the outcomes may materially change as more data become available. Additionally, preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

Therefore, positive preliminary results in any ongoing clinical trial may not be predictive of such results in the completed trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, preliminary data that we report may differ from future results from the same clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary data could significantly harm our business prospects.

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

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

Manufacturing defects, errors in product distribution or storage processes, improper administration or application and known or unknown side effects of product usage may result in liability claims against us or third parties with which we have relationships. These actions could include claims resulting from acts by our collaborators, licensees and subcontractors over which we have little or no control. For example, our liability could be sought by patients participating in clinical trials for potential therapeutic product candidates as a result of unexpected side effects, improper product administration or the deterioration of a patient's condition, patient injury or even death.

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

Clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities.

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

Our product candidates are complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs.

Our product candidates are cellular products or biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. The manufacture of our cellular product candidates involves complex processes which include, for example, harvesting white blood cells from healthy donors, transporting them from blood banks to our cGMP facility for donor GDT expansion, engineering, and cryopreservation, and finally shipping of the T cell product back to the patient for treatment. As a result of the complexities, the cost to manufacture cellular products per dose is generally higher than traditional small molecule chemical compounds or biologics, and the manufacturing process is less reliable, more variable and is more difficult to reproduce. Our manufacturing process may be susceptible to product loss or failure due to logistical issues associated with the collection of patients' blood cells, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product. Product loss or failure may also be caused by manufacturing issues associated with the variability in patient starting material especially from heavily treated cancer patients, interruptions in the manufacturing process, contamination, equipment failure, assay failures, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material, or any intermediate product at any point in the process, or if any product does not meet the preset specifications, the manufacturing process for that patient will need to be restarted, sometimes including re-collection of blood cells from the patient, and the resulting delay may adversely affect that patient's outcome. It may even happen, that failed product manufacture may prevent a patient from getting a T cell product. If microbial, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. If such contaminations or other product quality issues are not discovered and if as a result thereof patients are exposed to a health risk, we may be held liable. Our insurance may not cover those cases, or the financial coverage may not be sufficient.

Because our Procel and Isocel product candidates are manufactured specifically for each individual patient, we will be required to maintain a chain of identity with respect to the patient's cellular material as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials or otherwise necessitate the conduct of additional studies, including bridging clinical trials, which can be costly and time-consuming.

In addition, the manufacturing process and facilities for any products that we may develop is subject to FDA and comparable regulatory authority approval processes, and we will need to meet all applicable regulatory authority requirements, including cGMP and cGTP requirements, on an ongoing basis, including requirements pertaining to quality control, quality assurance, and the maintenance of records and documentation. The FDA and comparable regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must be approved by the FDA pursuant to inspections that will be conducted after we

submit our marketing applications. Manufacturers are also subject to continuing FDA and comparable regulatory authority inspections following marketing approval. Further, we must supply all necessary chemistry, manufacturing, and control documentation in support of a BLA on a timely basis.

Any failure to follow cGMP and cGTP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill and finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of drug product for our clinical trials or the termination of or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates.

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.

The market opportunities for our product candidates may be smaller than we estimate.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who are in a position to receive our product candidates, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates that have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. These estimates may be inaccurate or based on imprecise data. We do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which could materially adversely affect our business, financial condition, results of operations and prospects.

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, sale, 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 U.S. 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 have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected development in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by our regulators, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price.

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 allogeneic 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.

Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays or failure in reaching a consensus with regulatory agencies on trial design;
- delays or failures in obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- delays or failures in 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;
- delays or failures in obtaining approval at each clinical trial site by an independent IRB;
- delays or failures in recruiting suitable patients to participate in a trial;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites;
- failure to perform clinical trials in accordance with the GCP or applicable regulatory guidelines in other countries;
- 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;
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient-by-patient basis for use in clinical trials;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators or funders may require us, to conduct additional preclinical testing or clinical trials or to abandon projects that we expected to be promising;
- our third-party contractors (such as CROs, product manufacturers, or investigators) may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review or one or more of our marketing applications by regulatory agencies;
- the cost of our clinical trials may be greater than we anticipate;
- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction;
- evolution in the standard of care that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

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 may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our trials because of the COVID-19 pandemic and restrictions on travel or healthcare institution policies, negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by several factors, including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- willingness or availability of patients to participate in our clinical trials (including due to the COVID-19 pandemic);
- proximity and availability of clinical trial sites for prospective patients;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies.

Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients.

If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and/or regulatory authorities to interrupt, delay or halt clinical trials and could result in clinical trial challenges such as difficulties in patient recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole.

Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term

adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- we may be unable to obtain regulatory approval for our product candidates;
- regulatory authorities may withdraw approvals of our products;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approvals for and market acceptance of our product candidates and could have a material adverse effect on our business and financial results.

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 BPCIA 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 BPCIA, 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 BPCIA 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 if any of the product candidates we develop that are approved in the U.S. as a biological product under a BLA, the 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 U.S., 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 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 EMA 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 our planned Phase 1 clinical trials for ALEXIS-PRO-1 and ALEXIS-ISO-1 and our other initial product candidates are completed and, assuming positive data, we expect to advance to potential registrational trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials 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 that 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 U.S. 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.

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 U.S. 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.

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 U.S., 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 U.S., 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 U.S. 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.

Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and other restrictions, 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 may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval. We may also be required to conduct post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product potentially over many years. If the FDA or other regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product 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 cGMP and GTP, and compliance with cGMP, GTP, and GCP for any clinical trials that we conduct post-approval. Any such restrictions may result in significant additional expense or could limit sales of the approved product. If we, or any of the third parties on which we rely, fail to meet those requirements, the FDA or comparable regulatory authorities outside the United States could initiate enforcement action. Other consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, and permanent injunctions and consent decrees, including the imposition of civil or criminal penalties, among other consequences, that could significantly impair our ability to successfully commercialize a given product.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines or warning letters, or clinical holds on clinical trials involving related product candidates;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in governmental reimbursement programs, such as Medicare, Medicaid and other federal health care programs and curtailment or restructuring of our operations.

In addition, applicable regulatory policies of governmental authorities, such as the FDA, may change and additional government regulations may be enacted that could affect any regulatory approval that we may receive for our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Healthcare reform measures may have a material adverse effect on or prevent our product candidates' commercial success.

There have been, and we expect there will continue to be, a number of legislative and regulatory changes to health care systems in the United States and abroad that could impact our ability to sell our products profitably. The United States government and other governments have shown significant interest in pursuing healthcare reform. For example, in 2010, the Affordable Care Act was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. Healthcare reform measures like the Affordable Care Act may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to modify them or alter their interpretation or implementation. It is unclear how efforts to challenge or modify the ACA or its implementing regulations, or portions thereof, will affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted and we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could result in

more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product candidates, if commercialized, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or 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 revenues, attain profitability, or successfully commercialize our product candidates.

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 including under the SRA, 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.

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.

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.

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.

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 HIPPA 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 and its 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 the Centers for Medicare and Medicaid Services ("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 EU is governed by the General Data Protection Regulation (the "GDPR"), which extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU 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 EU laws and regulations are not successful, it could adversely affect our business in the EU. Moreover, the United Kingdom leaving the EU has created uncertainty with regard to data protection regulation in the United Kingdom. The European Commission has adopted an Adequacy Decision concerning the level of data protection in the UK. Personal data may now flow freely from the EEA to the UK, however, the European Commission may suspend the Adequacy Decision if it considers that the UK no longer provides for an adequate level of data protection. In addition, the California Consumer Privacy Act ("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 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 U.S. Patent and Trademark Office ("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 U.S. 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 U.S. 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-U.S. patent agencies. The USPTO and various non-U.S. 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, 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, 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, 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, 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 U.S. 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 cell/NK cells, including our own patents and publications, may make it increasingly difficult or impossible to patent new engineered nucleases and modified CAR-T cell/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, 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, 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 U.S. 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 U.S., 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 U.S. may be less willing to protect trade secrets.

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

Because we may rely on third parties to manufacture our potential product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our current and potential product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, are used inappropriately to create new inventions or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

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

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

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

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

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

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

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

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive. 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 U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

Risks Related to the Securities in this Offering

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

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

- quarterly variations in our operating results compared to market expectations;
- adverse publicity about us, the industries we participate in or individual scandals;
- announcements of new offerings or significant price reductions by us or our competitors;
- stock price performance of our competitors;
- changes in senior management or key personnel;
- regulatory actions with respect to our products or our competitors' products;
- competition from existing products or new products that may emerge;
- announcements by us, our potential future collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- actual or anticipated fluctuations in our competitors' operating results or growth rate;
- sales of our common stock by us, our insiders or our other stockholders;
- the outcome of any pending or threatened litigation;
- changes in financial estimates and/or the issuance of new or updated research reports by securities analysts;
- the market's reaction to our reduced disclosure as a result of being an "emerging growth company" under the JOBS Act;
- negative earnings or other announcements by us or our competitors;
- defaults on indebtedness, incurrence of additional indebtedness, or issuances of additional capital stock;
- global economic, legal and regulatory factors unrelated to our performance; and
- the other factors listed in this "Risk Factors" section.

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

An active trading market for our common stock may not be sustained and you may not be able to sell your shares at or above the public offering price, or at all.

Although our common stock is listed on the Nasdaq Capital Market, or Nasdaq, an active, liquid trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, you may not be able to sell your common stock at or above the public offering price or at the time that you would like to sell.

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

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

If you purchase shares of common stock in this offering, you will suffer immediate dilution in the book value of your shares.

The offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. As a result, and assuming no value is attributed to the Common Stock Warrants and no Pre-Funded Warrants are sold in this offering, the investor purchasing shares of our common stock in this offering will incur immediate dilution of $ per share, after giving effect to the sale of an aggregate of shares of our common stock at an offering price of $ per share, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us. See "Dilution" on page 52 of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase shares in this offering.

If an active, liquid trading market for our Common Stock Warrants or Pre-Funded Warrants does not develop, you may not be able to sell your Common Stock Warrants or Pre-Funded Warrants quickly or at or above the price you paid for it.

The Common Stock Warrants and Pre-Funded Warrants issued in this offering will be exercisable commencing on the date of issuance and expire on , 2027. The Common Stock Warrants will have an initial exercise price equal to $. In the event that our common stock price does not exceed the exercise price of the Common Stock Warrants during the period when the warrants are exercisable, the warrants may not have any value.

There is no established trading market for the Common Stock Warrants or Pre-Funded Warrants to be sold in this offering, and the market for the Common Stock Warrants and Pre-Funded Warrants may be highly volatile or may decline regardless of our operating performance. We are applying to list the Common Stock Warrants for trading on the Nasdaq Capital Market, but we cannot assure you that we will meet all of the required listing standards. Although we will apply to list our Common Stock Warrants on the Nasdaq Capital Market in connection with this offering, an active trading market for shares of our Common Stock Warrants may never develop or be sustained following this offering and it may be difficult for you to sell your Common Stock Warrants at the time you wish to sell them, at a price that is attractive to you, or at all.

We do not plan on applying to list the Pre-Funded Warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system. Accordingly, we do not expect an active market for our Pre-Funded Warrants to develop or be sustained and it may be difficult for you to sell your Pre-Funded Warrants at the time you wish to sell them, at a price that is attractive to you, or at all.

If we do not maintain a current and effective prospectus relating to the common stock issuable upon exercise of the Common Stock Warrants and Pre-Funded Warrants, public holders will only be able to exercise such warrants on a "cashless basis."

If we do not maintain a current and effective prospectus relating to the shares of common stock issuable upon exercise of the Common Stock Warrants and Pre-Funded Warrants at the time that holders wish to exercise such warrants, they will only be able to exercise them on a "cashless basis." As a result, the number of shares of common stock that holders will receive upon exercise of the Common Stock Warrants and Pre-Funded Warrants will be fewer than it would have been had such holders exercised their warrants for cash. If

we are unable to maintain a current and effective prospectus, the potential "upside" of the holder's investment in our company may be reduced.

Holders of our Common Stock Warrants and Pre-Funded Warrants will have no rights as a common stockholder until such holders exercise their warrants and acquire our common stock.

Until you acquire shares of our common stock upon exercise of your Common Stock Warrants or Pre-Funded Warrants, you will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of your Common Stock Warrants or Pre-Funded Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

We will not receive any meaningful amount of additional funds upon the exercise of the Pre-Funded Warrants.

Each Pre-Funded Warrant will be exercisable until it is fully exercised and by means of payment of the nominal cash purchase price upon exercise. Accordingly, we will not receive any meaningful additional funds upon the exercise of the Pre-Funded Warrants.

Significant holders or beneficial holders of shares of our common stock may not be permitted to exercise the Common Stock Warrants or Pre-Funded Warrants that they hold.

A holder of the Common Stock Warrants or Pre-Funded Warrants will not be entitled to exercise any portion of any Pre-Funded Warrant that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of our common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% (or, upon election of holder, 9.99%) of the number of shares of our common stock immediately after giving effect to the exercise; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 4.99% (or, upon election of holder, 9.99%) of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. As a result, you may not be able to exercise your Pre-Funded Warrants for shares of our common stock at a time when it would be financially beneficial for you to do so. In such a circumstance, you could seek to sell your pre-funded warrants to realize value, but you may be unable to do so in the absence of an established trading market and due to applicable transfer restrictions.

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.

Failure to meet the continued listing requirements of Nasdaq could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.

On March 18, 2022, we were notified by Nasdaq that on March 17, 2022 the average closing price of our common stock over the prior 30 consecutive trading days had fallen below $1.00 per share, which is the minimum average closing price required to maintain listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement"). To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of ten consecutive business days before September 14, 2022. On June 24, 2022, the closing price of our common stock was $0.36 per share.

In the event that we do not regain compliance by September 14, 2022, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market with the exception of the Minimum Bid Requirement and provide Nasdaq with written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. In the event we choose to effect a reverse stock split, there can be no assurances that we will be able to obtain the requisite stockholder votes to effect such reverse stock split. However, if it appears to Listing Qualifications staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, Nasdaq could provide notice that our common stock will become subject to delisting.

We intend to actively monitor the closing bid price of our common stock and will evaluate available options to regain compliance with the Minimum Bid Requirement.

There can be no assurance that we will be able to regain compliance with the Minimum Bid Requirement or maintain compliance with the other listing requirements. If we fail to comply with Nasdaq's continued listing requirements, including the Minimum Bid Requirement, our common stock will be subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by the Nasdaq staff to a Hearings Panel. If our common stock were to be delisted by Nasdaq, our common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock. This would adversely affect the ability of investors to trade our common stock and would adversely affect the value of our common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. The delisting of our common stock from Nasdaq would also adversely affect our ability to complete future financings.

We have broad discretion in how we use the net proceeds from this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not use the net proceeds from this offering in ways that ultimately increase the value of your investment. If we do not use these proceeds in ways that enhance stockholder value, we may fail to achieve expected financial results or cause delays to our clinical development timelines, which could cause our stock price to decline.

We are currently operating in a period of economic uncertainty and continued capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.

U.S. and global markets are experiencing volatility and continued disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, Russia launched a full-scale military invasion of Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets. Additionally, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Registration Statement.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to efficiently develop our existing product candidates and discover new product candidates;
- current and future IND filings, including statements regarding the scope, subject matter, or timing for any IND;
- our ability to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- partnerships or collaborations with any third-party, including statements regarding any such third-party's ability to perform adequately;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to discover and produce our products or product candidates with advantages in time or cost;
- our future business development, financial condition and results of operations;
- our expected timing of human clinical trials and other related milestones;
- 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;
- fluctuations in general economic and business conditions in the markets in which we operate; including those fluctuations caused by COVID-19;
- the Russia-Ukraine conflict;
- our use of the proceeds from this offering;
- relevant government policies and regulations relating to our industry; and
- the outcome of any pending or threatened litigation.

We often, although not always, identify forward-looking statements by using words or phrases such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue”. These statements are only predictions, and are subject to change due to 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 section titled “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. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus forms a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain.

This prospectus also contains estimates, projections and other information concerning our industry, our business and the markets for our programs and product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this prospectus.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock in this offering will be approximately $, or $ if the underwriters exercise in full their option to purchase additional shares (and/or Pre-Funded Warrants issued in lieu thereof) and accompanying Common Stock Warrants, at an offering price of $ per share of common stock (and/or Pre-Funded Warrants issued in lieu thereof) and accompanying Common Stock Warrants and after deducting underwriting discounts and commissions and estimated offering expenses payable by us and excluding any proceeds that we may receive upon exercise of the Common Stock Warrants being offered hereunder.

We plan to use the net proceeds of this offering primarily to (i) facilitate the IND submission and clinical trial activation of IND #1, which is for our Deltacel product candidate in combination with a standard anti-tumor modality, (ii) resubmit the IND for of our ALEXIS-PRO-1 clinical trial candidate, and the corresponding trial activation, (iii) intellectual property protection and reinforcement, (iv) IND applications and IND enabling trials for our other product candidates, (v) working capital and (vi) general corporate purposes. We also intend to use net proceeds and our existing cash and cash equivalents, (i) for research and development activities related to our pre-clinical and discovery programs (ii) for personnel expenses, working capital and other general corporate purposes, including but not limited to legal fees associated with pending matters, and (iii) to acquire or invest in complementary businesses, products, or technologies, or to obtain the right to use such complementary technologies.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above and we expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering.

Our cash and cash equivalents as of March 31, 2022 was $15,123,100. We do not believe this amount will be sufficient to fund our current and planned operations through the 12 months following the date of this prospectus, which raises substantial doubt about our ability to continue as a going concern. Further, the expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval. As a result of the foregoing, we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

Due to the many inherent uncertainties in the development of our programs and product candidates, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the timing and success of preclinical studies, our ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, any strategic alliances that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from this public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our total capitalization as of March 31, 2022:

- on an actual basis; and
- on a pro forma basis giving further effect to the sale and issuance by us of shares of common stock in this offering at an assumed offering price of $ per share of common stock and accompanying Common Stock Warrant, assuming no sale of Pre-Funded Warrants and no exercise of the Common Stock Warrants and after deducting estimated 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."

	March 31, 2022	
	As Reported	Pro Forma[1]
Cash and cash equivalents	$ 15,123,100	$
Stockholder's equity:		
Common stock	9,300	
Additional paid-in capital	94,607,100	
Accumulated deficit	(74,584,300)	
Total stockholders' equity	20,032,100	
Total capitalization	20,032,100	

DILUTION

If you purchase shares of our common stock in this offering (assuming no value is attributed to the Common Stock Warrants and no Pre-Funded Warrants are sold in the offering), your interest will be diluted to the extent of the difference between the public offering price per share and our net tangible book value per share after this offering. Dilution results from the fact that the 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 $20,032,100 or $1.29 per share, as of March 31, 2022. 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 the sale and issuance by us of shares of common stock and accompanying Common Stock Warrant in this offering assuming an offering price of $ per share (assuming no value is attributed to the Common Stock Warrants and no Pre-Funded Warrants are sold in the offering), and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2022 would have been $ or $ per share. This represents an immediate increase in net tangible book value of $ per share to our existing stockholders, and an immediate dilution in net tangible book value of $ per share to new investors. The following table illustrates this per share dilution (assuming no sale of Pre-Funded Warrants):

Assumed public offering price per share		
Net tangible book value as of March 31, 2022	$ 1.29	
Increase in net tangible book value attributable to this offering		
As adjusted net tangible book value, after this offering		
Dilution to new investors in this offering		

If the underwriters' over-allotment option is exercised in full, our as adjusted net tangible book value after this offering (assuming no value is attributed to the Common Stock Warrants and no Pre-Funded Warrants are sold in the offering) would be $ and dilution per share to new investors purchasing common stock in this offering would be $ assuming an offering price of $ per share of common stock and accompanying Common Stock Warrant, after deducting 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 offering price of our shares and other terms of this offering determined at pricing.

The number of shares of common stock to be outstanding after this offering is based on 15,839,112 shares of common stock outstanding as of June 24, 2022 and assumes the sale and issuance by us of the shares of common stock being offered hereunder (and no sale of any Pre-Funded Warrants) and excludes as of June 24, 2022:

- 338,872 shares of our common stock issuable upon the exercise of outstanding options, with a weighted-average exercise price of $8.49 per share;
- 225,018 shares of our common stock issuable upon the vesting of outstanding restricted stock units, with a weighted-average grant date fair value of $10.37 per share;
- 62,500 shares of our common stock underlying outstanding warrants that were issued in October 2020 with an exercise price of $15.00 per share;
- 400,000 shares of our common stock underlying outstanding warrants that were issued in July 2021 with an exercise price of $6.25 per share;
- 1,884,082 shares of our common stock reserved for future issuance under our Omnibus 2021 Equity Incentive Plan;
- shares of our common stock underlying the Common Stock Warrants being offered hereunder; and
- shares of our common stock underlying the warrants to be issued to the representative of the underwriters in connection with this offering, with an exercise price of .

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

Kiromic BioPharma, Inc. is an AI driven, end-to-end allogeneic cell therapy company, currently developing multi-indication allogeneic T cell therapies that exploits the natural potency of GDTs to target solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and GMP manufacturing, which we believe will allow us to leverage a new framework for the next generation of cell therapies. We also have new technologies in development that we believe will support our end-to-end approach.

From a development standpoint, we utilize innovative engineered and non-engineered GDT manufacturing technologies and are developing proprietary, virus-free gene editing tools, to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. Our Procel, Isocel, and Deltacel product platform candidates consists of allogeneic cell therapy candidates that are currently in the preclinical development stage. Our Procel product candidate consists of engineered GDTs targeting PD-L1. Our Isocel product candidate consists of engineered GDTs targeting Iso-Meso. Our Deltacel product candidate consists of non-engineered GDTs that have been expanded, enriched, and activated *ex-vivo* through a proprietary process, and are used to treat solid tumors regardless of the specific tumor antigen expression.

We currently have one clinical trial candidate with the Procel product candidate platform titled ALEXIS-PRO-1. We currently have one clinical trial candidate with the Isocel product candidate platform titled ALEXIS-ISO-1. Our ALEXIS-PRO-1 clinical trial candidate is our allogeneic GDT therapy product candidate targeting PD-L1. Our ALEXIS-ISO-1 clinical trial candidate is our allogeneic GDT therapy product candidate targeting an isoform of Mesothelin that is preferentially present on tumor cells, namely Iso-Meso. The IND applications for these trial candidates have been on a clinical hold since June 2021. We are currently working on addressing the FDA's comments. Accordingly, we expect the clinical hold on ALEXIS-PRO-1 will be lifted in the first half of 2023 allowing us to begin the activation process for the clinical trial by the end of the second quarter of 2023. For ALEXIS-ISO-1, we are targeting the activation process for the clinical trial to begin by the end of the last quarter of 2023. The beginning of the activation process for the clinical trials begins after the following two events: (1) the IND is considered effective (which would take place 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); and (2) commencing the review and approval process by an independent IRB or ethics committee at the first clinical trial site.

We have also entered into an SRA with MD Anderson Principal Investigator to facilitate the development of our Deltacel, Procel, and Isocel product candidate platforms. We believe the SRA will generate sufficient in-vivo pre-clinical data to support three new GDT therapy IND submissions that we hope to submit, including INDs for: (1) IND #1; (2) IND #2; and (3) IND #3. These three INDs have not been submitted to the FDA yet, and the trial candidates are described in further detail below.

IND #1 will evaluate Deltacel GDTs in combination with a standard anti-tumor modality. We are planning to submit this IND during the second half of 2022, and believe clinical activation will begin by the end of the fourth quarter of 2022. IND #2 combines the standard anti-tumor modality and our genetically engineered product candidate targeting PD-L1, which is the target associated with the ALEXIS-PRO-1 clinical trial candidate on the Procel product candidate platform. We are planning to submit this IND during the first half of 2023, and believe clinical activation will begin by the end of the second quarter of 2023. IND #3 combines the standard anti-tumor modality and our genetically engineered product candidate targeting Iso-Meso, the target associated with the ALEXIS-ISO-1 clinical trial candidate on the Isocel product candidate platform. We are planning to submit this IND during the second half of 2023, with clinical activation targeted to begin by the end of the fourth quarter of 2023.

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.

Recent Developments

Going Concern

We do not have sufficient cash on hand and available liquidity to meet our obligations through the twelve months following the date of this prospectus. Therefore, this condition raises substantial doubt about the Company's ability to continue as a going concern. Management's plans were updated to evaluate different strategies to obtain the required funding of future operations. These plans may include, but are not limited to, additional funding from current or new investors; however, if we are unable to raise additional funding to meet working capital needs, we will be forced to delay or reduce the scope of our research programs and/or limit or cease operations. The negative cash flows and lack of financial resources raised substantial doubt as to our ability to continue as a going concern, and that substantial doubt has not been alleviated.

Clinical Update

On June 21, 2022 the Company announced its revised pipeline to prioritize submission of IND #1, the Deltacel product candidate in combination with a standard antitumor modality.The Company believes that this action advances its non-viral, non-engineered product candidate while also reducing costs, and mitigating current supply chain headwinds associated with a virus-based approach. The Company also announced that it will also pursue new INDs for IND #2 and IND #3, which are the Procel and Isocel product candidates in combination with a standard antitumor modality in 2023. Clinical activation for IND #2 is expected to begin by the end of the second quarter of 2023. Clinical activation for IND #3 is targeted to begin by the end of the fourth quarter of 2023.

In the same press release, the Company announced its revised clinical timeline. Pursuant to the announcement, the Company plans to re-submit the IND for ALEXIS-PRO-1 in the first half of 2023, with clinical activation expected to begin by the end of second quarter 2023. Also, the Company plans to re-submit the IND for ALEXIS-ISO-1 in the second half of 2023, with clinical activation targeted to begin by the end of fourth quarter 2023.

Results from our Internal Review

On or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board of Directors ("the Board"), submitted substantially identical reports (the "Complaints") through our complaint hotline. These Complaints, alleged, among other topics, risks associated with our public disclosures in our securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the FDA authorization of our IND applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained an independent counsel to assist it in conducting the Internal Review.

On February 2, 2022, following the conclusion of the Internal Review, the Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that we had received communications from the FDA on June 16 and June 17, 2021. On July 13, 2021, we received the FDA's formal clinical hold letters, which asked us to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, we issued a press release disclosing that we had received comments from the FDA on our two INDs, but did not use the term "clinical hold." On August 13, 2021, we issued a press release announcing that these INDs were placed on clinical hold. We did not disclose the June 16 and 17, 2021 FDA Communications in (i) our Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) our Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the SEC on August 13, 2021. We consummated a public offering of $40 million of our common stock pursuant to the Registration Statement on July 2, 2021.

In the course of the Internal Review, the Special Committee also identified that Mr. Tontat submitted incorrect information regarding his educational background to us. Specifically, although Mr. Tontat represented to us that he held a BA in Economics from Harvard University, it was determined that he had actually received an ALB, a degree conferred by the Harvard Extension School. We have

implemented changes to our vetting process for prospective director and officer candidates including the implementation of thorough background checks to verify background information provided by such candidates.

Upon completion of the Internal Review, the Company voluntarily contacted the SEC to report certain information about the Internal Review. Since that time, the Company has been voluntarily cooperating with requests for information from the SEC and intends to fully cooperate with any further requests from the SEC.

Remediation Actions resulting from the Internal Review

1. The Board approved the inclusion of certain Risk Factors for inclusion in its periodic reports. See "Risk Factors" for further information.

2. On January 10, 2022, the Board approved the formation of a Disclosure Committee comprised of certain members of the management including (i) its Chief Executive Officer; (ii) the executive in charge of overseeing submissions of any nature to the FDA; (iii) its Chief Financial Officer; (iv) its General Counsel, if any; (v) its Controller, if any; (vi) any other finance executive overseeing financial disclosures; (vii) the executive in charge of investor relations, if any; and (viii) such other employees as the Chief Financial Officer, who serves as chairman of the Disclosure Committee, may invite from time to time. The Disclosure Committee shall be responsible for preparing and reviewing all corporate disclosures made by us to our security holders, the SEC and/or the broader investment community to ensure that such disclosures (i) shall be accurate and complete; (ii) shall fairly present, in all material respects, our financial condition, results of operations and cash flows; and (iii) shall be made on a timely basis in accordance with all applicable requirements of (A) the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder, (B) the Securities Act of 1933, as amended and the rules and regulations promulgated thereunder (C) the Nasdaq or such other stock exchange on which the our securities may be traded and (D) any other applicable laws or legal requirements. The Board adopted and approved the Disclosure Committee Charter.

3. The Board terminated Maurizio Chiriva-Internati as Chief Executive Officer for cause on January 27, 2022, after the Special Committee's Internal Review found evidence of conduct that the Board believed was inconsistent with the company policies. Under the terms of the Executive Employment Agreement between Dr. Chiriva and the Company effective as of July 1, 2020, as amended October 21, 2021, as the result of the termination of his employment, Dr. Chiriva also is deemed to have resigned as a Director on the Board effective as of January 27, 2022.

4. The Board named Pietro Bersani as Interim Chief Executive Officer, effective as of January 27, 2022. A search for a permanent Chief Executive Officer will be commenced with the assistance of an executive recruiter. Mr. Bersani has resigned from all Committees of the Board.

5. The Board named independent Director Michael Nagel as Chairperson of the Board, effective as of January 27, 2022.

6. The Board approved the appointment of Frank Tirelli as a member of the Board to fill a vacancy, effective as of January 28, 2022. The Board has determined that Mr. Tirelli is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Mr. Tirelli has been named Chairperson of the Audit Committee effective January 28, 2022. He was also nominated and appointed as a member of the Nominating and Corporate Governance Committee effective March 1, 2022. Mr. Tirelli was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all his background, relevant experience, and professional and personal reputations.

7. On February 10, 2022, we and Dr. Scott Dahlbeck ("Dr. Dahlbeck") entered into a Modification to Employment Agreement dated as of February 9, 2022 (the "Dahlbeck Agreement"). The Dahlbeck Agreement amends and supersedes certain terms of the Employment Agreement dated as of January 1, 2020, between the Company and Dr. Dahlbeck. Pursuant to the Dahlbeck Agreement, effective as of February 9, 2022, Dr. Dahlbeck's title was changed to Chief of Staff, and he ceased to be our Chief Medical Officer and Head of Clinical.

8. On February 10, 2022, we and Mr. Gianluca Rotino ("Mr. Rotino") entered into a Transition and Consulting Agreement dated as of February 9, 2022 (the "Rotino Agreement"). Pursuant to the terms of the Rotino Agreement, effective as of February 9, 2022, Mr. Rotino's employment as our Chief Strategy and Innovation Officer terminated and the Company retained Mr. Rotino to provide consulting services to the Company for a period of nine months (or until November 9, 2022).

Notwithstanding the foregoing, the Rotino Agreement may be terminated by either us or Mr. Rotino upon 30 days' prior written notice, except no such prior notice shall be required in the event we terminate the Rotino Agreement for cause.

Under the terms of the Executive Employment Agreement between Mr. Rotino and the Company effective as of July 1, 2020, as amended October 21, 2020, as the result of the termination of Mr. Rotino's employment, Mr. Rotino is deemed to have resigned as a member of the Board effective as of February 9, 2022.

9. The Board approved the appointment of Karen Reeves as a member of the Board to fill a vacancy, effective as of February 14, 2022. The Board has determined that Dr. Reeves is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Dr. Reeves was nominated and appointed to be the Nominating and Corporate Governance Committee Chairperson and a member of the Compensation Committee effective March 1, 2022. Dr. Reeves was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all her background, relevant experience, and professional and personal reputations.

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.

Impact of the COVID-19 Pandemic on Our Operations

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 Outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 Outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 Outbreak continues to evolve as of the date of this report. As a result, we cannot estimate the full magnitude that the pandemic will have on our business. If the COVID-19 Outbreak continues, it may have a material adverse effect on our financial condition, liquidity, and future results of operations for the future. We are actively monitoring the impact of the global pandemic on our financial condition, liquidity, operations, industry, and workforce. Given the daily evolution of the COVID-19 Outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 Outbreak on our results of operations, financial condition, or liquidity for the future. While we have not currently experienced any potential delays or increased costs as a result of these measures, we may do so in the future.

Impact of the War in Ukraine on Our Operations

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. The imposition of sanctions and counter sanctions may have an adverse effect on the economic markets generally and could impact our business, financial condition, and results of operations.

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.

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-PRO-1 and ALEXIS-ISO-1 product candidates and continue to discover and develop additional product candidates.

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

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

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

patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

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

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

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table sets forth key components of our results of operations for the three months ended March 31, 2022 and 2021.

	Three Months Ended March 31,		Increase (Decrease)	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 2,925,800	$ 1,885,600	$ 1,040,200	55.17%
General and administrative	4,439,200	2,071,000	2,368,200	114.35%
Total operating expenses	7,365,000	3,956,600	3,408,400	86.14%
Loss from operations	(7,365,000)	(3,956,600)	3,408,400	86.14%
Other income (expense)				
Gain on loan extinguishment	—	105,800	(105,800)	100.00%
Interest expense	(2,800)	(3,700)	900	(24.32)%
Total other income (expense)	(2,800)	102,100	(104,900)	102.74%
Net loss	$ (7,367,800)	$ (3,854,500)	$ 3,513,300	91.15%

Research and development expenses. Our research and development expenses increased by $1,040,200, or 55.17%, to $2,925,800 for the three months ended March 31, 2022, from $1,885,600 for the three months ended March 31, 2021. The following table summarizes our research and development expenses by product candidate or development program:

	Three Months Ended March 31,		Increase (Decrease)	
	2022	2021	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 229,300	$ 26,000	$ 203,300	781.92%
ALEXIS-ISO-1	67,700	484,700	(417,000)	(86.03)%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	1,303,700	855,900	447,800	52.32%
Laboratory supplies and services	330,800	120,700	210,100	174.07%
Outsourced research and development	405,400	150,000	255,400	170.27%
Laboratory equipment and maintenance	156,800	32,400	124,400	383.95%
Facility-related costs	330,500	155,800	174,700	112.13%
Intellectual Property	94,000	60,000	34,000	56.67%
Other research and development costs	7,600	100	7,500	7,500.00%
Total research and development expenses	$ 2,925,800	$ 1,885,600	$ 1,040,200	55.17%

As illustrated above, the increase in research and development expenses primarily resulted from (i) a $447,800 increase in employee related costs, which primarily included a $709,600 increase in wages, benefits and payroll taxes, offset by reduced stock compensation expenses of $257,400 attributable to research and development employees; (ii) a $255,400 increase in outsourced research and development costs, which primarily included a $141,500 increase in regulatory consulting fees, and a $73,600 increase in research studies; (iii) a $210,100 increase in laboratory supplies in services, which was driven by increased in spending on supplies, disposables, and consumables for experimentation, testing, validation of our other key value drivers; and (iv) a $203,300 increase in ALEXIS-PRO-1 direct research and development costs, which was mainly driven by increased disposables and consumables for GDT manufacturing, in-vitro, and in-vivo experimentation costs.

These cost increases were primarily incurred to support GDT manufacturing as well as experimentation and validation of our product candidates.

1. Augmented our research and development team: in the three months ended March 31, 2022 and 2021, our average headcount increased to 39 employees from 16 employees allocable to research and development and clinical trials preparation.

2. ALEXIS-PRO-1 Manufacturing and Experimentation: $203,300 increase in spending during the three months ended March 31, 2022, from manufacturing expanded GDTs in the recently expanded GMP facilities.

3. Increased regulatory consulting costs: in the three months ended March 31, 2022, we incurred an increase of $141,500 in regulatory and chemical manufacturing and control consulting fees compared to the same three months in 2021 as we are working towards addressing the FDA's comments regarding our IND applications filed during May 2021.

General and administrative expenses. Our general and administrative expenses increased by $2,368,200, or 114.35%, to $4,439,200 for the three months ended March 31, 2022, from $2,071,000 for the three months ended March 31, 2021.

During the three months ended March 31, 2022, the increase primarily resulted from an increase in professional services of $1,613,700, and employee related expenses of $1,090,900.

The increase in professional services expenses was primarily driven by an increase of $1,492,900 in legal expenses, $80,200 from corporate finance professional fees, and $40,600 from other professional services during the three months ended March 31, 2022, compared to the same period in the prior year. We incurred significant legal expenses and accounting professional fees related to the Internal Review. Between October 1, 2021 and March 31, 2022, we incurred $4,089,600 in legal fees and other professional services directly attributed to the Internal Review and related matters. During that same period, we incurred $680,700 in accounting professional fees directly related to the Internal Review. During the three months ended March 31, 2022, we incurred $941,800 in

legal fees and other professional services directly attributed to the Internal Review and related matters. During that same period, we incurred $253,500 in accounting professional fees directly related to the internal review.

Employee related expenses were impacted by increases to headcount, and recruiting. During the three months March 31, 2022 and 2021, the headcount for employees allocated to general and administrative purposes increased to 25.5 employees from 6.5 employees, respectively. In addition, the changes in headcount generated $146,400 in increased recruiting fees.

Gain on loan extinguishment. Gain on loan extinguishment was $0 and $105,800 for the three months ended March 31, 2022 and 2021, respectively. During the year ended December 31, 2020, we applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. On February 16, 2021, the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,800.

Interest expense. Interest expense was an expense of $2,800 and $3,700 for the three months ended March 31, 2022 and 2021, respectively. The increase is entirely driven by cash paid for interest attributed to the financing arrangement for our Director and Officer Insurance policy. In November 2020, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of March 31, 2021, the remaining payable balance on the financed amount was $227,800.

In November 2021, the Company entered into a financing arrangement to renew its Director and Officer Insurance policy. The total amount financed was approximately $665,900 with an annual interest rate of 4.59%, to be paid over a period of ten months. As of March 31, 2022, the remaining payable balance on the financed amount was $285,700.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased to $7,367,800 during the three months ended March 31, 2022, compared to $3,854,500 during the three months ended March 31, 2021.

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth key components of our results of operations for the years ended December 31, 2021 and 2020.

	Year Ended December 31,		Increase (Decrease)	
	2021	2020	$	%
Operating expenses:				
Research and development	$ 11,367,800	$ 5,052,900	$ 6,314,900	124.98%
General and administrative	13,937,900	14,144,000	(206,100)	(1.46)%
Impairment expense	430,000	—	430,000	100.00%
Total operating expenses	25,735,700	19,196,900	6,538,800	34.06%
Loss from operations	(25,735,700)	(19,196,900)	6,538,800	34.06%
Other income (expense)				
Gain on loan extinguishment	105,800	—	105,800	100.00%
Other income	53,400	—	53,400	100.00%
Interest expense	(12,200)	(3,300)	(8,900)	269.70%
Total other income (expense)	147,000	(3,300)	150,300	4,554.55%
Net loss	$ (25,588,700)	$ (19,200,200)	$ 6,388,500	33.27%

Research and development expenses. Our research and development expenses increased by $6,314,900, or 124.98%, to $11,367,800 for the year ended December 31, 2021 from $5,052,900 for the year ended December 31, 2020. The following table summarizes our research and development expenses by product candidate or development program:

	Year Ended December 31,		Increase (Decrease)	
	2021	2020	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 63,400	$ 89,900	$ (26,500)	(29.48)%
ALEXIS-ISO-1	1,754,700	331,600	1,423,100	429.16%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	4,424,200	2,821,700	1,602,500	56.79%
Laboratory supplies and services	1,107,800	385,500	722,300	187.37%
Outsourced research and development	2,547,000	800,400	1,746,600	218.22%
Laboratory equipment and maintenance	128,500	57,500	71,000	123.48%
Facility-related costs	940,400	344,700	595,700	172.82%
Intellectual Property	380,900	217,800	163,100	74.89%
Other research and development costs	20,900	3,800	17,100	450.00%
Total research and development expenses	$ 11,367,800	$ 5,052,900	$ 6,314,900	124.98%

As illustrated above, the increase in research and development expenses resulted from (i) a $1,423,100 increase in ALEXIS-ISO-1 direct research and development costs which primarily included a $1,199,500 increase in disposables and consumables, a $44,600 increase in outsourced research and development fees, and a $74,700 increase in supplies, all of which attributed to GDT manufacturing and in-vitro and in-vivo experimentation (ii) a $1,602,500 increase in employee related costs, which primarily included a $2,118,900 increase in wages, benefits and payroll taxes offset by a $574,000 decrease in stock compensation expenses attributable to research and development employees; (iii) a $722,300 increase in laboratory supplies in services, which primarily included a $558,700 increase in spending on disposables and consumables for in-vitro testing and validation of pipeline candidates, with the remaining balance driven by supplies spending; (iv) a $595,700 increase in facility-related costs, primarily driven by a $103,100 increase in allocated rent net of granting agency reimbursements, and a $260,100 increase in allocated depreciation expenses with the remaining amount attributed to repairs, maintenance, and utilities; (v) a $163,100 increase in intellectual property expenses, which was driven by legal expenses and intellectual property filings for new patents; (vi) a $71,000 increase in laboratory equipment and maintenance, which mainly consisted of increased spending on supplies, disposables, and consumables for experimentation, testing, validation of our other key value drivers; and (vii) a $1,746,600 increase in outsourced research and development costs driven by a $2,052,200 increase in research studies and other consulting fees offset by decreased stock based compensation expenses attributed to non-employees.

These cost increases were primarily incurred to support ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidate manufacturing, regulatory and chemical manufacturing and control consulting fees, as well as experimentation and validation of our product candidates.

1. Augmented our research and development team: in the year ended December 31, 2021 and 2020, our average headcount increased to 27.5 employees from nine employees allocable to research and development and clinical trials preparation.

2. ALEXIS-ISO-1 manufacturing and experimentation: $1,423,100 increase in spending during the year ended December 31, 2021, from manufacturing expanded GDTs in the GMP facilities. In addition, in-vivo experimentation costs in the recently completed vivarium facilities contributed to the increase.

3. Increased regulatory consulting costs: in the year ended December 31, 2021 we incurred an increase of $1,746,600 in regulatory and chemical manufacturing and control consulting fees as we were working to address the FDA's comments regarding our IND applications filed during May 2021.

General and administrative expenses. Our general and administrative expenses decreased by $206,100, or 1.46%, to $13,937,900 for the year ended December 31, 2021 from $14,144,000 for the year ended December 31, 2020.

During the year ended December 31, 2021, a decrease in stock compensation expenses of $8,617,800, was offset by an increase in professional services of $5,992,100, an increase in personnel and recruiting expenses totaling $1,552,700, and an increase in insurance expense of $476,200.

The decrease in stock compensation expense was driven by the June 2020 common stock issuances of 722,000 shares to our Chief Financial Officer, and Chief Strategy and Innovation Officer which resulted in $9,386,000 of non-recurring stock compensation expenses. The remaining offsetting balance is mainly driven by increased stock compensation expense during the year ended December 31, 2021 from stock grant modifications.

The increase in professional services were impacted primarily by increased legal fees of $4,105,300, increase in corporate finance and development fees of $312,400, and remaining increase driven by professional audit fees. Between October 1, 2021 and December 31, 2021, we incurred $3,147,900 in legal fees and other professional services directly attributed to the Internal Review and related matters. During that same period, we incurred $427,200 in accounting professional fees directly related to the Internal Review. These elevated legal, accounting, and other related professional services expenses are continuing through the date of this report, and are expected continue thereafter.

Personnel and recruiting expenses were impacted by increases to average headcount, and employee salary rates. During the twelve months December 31, 2021 and 2020, the average headcount for employees allocated to general and administrative purposes increased to 11.5 employees from 4.5 employees, respectively. This resulted in increases in salaries, wages, payroll taxes, and benefits totaling $1,297,800. The remaining difference was driven by recruiting expenses for all head count increases across the organization.

Impairment expense. Impairment expense was $430,000 and $0 for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we assessed events and circumstances under ASC 350, which caused us to incur an impairment expense on our Goodwill. The impairment was primarily related to a reduced stock price as of December 31, 2021, which resulted in the carrying value of our equity exceeding the market value of our equity. After analyzing this quantitative circumstance along with other qualitative considerations, we determined to incur impairment expense for the entire balance of our Goodwill.

Gain on loan extinguishment. Gain on loan extinguishment was $105,800 and $0 for the years ended December 31, 2021 and 2020, respectively. During the year ended December 31, 2020, we applied for forgiveness of the SBA Loan in accordance with the terms of the Coronavirus Aid Relief and Economic Security Act (the “CARES Act”). On February 16, 2021 the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,800.

Other income. Other income was $53,400 and $0 for the years ended December 31, 2021 and 2020, respectively. The increase is entirely driven by service billings from our bioinformatics employees to large academic institutions. The bioinformatics employees joined us in July 2021 as part of the InSilico acquisition. The contracts whereby these billings were generated is not considered part of our ordinary course of business.

Interest expense. Interest expense was $12,200 and $3,300 for the year ended December 31, 2021 and 2020, respectively. The increase is entirely driven by cash paid for interest attributed to the financing arrangement for our Director and Officer Insurance policy. In November 2020, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of December 31, 2021, this financing arrangement was paid in its entirety.

In November 2021, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $665,900 with an annual interest rate of 4.59%, to be paid over a period of ten months. As of December 31, 2021, the remaining payable balance on the financed amount was $454,500.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased to $25,588,700 during the year ended December 31, 2021 compared to $19,200,200 during the year ended December 31, 2020.

Liquidity and Capital Resources

As of March 31, 2022, we had cash and cash equivalents of $15,123,100. As of December 31, 2021, we had cash and cash equivalents of $25,353,900. As of April 30, 2022, we had cash and cash equivalents of $8,473,700. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sale of our convertible promissory notes, preferred stock, common stock from the initial public offering and follow-on offering.

We have known material contractual obligations which will require cash to meet their requirements. These applicable obligations include our facility lease agreement, our employment contracts, and our financing arrangement for our Director and Officer Insurance Policy. We also plan to deploy cash for other research and development and general and administrative operating expenses. Our ability to continue meeting these contractual obligations will be reliant upon our ability to secure significant additional capital funding.

Based on our forecasted expenditures related to our ongoing clinical trials and research and development efforts following the completion of our public offering on July 2, 2021, we determined that we do not have sufficient cash on hand and available liquidity to meet our obligations through the twelve months following the date of this prospectus. 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. These costs include conducting preclinical studies and clinical trials for our product candidates, contracting with clinical research organizations and building out internal capacity to have product candidates 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. Therefore, these conditions raise substantial doubt about our ability to continue as a going concern.

In fiscal year 2022, we intend to seek significant additional capital funding to develop our platform, additional hiring of scientific professionals, hiring other general and administrative employees, and clinical trials. However, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. Further, the results of our Internal Review demonstrated that we had ineffective disclosure controls and procedures during the first quarter of 2022 and earlier periods, which resulted in our failure to disclose certain information, which could result in our potential exposure to litigation and could adversely affect our ability to raise capital in the future. Further, there are other factors which may make financing our operations more difficult, including potential governmental investigation, continued elevated legal and accounting professional fees associated with the Internal Review, and other information listed in “Risk Factors” in this prospectus. In consideration of our plans, substantial doubt is not alleviated.

Summary of Cash Flow for the three months ended March 31, 2022 and 2021

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

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	$ (7,578,900)	$ (2,635,900)
Net cash used in investing activities	(2,483,100)	(44,700)
Net cash provided by financing activities	(168,800)	(134,600)
Net increase in cash and cash equivalents	(10,230,800)	(2,815,200)
Cash and cash equivalents at beginning of the period	25,353,900	10,150,500
Cash and cash equivalents at end of the period	15,123,100	7,335,300

Net cash used in operating activities was $7,578,900 for the three months ended March 31, 2022, as compared to $2,635,900 for three months ended March 31, 2021. In the three months ended March 31, 2022, the primary cash outflows were from the net loss of $7,367,800 and outflows from accounts payable of $882,800. These cash outflows were partly offset by accrued expenses and current liabilities of $295,600, and depreciation of $182,800. Net cash used in operating activities increased by a total of $4,943,000 period-over-period. The main driver for the increase is the change in net loss to $7,367,800 during the three months ended March 31, 2022, compared to $3,854,500 during the three months ended March 31, 2021. In addition, stock compensation expense was $80,100 and $945,200 during the three months ended March 31, 2022 and 2021, respectively. We primarily used cash to augment our headcount,

develop our ALEXIS-PRO-1 product candidate, and pay for legal and professional fees. See "Results of Operations" above for further details.

Cash flows from investing activities

Net cash used for in investing activities was $2,483,100 for the three months ended March 31, 2022, as compared to $44,700 for the three months ended March 31, 2021. Our net cash used in investing activities consisted of purchases of property and equipment. This increase was primarily driven by cash outflows from equipment and leasehold improvements attributed to our Clean Room and Vivarium cGMP facilities located in our Houston office.

Cash flows from financing activities

During the three months ended March 31, 2022 and 2021, we paid $168,800 and $134,600 towards our financing arrangement for our Director and Officer Insurance policy, respectively.

Summary of Cash Flow for the years ended December 31, 2021 and 2020

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

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (20,321,500)	$ (6,126,600)
Net cash used in investing activities	(1,810,800)	(1,457,600)
Net cash provided by financing activities	37,335,700	15,805,600
Net increase in cash and cash equivalents	15,203,400	8,221,400
Cash and cash equivalents at beginning of the period	10,150,500	1,929,100
Cash and cash equivalents at end of the period	25,353,900	10,150,500

Cash flows from operating activities

Net cash used in operating activities was $20,321,500 for the year ended December 31, 2021, as compared to $6,126,600 for year ended December 31, 2020. In the year ended December 31, 2021, net loss of $25,588,700, and outflows from prepaid expenses and other current assets in the amount of $1,117,400 and gain on loan extinguishment of $105,800 were the cash drivers. These cash outflows were partly offset by stock compensation expenses from stock options and RSUs of $3,762,900, accounts payable of $14,111,100, depreciation of $469,800, and accrued expenses and other current liabilities of $406,800. Net cash used in operating activities increased by a total of $14,194,900 period-over-period. The main driver for the increase is the $9,482,000 decrease in stock compensation expenses, along with the $6,388,500 increase in net loss. The increase in cash used was partly offset by the increase in accounts payable of $1,418,800, increase in accrued expenses and other current liabilities of $293,900, increase in depreciation of $269,800, as well as increase in impairment loss of $430,000. We primarily used cash to augment our headcount, develop our ALEXIS-ISO-1, and ALEXIS-PRO-1 product candidate, and pay for legal fees and other professional services. See "Results of Operations" above for further details.

Cash flows from investing activities

Net cash used in investing activities was $1,810,800 for the year ended December 31, 2021, as compared to $1,457,600 for the year ended December 31, 2020. Our net cash used in investing activities consisted of purchases of property and equipment, as well as $84,000 cash received from acquisition of InSilico. This increase was primarily driven by increased outflow used for leasehold improvements related to GMP 1.

Cash flows from financing activities

Net cash provided by financing activities was $37,335,700 during the year ended December 31, 2021 as compared to $15,805,600 for the year ended December 31, 2020

During the year ended December 31, 2021, net cash provided by financing activities primarily consisted of the public offering which closed on July 2, 2021. This public offering sold 8,000,000 shares of common stock with net proceeds of $37,118,100.

For the year ended December 31, 2020, the net cash provided by financing activities primarily consisted of net proceeds from the IPO of $12,332,700 and proceeds from preferred stock issuance in the amount of $3,000,000. In addition, there were proceeds from a note payable of $362,400 net of repayments, and loan payable of $105,600, net of repayments.

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, prepaid expenses and other assets, accounts payable, accrued expenses and other current liabilities approximate their fair value due to their short-term nature.

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

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

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

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

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

There were no changes in the fair value hierarchy leveling during the three months ended March 31, 2021 and 2020.

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

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

We estimate the grant-date fair value of stock options using the Black-Scholes option-valuation model. During the three months ended March 31, 2022 and 2021, all stock option equity grants under the 2017 Equity Incentive Plan and 2021 Equity Incentive Plan contained assumptions used to value such stock options, and were determined as follows:

Expected Term. The expected term represents the period that our stock options are expected to be outstanding. We have used the SAB No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period. We do not plan to continue to use the SAB 110 simplified method after we have sufficient trading history as a publicly traded company.

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

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

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

Common Stock Valuations. During the three months ended March 31, 2022 and 2021, we used our listed Nasdaq Capital Market closing price on the grant date to determine common stock valuation.

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

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

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

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

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

Dividend Yield. The fair value of our common stock when the initial public offering warrants were issued is equal to the initial public offering common stock issuance price of $12.00 per share. The fair value of our common stock when the July 2, 2021 warrants were issued is equal to the offering price of $5.00 per share.

Exercise Price. The representative warrants' exercise price to purchase common stock is $15.00 and $6.25 per share.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of

recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which requires lessees to recognize the following for all leases (with the exception of short term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right of use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On October 16, 2019, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. Accordingly, the Company has adopted Topic 842 beginning in the first quarter of 2022. Modified retroactive transition approach will be required for operating leases existing at or entered into after the beginning of the earliest comparative period presented. The Company notes that adopting the new standard resulted in recording a lease liability and right-of-use asset associated with the Company's facility lease agreement and subsequent amendments thereto totaling $2,067,000 and $2,063,400, respectively as of January 1, 2022.

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 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.

BUSINESS

Overview

We are an AI driven, end-to-end allogeneic cell therapy company, currently developing the multi-indication allogeneic T cell therapy that exploits the natural potency of the GDT to target solid tumors.

Our end-to-end approach consists of target discovery and validation, product development, and cGMP compliant manufacturing, which we believe will allow us to leverage a new framework for the next generation of cell therapies. We also have new technologies in development that we believe will support our end-to-end approach.

From a target discovery standpoint, our proprietary target discovery engine is called "Diamond." The Diamond platform is a suite of data mining algorithms that can process large amounts of data to identify and evaluate the quality of potential identifying cancer-specific immunotherapy targets using proprietary AI models. We believe that Diamond accelerates the development of new drug technologies by applying the latest in machine learning methods to quickly locate rare cancer-specific targets in vast databases of billions of genomic datapoints and eliminate targets likely to fail prior to costly laboratory validation and development.

From a development standpoint, we utilize innovative engineered and non-engineered GDT manufacturing technologies and are developing proprietary, virus-free gene editing tools, to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. Our Procel, Isocel, and Deltacel product platforms consists of allogeneic cell therapy product candidates that are currently in the preclinical development stage. Our Procel product candidate consists of engineered GDTs targeting PD-L1. Our Isocel product candidate consists of engineered GDTs targeting Iso-Meso. Our Deltacel product candidate consists of non-engineered GDTs that have been expanded, enriched, and activated *ex-vivo* through a proprietary process, and are used to treat solid tumors regardless of the specific tumor antigen expression.

We currently have one clinical trial candidate with the Procel product candidate platform titled ALEXIS-PRO-1. We currently have one clinical trial candidate with the Isocel product candidate platform titled ALEXIS-ISO-1. Our ALEXIS-PRO-1 clinical trial candidate is our allogeneic GDT therapy product candidate targeting PD-L1. Our ALEXIS-ISO-1 clinical trial candidate is our allogeneic GDT therapy product candidate targeting an isoform of Mesothelin that is preferentially present on tumor cells, namely Iso-Meso. The IND applications for these trial candidates have been on a clinical hold since of June 2021. We are currently working on addressing the FDA's comments and we expect the clinical hold on ALEXIS-PRO-1 will be lifted in the first half of 2023 allowing us to begin the activation process for the clinical trial by the end of the second quarter of 2023. For ALEXIS-ISO-1, we are targeting the activation process for the clinical trial to begin by the end of the last quarter of 2023.

We have also entered into the SRA with MD Anderson Principal Investigator to facilitate the development of our Deltacel, Procel, and Isocel product candidate platforms. We believe the SRA will generate sufficient in-vivo pre-clinical data to support the IND submissions for: (1) IND #1; (2) IND #2; and (3) IND #3. These three INDs have not been submitted to the FDA yet, and the trial candidates are described in further detail below.

IND #1 will evaluate Deltacel GDTs in combination with a standard anti-tumor modality. We are planning to submit this IND during the second half of 2022, and believe clinical activation will begin by the end of the fourth quarter of 2022. IND #2 will explore a combination of ALEXIS-PRO-1 with a standard anti-tumor modality. We are planning to submit IND #2 during the first half of 2023, and believe clinical activation will begin by the end of the second quarter of 2023. IND #3 will evaluate a combination of ALEXIS-ISO-1 and a standard anti-tumor modality. We are planning to submit IND #3 during the second half of 2023, with clinical activation targeted to begin by the end of the fourth quarter of 2023.

From a manufacturing standpoint, we use in-house R&D laboratory facilities, an on-site animal facility for non-clinical studies, and cGMP production facilities for vector and cell manufacturing with a dedicated on-site quality control laboratory, which we believe will ensure rapid discovery, validation, development and a streamlined clinical product release. We believe that our allogeneic, OTS manufacturing process will result in short lead times and low costs, opening up opportunities for outpatient treatment.

Finally, our other technologies in development consist of:

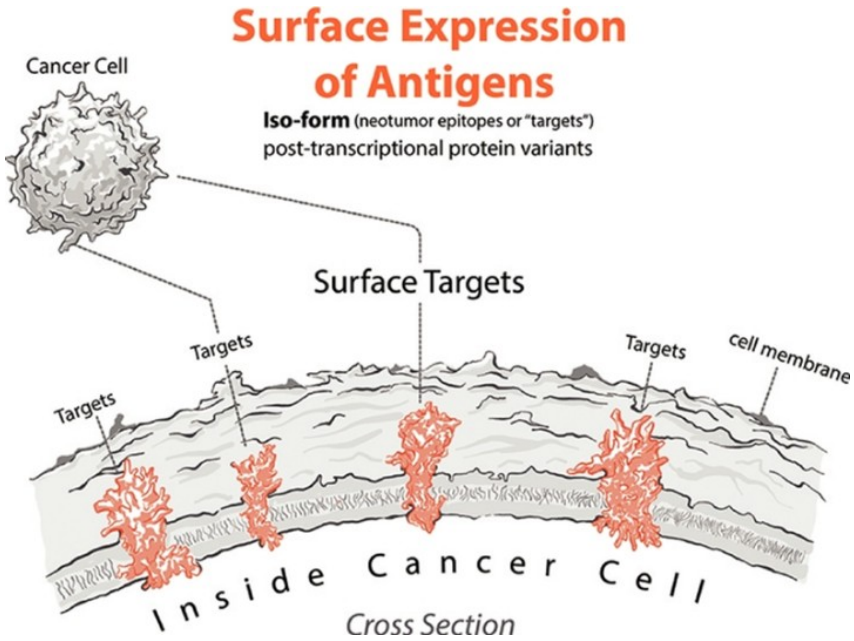
- An iNKT platform targeting PD-L1 and other tumor-preferred isoforms, similar to Iso-Meso. iNKT is considered as an unconventional T cell population with semi invariantly re-arranged TCR. They recognize many tumor-associated lipid antigens via their endogenous anti-tumor receptor, CD1d, which does not react against allogeneic cells, making iNKT ideally suitable for allogeneic cancer cell therapies. The innate ability of iNKTs to kill tumor cells combined with minimal GvHD risk provides an extremely attractive platform for developing OTS product. Although the relative percentage of iNKTs are very low in peripheral blood we believe that we have developed an efficient method of enriching, expanding, and engineering a pure population of iNKTs on a large scale, suitable for commercial manufacturing. We have proven the high efficiency of our iNKTs to kill tumor cells in-vitro and in an in-vivo pilot study, and this year we will commence extensive IND application enabling studies.

- ABBIE, which is a novel cell engineering system to manufacture GMP-grade off the shelf cell therapies without the use of a viral vector, thus making our products safer and easier to manufacture.

Target Discovery: Diamond (Identify, Screen, Prioritize)

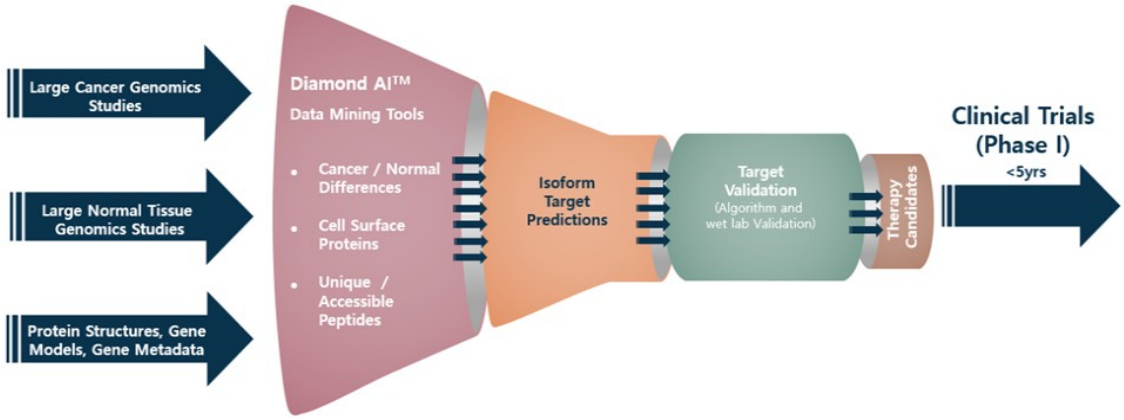
Diamond addresses one of the main challenges in developing a robust clinical pipeline: *target identification*.

Successful development of precision immunotherapies requires identifying a distinguishing feature of tumor cells, a target. The target must be common on tumor cells but not on normal cells. It also must be accessible and able to trigger an effective immune response. It is both critical and extremely difficult to find good immunotherapy targets.



Diamond is an integrated suite of data mining and AI algorithms that can identify and validate novel cancer immunological targets. The targets it identifies are segments of cell surface proteins (peptides) that are specific to tumor cells and that can be bound by

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



Development: Using Engineered Allogeneic GDT Based Therapies

After Diamond allows us to identify targets on solid tumors, we seek to use those targets to train immune cells. The trained immune cells generate a therapeutic immune response in patients. These peptide sequences, known as TSIA, generate an immunological response and therefore eradicate cancer cells.

Our Approach

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

We are currently in the process of completing the Nonclinical Research and Quality sections of the amendments to our INDs for ALEXIS-PRO-1 and ALEXIS-ISO-1 INDs, for first in-human OTS gamma delta chimeric PD-L1 GDTs, and CAR (Iso-Meso), respectively. Our target indications will be metastatic and progressive locally advanced solid malignancies which have no curative options. These biomarkers have been validated in-vitro and in-vivo, with preclinical animal models.

We are also in the process of compiling the key preclinical data under the SRA that we believe is needed to submit three new INDs. The first being for the Deltacel product candidate platform, for a first in-human, OTS, using non-engineered GDTs that are combined with a standard anti-tumor modality. The two other INDs, being for the Procel and Isocel product candidate platforms, for a first in-human, OTS, using engineered GDTs that are combined with a standard anti-tumor modality.

Next Generation Allogeneic Therapy Summary

We believe that our Next Generation Allogeneic Approach results in the following:

1. Address a Growing Market: Solid tumors represent approximately 90% of new cases according to the American Cancer Society, we believe that our therapies can address a significant contingency of these cases. Further, we believe that the overall global CAR-T cell therapy market could expand to over $33 billion by 2027.

2. Thwarting Antigen Escape by Targeting PD-L1: Similarly, since many solid tumors have a wide expression of PD-L1, we believe that our ALEXIS-PRO-1 and IND #2 trial candidates can effectively treat most solid cancers.

3. Exploitation of GDT's Natural Potency: Further, by using GDTs, we believe that our trial candidates can achieve superior efficacy.

Manufacturing Allogeneic OTS Therapies

Our proprietary manufacturing approach utilizes unique in-house processes that we believe maximize yield and deliver engineered and non-engineered T cells that are significantly more potent compared to the competition. The discussion below shows our unique process compared to traditional processes.

For our allogeneic products, the T cells are collected from a healthy donor. The collected cells are then sent to our central processing facility, where the peripheral blood mononuclear cells, including GDTs, are isolated.

For our Procel and Isocel product candidates, these T cells are then engineered by stimulating the cells to proliferate, then transduced with a non-replicating retroviral vector.

These engineered cells are then propagated in cell culture bags until sufficient cells are available. The engineered GDTs are then washed and frozen at the cell processing site. For our Deltacel product candidate, which consists of non-engineered GDTs that have been expanded and enriched ex-vivo and activated through a proprietary process used to treat solid tumors, there is no retroviral transduction required because it is a non-viral approach.

This inventory will be securely stored and then shipped to oncology centers as needed.

As noted previously, GDTs are currently engineered by using an industry standard retroviral vector, however, in future versions we expect to utilize our non-viral ABBIE gene editing platform.

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

For all of our ALEXIS and Deltacel trial candidates, we believe that all materials and components utilized in the production of the cell line, retroviral vector (for Procel and Isocel only) and final T cell product will be readily available from qualified suppliers in line with the clinical timelines discussed previously.

In addition, we believe we have sufficient space at our headquarters in Houston, Texas, to support clinical grade operations.

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.

Potential Benefits

We believe that the manufacturing of our therapies with these process and infrastructure results in the following key benefits:

4. No Lead Time – OTS therapies are ready on demand. They are produced in advance of patient visits and are cryogenically frozen. Conversely, autologous therapies have approximately three to five weeks of lead time.

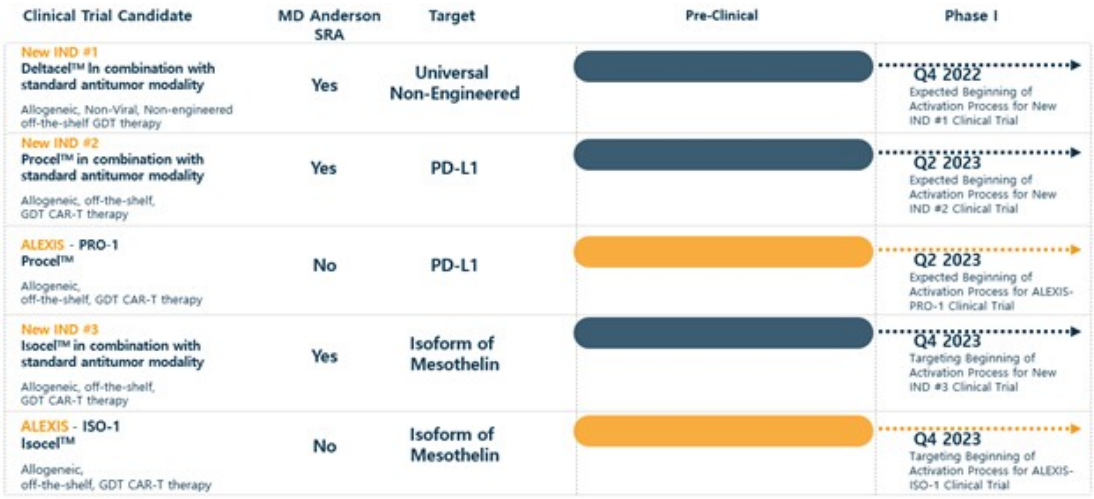
5. Outpatient Treatment – This means reduced hospitalization and other treatment related costs. Current hospitals struggle to break even if CAR-T cell therapies are administered in the inpatient setting.

6. Lower Production Costs – We have In-house cGMP manufacturing (full control and vertical integration of the manufacturing process) for vector production and cell therapy production.

Our Product Pipeline and Development

Using our proprietary technologies, we are researching and developing multiple product candidates for the treatment of solid tumors. Our product candidates are allogeneic engineered and non-engineered GDTs to be used for specific patients as OTS treatments for patients solid tumors.

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



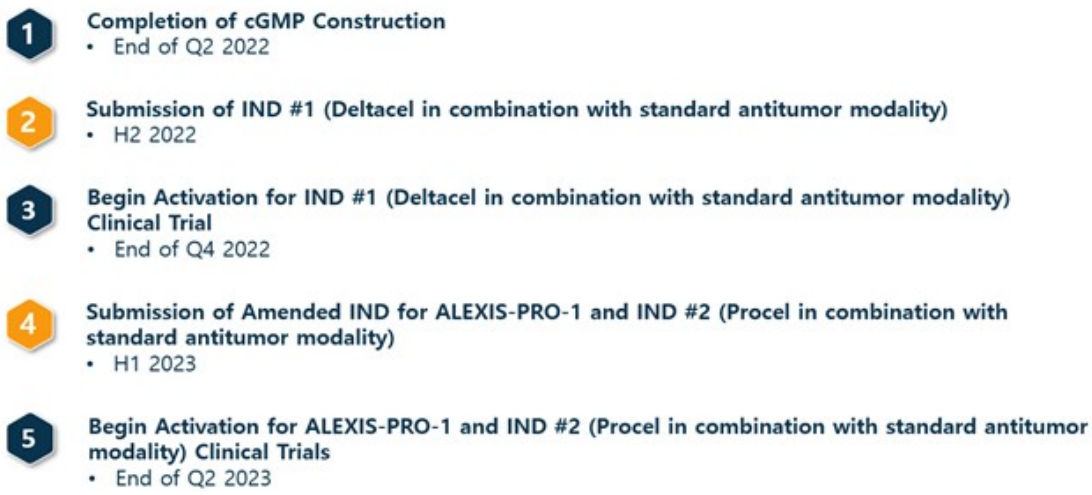
Clinical Program

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

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

The field of immunotherapy is currently expanding with a variety of approaches and we believe that our suite of GDT therapies is uniquely positioned to make an impact in this setting based upon our promising preclinical in-vitro and in-vivo studies which have revealed strong and specific tumor cytotoxicity with minimal adverse effects.

As previously discussed, our INDs for ALEXIS-PRO-1 and ALEXIS-ISO-1 are currently on a clinical hold. We hope to be able to submit IND #1, IND #2, and IND #3 in the future using the in-vivo preclinical data that will be generated under the SRA with MD Anderson. Below is a graphic outlining what we believe are our clinical milestones for the next twelve months and anticipated timing for achieving each based on our current expectations.



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

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

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

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

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

We intend to go through a vendor qualification process with multiple contract 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 contract manufacturers, if necessary, would not result in significant delay or material additional costs.

Our Intellectual Property

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

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

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

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

Patents

We are actively building an intellectual property portfolio around our product candidate platforms and our discovery programs, based on intellectual property we own as well as licensed intellectual property. We are the owners of, co-owners of, or the licensee of multiple patents and patent applications in the United States and worldwide. Our patent portfolio includes patent applications having claims directed to aspects of our lead product candidate platforms, Procel, Isocel, and Deltacel, as well as other research-stage candidates. Our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward: (1) antigen binding domains directed to the targets of our product candidate platforms; (2) CAR constructs used in our product candidates; (3) methods of treatment for therapeutic indications; (4) manufacturing processes; and (5) and methods for genetically engineering immune cells suitable for autologous and allogeneic 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 (“PTA”), which compensates a patentee for administrative delays by the USPTO 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 (“PTE”) 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 PTE involves a complex calculation based on the length of time it takes for regulatory review. A PTE 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. All expected expiration dates are provided in accordance with the 20 year patent term absent any patent term adjustment or patent term extension that may be applied in the future.

As of June 21, 2022, our patent estate includes two issued patents (one of which is in the U.S) and 27 pending patent applications (including 7 U.S. patent applications and 4 PCT patent applications), each of which we either own or 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 (Identifying, Screening, and Prioritizing)

Our tumor targets patent estate includes portfolio families directed to target identification processes, therapeutics and treatments we co-developed or developed internally and include:

1. Patent applications entitled “Methods for Identifying and Using Diseases-Associated Antigens” pending in the U.S. and Europe, and are expected to expire on May 29, 2040. The claims in these patent applications are directed in part to methods for identifying proteins encoded by genes having tumor-associated hot-spot mutations and/or tumor-associated mRNA splice variants, methods for identifying immunogenic portions of such proteins, and uses thereof.

2. An International PCT application entitled “Peptide Compositions for the Treatment of Pathogenic Infections” is pending, from which national/regional applications, if filed, are expected to expire on May 7, 2041.

3. An International PCT application entitled “Disease-Associated Isoform Identifier” is pending, from which national/regional applications, if filed, are expected to expire on November 8, 2041.

Chimeric PD1 Receptor

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

The Chimeric PD1 Receptor patent family includes patent applications entitled, “PD1-Specific Chimeric Antigen Receptor as an Immunotherapy” that have been exclusively in-licensed from Longwood University. The patent family contains patent applications filed in the United States and in other jurisdictions and are expected to expire on September 26, 2038. The claims in the patent applications are directed to a CAR polypeptide; a vector comprising the CAR polypeptide; and a T lymphocyte genetically modified to express the CAR polypeptide. The claims in the patent application also are directed to a method of treating cancer using T lymphocytes genetically modified to express the CAR polypeptide.

Iso-Mesothelin Binding Molecules, Chimeric PD1 Molecule and Gamma-Delta T-cell Expansion

We have developed binding molecules directed to an iso-mesothelin isoform expressed in tumors at a higher level than in non-tumor tissues, including CAR binding molecules. We also have developed a chimeric PD1 molecule and effector cell expansion processes, e.g., GDT expansion processes and iNKT manufacturing processes, for manufacturing allogeneic effector cells.

The family includes an International PCT patent application entitled “Mesothelin Isoform Binding Molecules and Chimeric PD1 Receptor Molecules, Cells Containing the Same and Uses Thereof” and an International PCT patent application entitled “Cell Manufacturing Processes and Chimeric PD1 Receptor Molecules,” from which national/regional applications, if filed, are expected to expire on July 2, 2041. The family also includes an International PCT patent application entitled “Mesothelin Isoform Binding Molecules and Chimeric PD1 Receptor Molecules, Cells Containing the Same and Uses Thereof” from which national/regional applications, if filed, are expected to expire on November 17, 2041. The claims in the patent applications include those directed to iso-mesothelin isoform-binding antibody compositions, CARs that include the compositions, cells including the compositions, methods of manufacture, and methods of enriching T cell populations for GDTs.

Related to T cell populations enriched for GDTs, also pending are a provisional patent application entitled "Methods of Treating Cancer By Combination Therapy with Gamma Delta T-cell Compositions", from which national/regional applications, if filed and if a nonprovisional patent application is filed on the anniversary of the filing date, are expected to expire on June 21, 2043 and a provisional patent application entitled "Methods for Generating Gamma Delta T-Cells", from which national/regional applications, if filed and if a nonprovisional patent application is filed on the anniversary of the filing date, are expected to expire on June 21, 2043.

ABBIE (Genetic Delivery Vehicle)

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

The ABBIE patent family has been exclusively in-licensed from CGA 369 Intellectual Holdings, Inc. It is entitled, "CAS 9 Retroviral Integrase and CAS 9 Recombinase Systems for Targeted Incorporation of a DNA Sequence into a Genome of a Cell or Organism." The patent family includes an issued Chinese patent and patent applications that were filed in Europe, China, Japan, Korea, and the United States and patents granted are expected to expire on March 31, 2036. The claims in this patent family are directed to recombinant proteins, compositions that include such proteins and guide RNA, vectors encoding such proteins, and methods of use.

License Agreements

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, and pertains to the technology described above in the section titled "ABBIE (Genetic Delivery Vehicle)". 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, TALEN, and Zinc finger proteins attached by a linker with viral integrases or a recombinase in order 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 ("Longwood") pertaining to the technology described above in the section titled "Chimeric PD-1 Receptor". 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 PD1-specific chimeric

antigen receptor compositions for immunotherapy. 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

MD Anderson Grant and Sponsored Research Agreement

On April 8, 2021, we entered into a letter of intent (the "Letter of Intent") with MD Anderson pursuant to which MD Anderson shall receive a research grant from us titled, "Validation of biomarker Iso-Meso for pancreatic cancer," which is aimed at discovering new cancer-specific antigen targets (the "Grant"). The total costs to be paid in connection with the Grant shall be $300,000. Pursuant to the Letter of Intent, the Grant shall commence on April 1, 2021 and end on March 31, 2022. The Company extended the Grant until March 31, 2023 at no additional cost.

On June 1, 2022, we entered into an SRA with MD Anderson pursuant to which MD Anderson shall perform a research study with the Company to evaluate a standard anti-tumor modality with Kiromic's GDT product candidate platforms. The Study consists of three milestones which aim to (1) test the hypothesis that a standard anti-tumor modality in the tumor microenvironment ("TME") favorably modulate the efficacy, tolerability and biodistribution of adoptively transferred Deltacel GDTs; (2) to understand of how the standard anti-tumor modality in the TME modulate the homing, and antitumor activity of adoptively transferred Procel GDTs; and (3) to expand our understanding of how the standard anti-tumor modality in the TME modulate the homing, and antitumor activity of Isocel GDTs.

Pursuant to the Study, Professor James Welsh M.D., who works in the Department of Radiation Oncology at The University of Texas MD Anderson Cancer Center, will serve as principal investigator. Pursuant to the SRA, the SRA shall commence on June 1, 2022 and end on June 1, 2024.

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 allogeneic T cell therapies.

Potential cell therapy competitors include:

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

- *Allogeneic Gamma Delta T cell therapy competition:* Gamma Delta Therapeutics, Lava Therapeutics, N.V., TC Biopharm, Ltd., Gadeta Therapeutics, B.V., and Adicet Bio, 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 TCR, 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.

InSilico Solutions, LLC

Our wholly owned subsidiary, InSilico Solutions, LLC (“InSilico”), operates a world class bioinformatics and AI services company. The Company completed its acquisition of InSilico on July 26, 2021.

This business has not generated any revenues for Kiromic. However, it did generate $53,400 in other income during the year ended December 31, 2021.

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 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 PTE 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 USPTO Office, in consultation with the FDA, reviews and approves the application for any PTE 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 former 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 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 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.

Human Capital

Our Employees. As of June 27, 2022, we had a total of 73 employees. Our highly qualified and experienced team includes scientists, physicians, laboratory technicians, finance professionals, and administrative professionals. We also utilize a number of consultants for financial reporting, clinical, regulatory, and SEC compliance.

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

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

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

Legal Proceedings

From time to time in the future, we may become involved in litigation or other legal proceedings that arise in the ordinary course of business.

Dr. Terrell Claim

On March 22, 2021, Jason Terrell ("Terrell"), a former consultant for and director of the Company, commenced an action against us in the Court of Chancery of the State of Delaware, C.A. No. 2021-0248-MTZ (the "Action"). In the Action, Terrell seeks a declaratory judgment that we are obligated to issue him (i) options to purchase 500,000 shares of our common stock at a price of $0.50 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 500,005 shares of our common stock at a price of $0.17 per share pursuant to an alleged January 2017 non-employee director options agreement. In his complaint, Terrell also claimed that, pursuant to our operative certificate of incorporation, he is entitled to indemnification from us for attorneys' fees and costs he incurs in connection with the Action because the Action arises in connection with his position as a former director.

We dispute Terrell's claims and allegations in the Action and intend to vigorously defend against them. On May 21, 2021, we filed a motion to dismiss Terrell's claims in the actions with prejudice, arguing that (i) Terrell's options-related claims fail because his 2014 and January 2017 agreements were explicitly superseded by a later options agreement, under which Terrell relinquished his prior options; and (ii) Terrell is not entitled to indemnification because the Action relates to contracts between the Company and Terrell in his personal capacity, and not in connection with any activities or duties of Terrell in his official capacity as former director. In

response to the motion, filed on June 21, 2021, Terrell withdrew his claim for indemnification, but opposed the portion seeking dismissal of his declaratory judgment claim. The motion was fully briefed with the filing of our reply brief on July 7, 2021.

Oral argument was held before the Vice Chancellor on October 20, 2021. During oral argument, the Vice Chancellor invited the parties to submit supplemental letter briefs on the question of whether the Court of Chancery even had the authority to adjudicate the Action in light of the delegation of authority in Terrell's most recent stock option agreement with the Company (the "SOA") to our Compensation Committee to resolve all disputes regarding the interpretation of the SOA. The parties submitted simultaneous supplemental letters briefs on this issue on November 15, 2021. On January 20, 2022, the Vice Chancellor issued her decision on our motion to dismiss, ruling that the Action is stayed until the Compensation Committee itself resolves whether it has sole authority to resolve the parties' contract interpretation dispute.

Subsequently, the parties agreed upon a process for coordinating submissions and/or presentations to the Compensation Committee. The parties made their respective written submissions to the Compensation Committee on March 31, 2022 and are awaiting the Compensation Committee's determination(s).

In the interim, as noted, the Action is stayed and no further proceedings are taking place.

Sabby and Empery Claim

Sabby Volatility Warrant Master Fund Ltd., et al. v. Kiromic BioPharma, Inc. et al., Case No. 22-cv-1927 (SDNY). On March 7, 2022, Sabby Entities and Empery Entities filed a complaint in the District Court for the Southern District of New York alleging claims against the Company and certain current and former officers and directors of the Company for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021. The plaintiffs seek unspecified damages; rescission to the extent they still hold Kiromic securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The parties have agreed that the Defendants' shall respond to the complaint on June 30, 2022. The Company has evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000. Similarly, the Company has evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, the Company is unable to estimate any possible range of loss attributed to other unasserted claims at this time.

In addition to the above, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of stockholders of the Company. These press releases were in response to an approximately 15% decline in the Company's stock price on July 16, 2021, the date we had first announced we had received comments from the FDA on our two INDs, resulting in clinical holds. If claims are ultimately made pursuant to these investigations or otherwise, we intend to defend ourselves vigorously, but are unable to predict the outcome of any such litigation. Even if we are successful, securities litigation is costly to defend and would likely divert management's attention away from the business. To the extent that we are subject to a legal proceeding, it could have a material adverse impact on us.

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(s)
Pietro Bersani	54	Chief Executive Officer
Daniel Clark	33	Chief Financial Officer
Scott Dahlbeck	61	Chief of Staff
Michael Ryan	56	Chief Bioinformatics Research Computing Officer
Americo Cicchetti	54	Director
Michael Nagel	60	Director
Karen Reeves	72	Director
Frank Tirelli	69	Director

Pietro Bersani, CPA. Mr. Bersani has served as the Company's Chief Executive Officer since May 10, 2022. Previously, Mr. Bersani has served as our interim Chief Executive Officer from January of 2022 to May 2022, and as a member of our Board since June 2020. From April 2020 to January 2022, Mr. Bersani was a Partner with B2B CFO Partners, LLC, which provides strategic management advisory services to owners of privately held companies. From November 2019 to March 2020, he served as the President, and Chief Executive Officer of K.P. Diamond Eagle, Inc., a consulting firm specialized in development of innovative commercial and private aviation business models. He served as a Senior Director within Alvarez & Marsal's Private Equity Performance Improvement Practice, LLP between August 2018 and October 2019. From October 2016 to July 2018, he served as President and Chief Executive Officer of K.P. Diamond Eagle, Inc. 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.

We believe Mr. Bersani is qualified to serve as a member of our Board because of his strong record of leadership as an executive officer and his financial background.

Daniel Clark, CPA, MBA. Mr. Clark has served as the Company's Chief Financial Officer since May 10, 2022. Previously, Daniel Clark has served as our as Interim Chief Financial Officer from September 2021 to May 2022. Mr. Clark joined the Company in February 2020 and served as the Company's Corporate Controller until September 2021, when he was promoted to Vice President – Finance Operations prior to his appointment as interim Chief Financial Officer. Before joining the Company, Mr. Clark was a Manager with The Siegfried Group, a national accounting services firm, from June 2018 to February 2020. Prior to his employment with The Siegfried Group, Mr. Clark served as Senior Consultant - Office of the CFO Solutions for FTI Consulting, a global financial consulting firm, from January 2017 to May 2018. Prior to that, Mr. Clark was Senior Associate - Audit at KPMG US, a member of Big Four global accounting firm KPMG, from August 2011 to June 2015. Mr. Clark holds a Master of Business Administration from Texas A&M University, Mays School of Business, and a Bachelor of Science in Business Administration with a major in Accounting from the University of Richmond, Robins School of Business. Mr. Clark is a licensed Certified Public Accountant in the state of Texas.

Scott Dahlbeck, MD, PharmD. Dr. Dahlbeck has served as our Chief of Staff since February 2022. He previously served as our President from January 2013 to October 2019, and Chief Medical Officer from October 2019 to February 2022. 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.

Michael Ryan, PhD. Dr. Ryan has served as the Chief BioInformatics Research Computing Officer as of July 2021 after his bioinformatics services company, InSilico Solutions, LLC ("InSilico"), was acquired by Kiromic. He has worked with Kiromic for the

past two years as an external consultant leading the team that developed Kiromic's revolutionary target discovery system, Diamond. Dr. Ryan first worked for AMS as a software consultant where he gained a reputation for designing effective architectures for complex, large-data systems and for leading development teams that consistently delivered excellent software on aggressive timelines. He then founded his first software company, Tiger Team Consulting, which he grew into a 40+ person consulting firm. During his tenure at Tiger Team, he led multi-million dollar software development projects for telecommunications firms, stock brokerages, Customs and Border Patrol, and the US Patent Office.

While working, Dr. Ryan earned a PhD in Bioinformatics from George Mason University with John Weinstein of NIH (now chair of BCB at MD Anderson) as his dissertation advisor. He sold his interest in Tiger Team in 2009 and founded his next software company, InSilico, focused on genomics analysis and bioinformatics. InSilico quickly gained a reputation in the cancer research community for developing analysis tools and visualizations that made large, complex genomics datasets accessible to researchers. In long-term collaborations with the National Cancer Institute, Johns Hopkins School of Medicine, and MDACC he and his team have developed numerous published, open-source bioinformatics and AI applications that are in widespread use by cancer researchers.

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); and Member of the National Immunization Technical Advisory Group at the Ministry of Health, Italy since 2019.

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 has served as the Chief Executive Officer and a Director for Molipharma S.R.L. since January 2020, whose core business is the research and development of new drugs and diagnostics aimed at predicting, detecting and treating female oncological diseases. He has also served 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.

We believe Dr. Cicchetti's qualifications to serve on our board include his extensive medical knowledge and experience in the pharmaceutical industry.

Michael Nagel. Mr. Nagel has served on our board of directors since October 2020. 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.

We believe Mr. Nagel's qualifications to serve on our board include his industry knowledge and sales and marketing experience.

Frank Tirelli. Mr. Tirelli has served on our board of directors since January 2022. Mr. Tirelli has served as Chairman of Professional Services and a member of the Strategic Advisory Board at alliantgroup, LP, an international consulting firm since September 2018. Mr. Tirelli has also served on the Strategic Advisory Board of Alliant Cybersecurity. Since January 2017, Mr. Tirelli has also served as Chief Executive Officer of Finaxstrure Associates LLC, a company that provides board of director advisory services and expert witness services. From 2000 to 2003, Mr. Tirelli served as the President and Chief Executive Officer of Herbalife International Inc.

(NYSE: HLF), a publicly traded nutrition company that conducted business in 52 countries and generated $2 billion in sales. Mr. Tirelli has 30 years of experience with Deloitte & Touche LLP ("Deloitte"), one of the world's premier accounting firms, including service as Chairman and CEO of Deloitte Italy and Vice Chairman of Deloitte U.S. Mr. Tirelli is a licensed CPA in Connecticut and California. He received a BS in Accounting from Boston College and an MBA from Babson College. Mr. Tirelli was selected to serve on the board of directors due to his being an audit committee "financial expert" under the SEC regulations.

We believe Mr. Tirelli's qualifications to serve on our board include his financial background and leadership experience.

Dr. Karen Reeves. Dr. Reeves has served on our board of directors since February 2022. Dr. Reeves has served as President and Chief Medical Officer of AZTherapies, Inc., an advanced clinical-stage biopharmaceutical company, since September 2017. Dr. Reeves began her biopharma career at Pfizer Inc. where she served in roles of increasing responsibility including as VP, Head, Global Clinical Submissions Quality. She has more than 25 years of experience in clinical R&D, business development, regulatory, operational development, and management gained at small, medium, and large life science companies. She has also served as Global Head of Medical Science at Astellas Pharma Global Development, Inc., a pharmaceutical company. Dr. Reeves has worked across a variety of therapeutic areas including neuroscience, oncology, immunology, infectious diseases, cardiovascular, and urology, as well as early and late stages of drug development, and is experienced in successful regulatory filings with the FDA and global regulators. She has held faculty positions at Harvard University and Tufts Medical School. Dr. Reeves received her BA from Yale University and her MD degree from University of Vermont Medical School. Dr. Reeves was elected to our board of directors due to her industry experience.

We believe Dr. Reeves' qualifications to serve on our board include her extensive medical knowledge and experience in the pharmaceutical industry.

Family Relationships

There are no family relationships among any of our officers or directors.

Involvement in Certain Legal Proceedings

Dr. Terrell Claim

On March 22, 2021, Jason Terrell ("Terrell"), a former consultant for and director of the Company, commenced an action against us in the Court of Chancery of the State of Delaware, C.A. No. 2021-0248-MTZ (the "Action"). In the Action, Terrell seeks a declaratory judgment that we are obligated to issue him (i) options to purchase 500,000 shares of our common stock at a price of $0.50 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 500,005 shares of our common stock at a price of $0.17 per share pursuant to an alleged January 2017 non-employee director options agreement. In his complaint, Terrell also claimed that, pursuant to our operative certificate of incorporation, he is entitled to indemnification from us for attorneys' fees and costs he incurs in connection with the Action because the Action arises in connection with his position as a former director.

We dispute Terrell's claims and allegations in the Action and intend to vigorously defend against them. On May 21, 2021, we filed a motion to dismiss Terrell's claims in the actions with prejudice, arguing that (i) Terrell's options-related claims fail because his 2014 and January 2017 agreements were explicitly superseded by a later options agreement, under which Terrell relinquished his prior options; and (ii) Terrell is not entitled to indemnification because the Action relates to contracts between the Company and Terrell in his personal capacity, and not in connection with any activities or duties of Terrell in his official capacity as former director. In response to the motion, filed on June 21, 2021, Terrell withdrew his claim for indemnification, but opposed the portion seeking dismissal of his declaratory judgment claim. The motion was fully briefed with the filing of our reply brief on July 7, 2021.

Oral argument was held before the Vice Chancellor on October 20, 2021. During oral argument, the Vice Chancellor invited the parties to submit supplemental letter briefs on the question of whether the Court of Chancery even had the authority to adjudicate the Action in light of the delegation of authority in Terrell's most recent stock option agreement with the Company (the "SOA") to our Compensation Committee to resolve all disputes regarding the interpretation of the SOA. The parties submitted simultaneous supplemental letters briefs on this issue on November 15, 2021. On January 20, 2022, the Vice Chancellor issued her decision on our motion to dismiss, ruling that the Action is stayed until the Compensation Committee itself resolves whether it has sole authority to resolve the parties' contract interpretation dispute.

Subsequently, the parties agreed upon a process for coordinating submissions and/or presentations to the Compensation Committee. The parties made their respective written submissions to the Compensation Committee on March 31, 2022 and are awaiting the Compensation Committee's determination(s).

In the interim, as noted, the Action is stayed and no further proceedings are taking place.

Sabby and Empery Claim

Sabby Volatility Warrant Master Fund Ltd., et al. v. Kiromic BioPharma, Inc. et al., Case No. 22-cv-1927 (SDNY). On March 7, 2022, entities related to the Sabby Entities and Empery Entities filed a complaint in the District Court for the Southern District of New York alleging claims against the Company and certain current and former officers and directors of the Company for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021. The plaintiffs seek unspecified damages; rescission to the extent they still hold Kiromic securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The parties have agreed that the Defendants shall respond to the complaint on June 30, 2022. The Company has evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000. Similarly, the Company has evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, the Company is unable to estimate any possible range of loss attributed to other unasserted claims at this time.

In addition to the above, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of stockholders of the Company. These press releases were in response to an approximately 15% decline in the Company's stock price on July 16, 2021, the date we had first announced we had received comments from the FDA on our two INDs, resulting in clinical holds. If claims are ultimately made pursuant to these investigations or otherwise, we intend to defend ourselves vigorously, but are unable to predict the outcome of any such litigation. Even if we are successful, securities litigation is costly to defend and would likely divert management's attention away from the business. To the extent that we are subject to a legal proceeding, it could have a material adverse impact on us.

We are not currently party to any other legal proceedings that we believe could have a material adverse effect on our business, operating results or financial condition.

Corporate Governance

Governance Structure

Our bylaws and governance principles provide the Board with the flexibility to combine or separate the positions of Chairman and Chief Executive Officer. Michael Nagel currently serves as the Chairman of our Board. Our Board believes that the separation of these positions strengthens the independence of our Board and allows us to have a Chairman focused on the leadership of the Board while allowing our Chief Executive Officer to focus more of his time and energy on managing our operations. The Board currently believes this structure works well to meet the leadership needs of the Board and of the Company. Mr. Pietro Bersani, our Interim-Chief Executive Officer, has comprehensive industry expertise and is able to devote substantial time to the Company, and Mr. Nagel, our Chairman, is able to focus on longer term and strategic matters, and to provide related leadership to the Board. As a result, we do not currently intend to combine these positions; however a change in this leadership structure could be made if the Board determines it is in the best long-term interests of stockholders. For example, if the two roles were to be combined, we believe that the independence of the majority of our directors, and the three fully independent Board committees, would provide effective oversight of our management and the Company.

The Board's Role in Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of the risks we face, while the Board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the Board is responsible for satisfying itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The Board believes that establishing the right "tone at the top" and that full and open communication between executive management and the Board are essential for effective risk management and oversight. Our CEO communicates frequently with members of the Board to discuss strategy and challenges facing our company. Senior management usually attends our regular quarterly Board meetings and is available to address any questions or concerns raised by the Board on risk management-related and any other matters. Each quarter, the Board receives presentations from senior management on matters involving our key areas of operations.

Director Independence

Our Board has determined that a majority of the Board consists of members who are currently "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). The Board considers Americo Cicchetti, Michael Nagel, Karen Reeves, and Frank Tirelli to be "independent." Pietro Bersani, our Chief Executive Officer, Daniel Clark, our Chief Financial Officer, Dr. Scott Dahlbeck, our Chief of Staff, and Michael Ryan, our Chief Bioinformatic Research Computing Officer are not considered to be "independent" as defined by Nasdaq Listing Rule 5605(a)(2).

Committees of the Board of Directors

Our Board has established standing Audit, Compensation and Corporate Governance/Nominating Committees to devote attention to specific subjects and to assist it in the discharge of its responsibilities. All committees operate under a written charter adopted by our Board, each of which is available on our Internet website at https://ir.kiromic.com.

Audit Committee

The Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent registered public accountants, (ii) appointing, replacing and discharging the independent registered public accounting firm, (iii) pre-approving the professional services provided by the independent registered public accounting firm, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent registered public accounting firm, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent registered public accounting firm. The Audit Committee also prepares the Audit Committee report that is required pursuant to the rules of the SEC.

The Audit Committee currently consists of Frank Tirelli, chairman, Michael Nagel, and Americo Cicchetti. We believe that each of Frank Tirelli, Michael Nagel, and Americo Cicchetti is "independent" as that term is defined under applicable SEC and Nasdaq rules. Frank Tirelli is our audit committee financial expert. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee. The charter is available on our website at https://ir.kiromic.com.

Compensation Committee

The Compensation Committee has responsibility for assisting the board of directors in, among other things, (i) evaluating and making recommendations regarding the compensation of the executive officers and directors of our company, (ii) assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy, (iii) producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC, (iv) periodically evaluating the terms and administration of our incentive plans and benefit programs and (v) monitoring of compliance with the legal prohibition on loans to our directors and executive officers.

The Compensation Committee currently consists of Karen Reeves, chairman, Michael Nagel, and Americo Cicchetti. We believe that all of the members are "independent" under the current listing standards of Nasdaq. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee which is available on our website at https://ir.kiromic.com.

Corporate Governance/Nominating Committee

The Corporate Governance/Nominating Committee has responsibility for assisting the board of directors in, among other things, (i) effecting board organization, membership and function including identifying qualified board nominees, (ii) effecting the organization, membership and function of board committees including composition and recommendation of qualified candidates, (iii) establishment of and subsequent periodic evaluation of successor planning for the chief executive officer and other executive

officers, (iv) development and evaluation of criteria for board membership such as overall qualifications, term limits, age limits and independence and (v) oversight of compliance with the Corporate Governance Guidelines. The Corporate Governance/Nominating Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors. Potential nominees are identified by the board of directors based on the criteria, skills and qualifications that have been recognized by the Corporate Governance/Nominating Committee. While our nomination and corporate governance policy does not prescribe specific diversity standards, the Corporate Governance/Nominating Committee and its independent members seek to identify nominees that have a variety of perspectives, professional experience, education, differences in viewpoints and skills, and personal qualities that will result in a well-rounded board of directors.

The Corporate Governance/Nominating Committee currently consists of Karen Reeves, chairperson, Frank Tirelli and Americo Cicchetti. We believe that all of the members are "independent" under the current listing standards of Nasdaq. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee which is available on our website at https://ir.kiromic.com.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics to ensure that our business is conducted in a consistently legal and ethical manner. All of our employees, including our executive officers and directors, are required to comply with our Code of Business Conduct and Ethics.

The full text of the Code of Business Conduct and Ethics is posted on our website at https:// ir.kiromic.com/. Any waiver of the Code of Business Conduct and Ethics for directors or executive officers must be approved by our Audit Committee. We will disclose future amendments to our Code of Business Conduct and Ethics, or waivers from our Code of Business Conduct and Ethics for our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on our website within four business days following the date of the amendment or waiver. In addition, we will disclose any waiver from our Code of Business Conduct and Ethics for our other executive officers and our directors on our website. A copy of our Code of Business Conduct and Ethics will also be provided free of charge upon request to: Secretary, Kiromic BioPharma, Inc. 7707 Fannin Street, Suite 140, Houston, TX 77054.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table contains compensation information for our Chief Executive Officer and certain other executives who were the most highly compensated executive officers for the years ended December 31:

Name & Principal Position	Year	Salary	Bonus	Stock In Lieu of Cash Bonus[1]	Equity incentive plan grants[2]	Other [3]	Total
Maurizio Chiriva Internati,	2021	$ 504,000	$ 52,769	$ —	$ —	$ 21,913	$ 578,682
Former Chief Executive Officer[4]	2020	$ 437,900	$ —	$ —	$ 6,535,000	$ —	$ 6,972,900
Tony Tontat,	2021	$ 225,000	$ —	$ —	$ —	$ —	$ 225,000
Former Chief Operating Officer and Chief Financial Officer[5]	2020	$ 75,000	$ —	$ 5,226,000	$ 2,654,800	$ 90,000	$ 8,045,800
Gianluca Rotino,	2021	$ 300,000	$ —	$ —	$ 609,713	$ —	$ 909,713
Former Chief Strategy and Innovation Officer[6]	2020	$ 75,000	$ —	$ 4,160,000	$ 2,665,600	$ 579,700	$ 7,480,300
Scott Dahlbeck,	2021	$ 365,000	$ —	$ —	$ —	$ 77,123	$ 442,123
Chief of Staff[7]	2020	$ 120,000	$ —	$ 40,378	$ 220,300	$ —	$ 380,678

(1) 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 and Chief Strategy and Innovation Officer, respectively. The shares were issued in exchange for services rendered and no cash considerations.

(2) Represents the grant date fair value of Restricted Stock Units ("RSUs") and non-qualified stock options granted to executives. None of the RSUs had vested as of December 31, 2020. Our NEOs will only realize compensation to the extent the fair market value of our common stock is greater than the exercise price of such stock options. The grant date fair value of option awards granted in 2020 is in accordance with ASC Topic 718, or ASC 718. For information regarding assumptions underlying the valuation of equity awards, see Note 11 and Note 10 contained in the Annual Reports on Form 10-K for the years ended December 31, 2021 and 2020, respectively.

(3) Represents a payment for accrued paid time off as of December 31, 2020. The Company's policy does not allow employees to carry over more than 80 hours of paid time off into any new fiscal year. If an employee has accrued greater than 80 hours of paid time off, the employee may be eligible for a payment calculated by the excess hours of accrued paid time off, multiplied the employee's hourly pay rate.

(4) Dr. Chiriva-Internati ceased serving as our Chief Executive Officer and Chairman on January 27, 2022.

(5) As of April 21, 2021, the Company and Mr. Tontat signed an addendum to Mr. Tontat's employment agreement which removed the title of Chief Operating Officer from Mr. Tontat's principal position at the Company. Mr. Tontat ceased serving as our Chief Financial Officer and Director on September 29, 2021.

(6) On February 10, 2022, the Company and Mr. Rotino entered into a Transition and Consulting Agreement dated as of February 9, 2022 (the "Rotino Agreement"). Pursuant to the terms of the Rotino Agreement, effective as of February 9, 2022, Mr. Rotino's ceased serving as the Company's Chief Strategy and Innovation Officer and Director. The Company retained Mr. Rotino to provide consulting services to the Company for a period of nine months (or until November 9, 2022).

(7) On February 10, 2022, the Company and Dr. Dahlbeck entered into a Modification to Employment Agreement dated as of February 9, 2022 (the "Dahlbeck Agreement"). The Dahlbeck Agreement amends and supersedes certain terms of the Employment Agreement dated as of January 1, 2020, between the Company and Dr. Dahlbeck. Pursuant to the Dahlbeck Agreement, effective as of February 9, 2022, Dr. Dahlbeck's title was changed to Chief of Staff, and he ceased to be the Company's Chief Medical Officer.

Employment Agreements

Gianluca Rotino

On February 10, 2022, we entered into Transition and Consulting Agreement, dated as of February 9, 2022, with Mr. Rotino (the "Rotino Agreement"). Pursuant to the terms of the Rotino Agreement, Mr. Rotino's employment as the Company's Chief Strategy and Innovation Officer terminated and the Company retained Mr. Rotino to provide consulting services to the Company for a period of nine months (or until November 9, 2022). Notwithstanding the foregoing, the Rotino Agreement may be terminated by either the Company or Mr. Rotino upon 30 days' prior written notice, except no such prior notice shall be required in the event the Company terminates the Rotino Agreement for cause. Under the terms of the Rotino Agreement, Mr. Rotino will be compensation $25,000 per month. In addition, the Company agreed that Mr. Rotino's service under the Rotino Agreement shall constitute continued service to the Company under the terms of the award agreements governing certain RSUs that were previously issued to Mr. Rotino and that Mr. Rotino's previously issued RSUs will continue to vest.

Outstanding Equity Awards as of December 31, 2021

	Number of Securities Underlying Unexercised Options		Option Exercise Price	Option Expiration Date	Number of Securities Underlying RSU Grants		RSU Expiration Date
	Exercisable	Unexercisable			Vested	Unvested	
Maurizio Chiriva Internati, Former Chief Executive Officer	—	—			175,877	334,271	8/19/2030
Gianluca Rotino, Former Chief Strategy and Innovation Officer	147,806	—	$ 6.64	11/09/27	144,258	135,818	8/19/2030
Tony Tontat, Former Chief Operating Officer and Chief Financial Officer	—	—			—	—	
Scott Dahlbeck, Chief of Staff	14,311	—	$ 24.25	6/8/2030	17,240	—	8/19/2030

Director Compensation

Generally, our Board believes that the level of director compensation should be based on time spent carrying out Board and committee responsibilities and be competitive with comparable companies. In addition, the Board believes that a significant portion of director compensation should align director interests with the long-term interests of stockholders. The Board allows changes in its director compensation practices based on recommendations and approvals of the compensation committee.

Our compensation committee approved the compensation of our non-employee directors, as described below. For 2022, our payment structures are in the list below.

The cash component of our non-employee director compensation is as follows:

- $38,000 annual cash retainer for Board members;
- $33,000 annual cash retainer for the Chairman of the Board;
- $15,000 annual cash retainer for the Chairman of the audit committee;
- $10,000 annual cash retainer for the Chairman of our compensation committee;
- $8,000 annual cash retainer for the Chairman of our governance and nominating committee;
- $7,500 annual cash retainer for each non-Chairman audit committee member;
- $5,000 annual cash retainer for each non-Chairperson compensation committee member; and

- $4,000 annual retainer for each non-Chairman governance and nominating committee member.

Each current and new director is also eligible for an option grant, upon commencement of services, with a fair value of $57,000, vesting over one year in equal, quarterly installments as measured from the grant date.

The compensation of our other non-employee directors remains the same as in 2021. The compensation committee believes that our non-employee director compensation remains aligned with director compensation practices at our peer companies while considering the ongoing cash constraints of the Company.

During year ended December 31, 2021, our non-employee directors received the following compensation for their services on the Board and its committees:

	Cash Fees	Total
Pietro Bersani	$ 167,756	$ 167,756
Americo Cicchetti	$ 42,000	$ 42,000
Michael Nagel	$ 38,971	$ 38,971
Jerry Schneider	$ 37,750	$ 37,750

Securities authorized for issuance under equity compensation plans

The following table provides information relating to our equity compensation plans as of December 31, 2021. As of December 31, 2021, we had our 2021 Plan, which was approved by our Board of Directors and our stockholders.

	Equity Compensation Plans		
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	1,309,916[1]	$ 8.57[2]	598,699[3]
Equity compensation plans not approved by security holders	—	—	—
Total	1,309,916	$ 8.57	598,699

(1) Includes 929,007 restricted stock units that were outstanding on December 31, 2021 under the Company's 2021 Plan. Restricted stock unit awards may be settled only for shares of common stock on a one-for-one basis.

(2) Only option awards were used in computing the weighted-average exercise price.

(3) This amount represents shares of common stock available for issuance under the Company's 2021 Plan. Awards available for grant under the Company's 2021 Plan include stock options, stock appreciation rights, restricted stock, restricted stock units, other stock awards, performance awards, and any combination of the foregoing awards.

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 regarding beneficial ownership of shares of our common stock as of June 24, 2022 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers, and (iv) all of our directors and executive officers as a group. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of June 24, 2022, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 15,839,112 shares of common stock outstanding on June 24, 2022.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Kiromic BioPharma, Inc., 7707 Fannin Street, Suite 140, Houston, TX 77054.

		Percentage of Common Stock Beneficially Owned	
Beneficial Owner	**Number of shares beneficially owned**	**Before Offering**	**After Offering**
Directors and Executive Officers			
Pietro Bersani[1]	5,278	*	*
Daniel Clark[2]	18,168	*	*
Scott Dahlbeck[3]	461,068	2.91%	*
Michael Ryan[4]	53,052	*	*
Americo Cicchetti[5]	5,278	*	*
Michael Nagel[6]	5,278	*	*
Karen Reeves	—	*	*
Frank Tirelli	—	*	*
All current directors and executive officers as a group (8 persons)	548,122	3.45%	*
Other 5% Stockholders	*		
Maurizio Chiriva Internati [7]	1,474,588	9.31%	*

* Represents beneficial ownership of less than 1%.

(1) Includes options to purchase 5,278 shares of common stock that are exercisable within 60 days of June 24, 2022.

(2) Includes (i) 6,866 shares of common stock, (ii) options to purchase 5,398 shares of common stock that are exercisable within 60 days of April 25, 2022 and (iii) 5,904 shares of restricted stock that will vest within 60 days of June 24, 2022.

(3) Includes (i) 429,517 shares of common stock, and (ii) options to purchase 14,311 shares of common stock that are exercisable within 60 days of April 25, 2022 and (iii) 17,240 shares of vested restricted stock that will be released within 60 days of June 24, 2022.

(4) Includes (i) 50,189 shares of common stock and (ii) options to purchase 2,863 shares of common stock that are exercisable within 60 days of June 24, 2022.

(5) Includes options to purchase 5,278 shares of common stock that are exercisable within 60 days of June 24, 2022.

(6) Includes options to purchase 5,278 shares of common stock that are exercisable within 60 days of June 24, 2022.

(7) The address of Maurizio Chiriva-Internati is 8030 Mason Road, Manvel, TX 77578.

TRANSACTIONS WITH RELATED PERSONS

The following is a description of transactions or series of transactions since January 1, 2021 or any currently proposed transaction, to which we were or are to be a participant and in which the amount involved in the transaction or series of transactions exceeds $120,000, and in which any of our directors, executive officers or persons who we know hold more than five percent of any class of our capital stock, including their immediate family members, had or will have a direct or indirect material interest, other than compensation arrangements with our directors and executive officers.

Employment Agreements

We have entered into employment agreements and offer letter agreements with certain of our executive officers. See "Executive Compensation — Employment Agreements" and "Executive Compensation — Potential Payments Upon Termination or Change in Control."

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and our Bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Policies and Procedures for Transactions with Related Persons

We have adopted a written Related Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration, and oversight of "related person transactions." For purposes of our policy only, a "related person transaction" is a transaction, arrangement, or relationship (or any series of similar transactions, arrangements or relationships, including any indebtedness or guarantee of indebtedness) in which we or any of our subsidiaries are participants, in which any "related person" has a material interest.

Transactions involving compensation for services provided to us as an employee, consultant, or director are not considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director, or a holder of more than 5% of any class of our voting securities (including our common stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of our voting securities, an executive officer with knowledge of the proposed transaction, must present information regarding the proposed related person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. To identify related person transactions in advance, we rely on information supplied by our executive officers, directors, and certain significant stockholders. In considering related person transactions, our audit committee takes into account the relevant available facts and circumstances, which may include, but are not limited to:

- the risks, costs, and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

Our audit committee will approve only those transactions that it determines are fair to us and in our best interests.

DESCRIPTION OF SECURITIES

General

The following description summarizes important terms of the classes of our capital stock, the Common Stock Warrants and the Pre-Funded Warrants. 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.

As of March 31, 2022, the Company was authorized to issue 300,000,000 shares of common stock and 60,000,000 shares of Preferred Stock.

As of the date of this prospectus, there are 15,839,112 shares of common stock issued and outstanding that are held by 83 holders of record.

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

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors.

Authority is granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the Delaware General Corporate Law, or DGCL, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the fullest extent now or hereafter permitted by the DGCL. The powers, preferences and relative, participating, optional and other special rights of each such series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. Without limiting the generality of the foregoing, the resolution or resolutions providing for the issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

Warrants

As of the date of the prospectus, there are 462,500 representative warrants outstanding. In connection with the initial public offering on October 15, 2020, we granted the Underwriters' Warrants to purchase an aggregate of 62,500 shares of common stock at an

exercise price of $15.00 per share, which is 125% of the initial public offering price. The Underwriters' Warrants have a five-year term and are not exercisable prior to April 13, 2021. In connection with the July 2, 2021 public offering, we granted the Underwriters' Warrants to purchase an aggregate of 400,000 shares of common stock at an exercise price of $6.25 per share, which is 125% of the public offering price. The Underwriters' Warrants have a five-year term and are not exercisable prior to December 25, 2021.

Common Stock Warrants

The following is a brief summary of certain terms and conditions of the Common Stock Warrants to be issued in connection with this offering and are subject in all respects to the provisions contained in the warrants.

Form. The Common Stock Warrants will be issued in electronic book-entry form to the investors. You should review a copy of the form of Common Stock Warrant, which is filed as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions applicable to the Common Stock Warrants.

Exercisability. The warrants are exercisable at any time after their original issuance, and at any time up to the date that is five years after their original issuance. The Common Stock Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the Common Stock Warrants under the Securities Act is effective and available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the Common Stock Warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the Common Stock Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Common Stock Warrant. No fractional shares of common stock will be issued in connection with the exercise of a Common Stock Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Exercise Limitation. A holder will not have the right to exercise any portion of the Common Stock Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Common Stock Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price. The exercise price per whole share of common stock purchasable upon exercise of the Common Stock Warrants is expected to be $ per share (125% of public offering price of common stock) of common stock. The exercise price is also subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the Common Stock Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We have applied for the listing of the Common Stock Warrants offered in this offering on The Nasdaq Capital Market under the symbol "KBPRW". No assurance can be given that such listing will be approved or that a trading market will develop.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Common Stock Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Common Stock Warrants will be entitled to receive upon exercise of the Common Stock Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Common Stock Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Common Stock Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Common Stock Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Common Stock Warrant.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being offered hereby in lieu of a share of common stock is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

Duration and Exercise Price. Each Pre-Funded Warrant offered hereby will have an initial exercise price per share equal to $0.001. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full or they expire. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability. The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). There is no expiration date for the Pre-Funded Warrants. A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or at the election of the holder prior to the issuance of any Pre-Funded Warrants, 9.99%) of the outstanding shares of common stock immediately after exercise. Any holder may increase such percentage to any percentage not in excess of 9.99% upon at least 61 days' prior notice to us. No fractional shares of common stock will be issued in connection with the exercise of a Pre-Funded Warrant. In lieu of fractional shares of common stock, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price of such Pre-Funded Warrant or round up to the next whole share.

Cashless Exercise. In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of common stock, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Transferability. Subject to applicable laws, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer.

Exchange Listing. We do not intend to list the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.

Rights as a Stockholder. Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Pre-Funded Warrants.

Options

As of the date of this prospectus, there are options for the purchase of 338,872 shares of common stock outstanding under our 2017 Equity Incentive Plan with a weighted average exercise price of $8.49 per share.

Restricted Stock Units

As of the date of this prospectus, there are 225,018 shares of common stock issuable upon the vesting of restricted stock units with a weighted-average grant date fair value of $10.37 per share.

Transfer Agent and Registrar

VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598 telephone 212-828-8436, is 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, 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.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion is a summary of the material U.S. federal income tax consequences of the purchase, ownership and disposition of shares of our common stock (including any common stock received upon the exercise of the warrants), common stock warrants and pre-funded warrants issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder of our common stock, common stock warrants or pre-funded warrants. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock, common stock warrants or pre-funded warrants.

This discussion is limited to holders that hold our common stock, common stock warrants or pre-funded warrants as a "capital asset" within the meaning of Section 1221 of the Code (property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances, including the impact of the alternative minimum tax or the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the U.S.;
- persons holding our common stock, common stock warrants or pre-funded warrants as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- controlled foreign corporations, "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock, common stock warrants or pre-funded warrants under the constructive sale provisions of the Code;
- persons for whom our common stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- persons who hold or receive our common stock, common stock warrants or pre-funded warrants pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(1)(2) of the Code and entities, all of the interests of which are held by qualified foreign pension funds.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, common stock warrants or pre-funded warrants, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock, common stock warrants or pre-funded warrants and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, COMMON STOCK WARRANTS OR PRE-FUNDED WARRANTS ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

For purposes of this discussion, a "U.S. holder" is any beneficial owner of our common stock, common stock warrants or pre-funded warrants that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the U.S.;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes)
- created or organized under the laws of the U.S., any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a U.S. person.

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of our common stock, common stock warrants or pre-funded warrants that is neither a U.S. holder nor an entity treated as a partnership for U.S. federal income tax purposes.

Allocation of Purchase Price Between our Common Stock or Pre-Funded Warrants and Warrants

For U.S. federal income tax purposes, the common stock (or, in lieu of common stock, the pre-funded warrants) and common stock warrants issued pursuant to this offering will be treated as a unit consisting of one share of common stock (or, in lieu of common stock, one pre-funded warrant) and the accompanying common stock warrant. The purchase price for each unit will be allocated between these two components in proportion to their relative fair market values at the time the unit is purchased by the holder. This allocation of the purchase price for each unit will establish the holder's initial tax basis for U.S. federal income tax purposes in the common stock (or, in lieu of common stock, the pre-funded warrant) and the common stock warrant included in each unit. A holder's allocation of purchase price between each share of common stock (or, in lieu of common stock, each pre-funded warrant) and the accompanying warrant is not binding on the IRS or the courts, and no assurance can be given that the IRS or the courts will agree with a holder's allocation. The separation of the common stock (or, in lieu of common stock, the pre-funded warrant) and the common stock warrant included in each unit should not be a taxable event for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price between the common stock (or, in lieu of common stock, the pre-funded warrant) and the common stock warrant.

General Treatment of Pre-Funded Warrants

Although the law in this area is not completely settled, the pre-funded warrants are generally expected to be treated as shares of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. Under this treatment, no gain or loss would be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant would carry over to the share of common stock received. Similarly, the tax basis of the pre-funded warrant would carry over to the share of common stock received upon exercise, increased by the exercise price of $[0.001] per share. You should discuss with your tax advisor the consequences of the purchase, ownership and disposition of the pre-funded warrants, as well as the exercise of, certain adjustments to, and any payments in respect of the pre-funded warrants (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Distributions

We do not anticipate declaring or paying distributions to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce a U.S. holder's basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "Tax Considerations Applicable to U.S. Holders—Gain on Disposition of Common Stock, Common Stock Warrants or Pre-Funded Warrants." A preferential U.S. federal income tax rate may apply to any dividends paid to non-corporate U.S. holders meeting certain holding period requirements.

The taxation of property received with respect to a common stock warrant or a pre-funded warrant on exercise other than common shares is unclear. It is possible such a receipt of property would be treated as a distribution on common stock as described in this section, although other treatments may also be possible. U.S. holders should consult their tax advisors regarding the proper treatment of any such receipt of property in respect of the common stock warrants or pre-funded warrants on exercise.

Gain on Disposition of Our Common Stock, Common Stock Warrants or Pre-Funded Warrants

Upon a sale or other taxable disposition of our common stock, common stock warrants or pre-funded warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock, common stock warrant or pre-funded warrant. Capital gain or loss will constitute long-term capital gain or loss if such U.S. holder's holding period for the common stock, common stock warrant or pre-funded warrant exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. holders who recognize losses with respect to a disposition of our common stock, common stock warrant or pre-funded warrants should consult their own tax advisors regarding the tax treatment of such losses.

Exercise of Common Stock Warrants and Pre-Funded Warrants

As discussed above under the section titled "Description of Securities—Pre-Funded Warrants" and "Description of Securities—Common Stock Warrants—Exercisability," a U.S. holder may exercise the common stock warrants or pre-funded warrant by payment of exercise price or through a cashless exercise. The U.S. federal income tax treatment of a cashless exercise of common stock warrants or pre-funded warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a common stock warrant described in the remainder of this paragraph, a U.S. holder should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of common stock warrants or pre-funded warrants. In general, a U.S. holder should not recognize gain or loss for U.S. federal income tax purposes upon exercise of a common stock warrant or pre-funded warrant, except to the extent such U.S. holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the common stock warrant pre-funded warrant, which will be treated as a sale subject to the rules described above under "Tax Considerations Applicable to U.S. Holders—Gain on Disposition of Our Common Stock, Common Stock Warrants or Pre-Funded Warrants." A U.S. holder's initial tax basis in the share of common stock received upon exercise of the common stock warrant or pre-funded warrant generally should be equal to the sum of (i) such U.S. holder's tax basis in the common stock warrant or pre-funded warrant and (ii) the exercise price paid or treated as paid by such U.S. holder on the exercise of the common stock warrant or pre-funded warrant. A U.S. holder's holding period in the common stock received upon exercise of a common stock warrant will begin on the day after such exercise (or possibly on the date of exercise) and will not include the period during which the U.S. holder held the common stock warrant. A U.S. holder's holding period in the common stock received upon exercise of a pre-funded warrant generally should include such U.S. holder's holding period in the pre-funded warrant exchanged therefor.

Certain Adjustments to the Common Stock Warrants and Pre-Funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the common stock warrants and pre-funded warrants, or an adjustment to the exercise price of the commons stock warrants or pre-funded warrants, may be treated as a constructive distribution to a U.S. holder of the commons stock warrants or pre-funded warrants if, and to the extent that, such adjustment has the effect of increasing your proportionate interest in our earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of a common stock warrant or pre-funded warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holder of the common stock warrant or prefunded warrant should generally not result in a constructive distribution. Any constructive distributions generally would be subject to the tax treatment described above under "— Distributions."

Lapse of Common Stock Warrants and Pre-Funded Warrants

If a U.S. holder allows a common stock warrant or pre-funded warrant to expire unexercised, such U.S. holder will recognize a capital loss in an amount equal to such U.S. holder's tax basis in the common stock warrant or pre-funded warrant. The deductibility of capital losses is subject to certain limitations.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock, common stock warrants or pre-funded warrants and to the proceeds of a sale or other disposition of common stock, common stock warrants or pre-funded warrants paid by us to you unless you are an exempt recipient, such as certain corporations. Backup withholding will apply to those payments if a U.S. holder fails to provide their taxpayer identification number, or certification of exempt status, or if a U.S. holder otherwise fails to comply with applicable requirements to establish an exemption.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, if any, provided the required information is timely furnished to the IRS. Investors should consult their own tax advisors regarding their qualification for exemption from information reporting and backup withholding and the procedure for obtaining such exemption.

Tax Consequences Applicable to Non-U.S. Holders

Distributions

We do not anticipate declaring or paying distributions to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below we or the applicable withholding agent may treat the entire distribution as a dividend.

Subject to the discussion below on backup withholding and FATCA, dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the U.S. will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders may be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock in connection with the conduct of a trade or business within the U.S. and dividends being effectively connected with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the U.S. and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the U.S., as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the U.S. (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the U.S. to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

The taxation of property received with respect to a common stock warrant or a pre-funded warrant on exercise other than common shares is unclear. It is possible such a receipt of property would be treated as a distribution on common stock as described in this section, although other treatments may also be possible. Non-U.S. holders should consult their tax advisors regarding the proper treatment of any such receipt of property in respect of the common stock warrants or pre-funded warrants on exercise.

Sale or Other Disposition of Common Stock, Common Stock Warrants or Pre-Funded Warrants

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock, common stock warrants or pre-funded warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the U.S. (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the U.S. to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the U.S. for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock, common stock warrants or pre-funded warrants constitute U.S. real property interests, or USRPIs, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the U.S.) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market such as the Nasdaq Global Market, and such non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. Holder's holding period. Special rules may apply to non-U.S. holders of pre-funded warrants, who should consult their tax advisors. Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Exercise of the Common Stock Warrants and Pre-Funded Warrants

As discussed above under the section titled "Description of Pre-Funded Warrants—Exercisability" and "Description of Securities—Common Stock Warrants—Exercisability," a non-U.S. holder may exercise the common stock warrants and pre-funded warrants by payment of the exercise price or through a cashless exercise. The U.S. federal income tax treatment of a cashless exercise of common stock warrants and pre-funded warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a common stock warrant or pre-funded warrant described in the remainder of this paragraph, non-U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of common stock warrants or pre-funded warrants. In general, a non-U.S. holder should not recognize gain or loss for U.S. federal income tax purposes upon exercise of a common stock warrant or pre-funded warrant, except to the extent such non-U.S. holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the common stock warrant or pre-funded warrant, which will be treated as a sale subject to the rules described above under "Tax Considerations Applicable to Non-U.S. Holders—Gain on Disposition of Our Common Stock, Common Stock Warrants or Pre-Funded Warrants."

Certain Adjustments to the Common Stock Warrants and Pre-Funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the common stock warrants or pre-funded warrants, or an adjustment to the exercise price of the common stock warrants or pre-funded warrants, may be treated as a constructive distribution to a non-U.S. holder of the pre-funded warrants if, and to the extent that, such adjustment has the effect of increasing such non-U.S. holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of a common stock warrant or pre-funded warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holder of the common stock warrant or prefunded warrant should generally not result in a constructive distribution. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the non-U.S. holder. Non U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants.

In addition, regulations governing "dividend equivalents" under Section 871(m) of the Code may apply to the common stock warrants and pre-funded warrants. Under those regulations, an implicit or explicit payment under the common stock warrants or pre-funded warrants that references a dividend distribution on our common stock would generally be taxable to a non-U.S. holder as described under "Distributions" above. Such dividend equivalent amount would be taxable and subject to withholding whether or not there is actual payment of cash or other property, and the Company may satisfy any withholding obligations it has in respect of the common stock warrants or pre-funded warrants by withholding from other amounts due to the non-U.S. holder. Non-U.S. holders are encouraged to consult their own tax advisors regarding the application of Section 871(m) of the Code to the common stock warrants and pre-funded warrants.

Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding with respect to distributions we make on our common stock, common stock warrants or pre-funded warrants to the non-U.S. holder, provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a U.S. person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on our common stock, common stock warrants or pre-funded warrants to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale or other taxable disposition of our common stock or pre-funded warrants within the U.S., and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale or other taxable disposition of our common stock, common stock warrants or pre-funded warrants outside the U.S. conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or W-8BEN-E, or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption. Proceeds of a disposition of our common stock, common stock warrants or pre-funded warrants conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) paid on our common stock or pre-funded warrants, to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules, in each case subject to the proposed Treasury Regulations discussed below. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we or the applicable withholding agent may treat the entire distribution as a dividend. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the U.S. governing FATCA may be subject to different rules.

UNDERWRITING

ThinkEquity LLC ("ThinkEquity") is acting as representative of the underwriters of this offering. Subject to the terms and conditions of the underwriting agreement dated June , 2022, 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 shares of common stock, Common Stock Warrants or Pre-Funded Warrants listed next to its name in the following table:

Underwriter	Number of Shares of Common Stock	Number of Common Stock Warrants	Number of Pre-Funded Warrants
ThinkEquity LLC			
Total			

The underwriters are committed to purchase all of the securities 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 to pay for and accept delivery of the shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants offered by this prospectus, 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 securities 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 securities offered by us to the public at the public offering price set forth on the cover of the prospectus. After the securities 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 a 45-day option to the representative of the underwriters, solely to cover over-allotments, if any, to purchase up to additional shares of our common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants, representing 15% of the shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants sold in the offering. The purchase price to be paid per additional share of common stock shall be equal to the public offering price of one share of common stock, less the underwriting discount, the purchase price to be paid per Pre-Funded Warrant shall be equal to the public offering price of one Pre-Funded Warrant, and the purchase price to be paid per additional Common Stock Warrant shall be $. The underwriters may exercise this option for 45 days from the date of this prospectus solely to cover sales of shares of common stock. If any of these additional shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants are purchased, the underwriters will offer the additional shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants on the same terms as those which are being offered hereunder.

Discount

The underwriters propose initially to offer the shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants to the public at the public offering price set forth on the cover page of this prospectus and to dealers at those prices less a commission not in excess of $ per share of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants.

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 and Common Stock Warrant	Per Pre-Funded Warrant and Common Stock Warrant	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	$	$		$
Underwriting discount (7.0%)	$	$		$
Proceeds, before expense, to us	$	$		$

We have agreed to pay a non-accountable expense allowance to the underwriters equal to 1% 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 $25,000 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 $125,000; fees and expenses related to the use of Ipreo's book building, prospectus tracking and compliance software for the offering in the amount of $29,500; up to $5,000 in the aggregate for all fees, expenses and disbursements relating to background checks of our officers, directors and entities; $10,000 for data services and communications expenses; costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, in an amount not to exceed $3,000; up to $10,000 for the representative's actual accountable "road show" expenses; and up to $25,000 of the representative's market making and trading, and clearing firm settlement expenses for the offering.

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 $479,000.

Representative's Warrants

We have agreed to issue to the representative warrants to purchase up to a total of shares of our common stock (5% of the aggregate number of shares of common stock (and/or Pre-Funded Warrants in lieu thereof) sold in this offering) (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. The Representative's Warrants will provide for registration rights (including a one-time demand registration right and unlimited piggyback rights) consistent with FINRA Rule 5110.05. The demand for registration may be made at any time beginning on the initial exercise date of the Representative's Warrants and expiring on the fifth anniversary of the effective date of this registration statement in accordance with FINRA Rule 5110(g)(8)(C). In addition to the one-time demand registration right, the Representative's Warrants shall have unlimited piggyback rights, for a period of no more than two years from the initial exercise date of the Representative's Warrants in accordance with FINRA Rule 5110(g)(8)(D). The

Representative's Warrants will also provide for customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110, and further, the number of shares underlying the Representative's Warrants shall be reduced if necessary to comply with FINRA rules and regulations.

Discretionary Accounts

The underwriters do not intend to confirm sales of the shares of common stock (and/or Pre-Funded Warrant in lieu thereof) and accompanying Common Stock Warrants offered hereunder 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, issue, sell, contract to sell, assign, transfer, pledge, 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 six (6) months from the date of this prospectus, in the case of our directors and officers, and for a period of three (3) months, in the case of any other 5% of greater holder of our outstanding shares.

Right of First Refusal

The underwriting agreement will provide that in the event of a closing whereby we receive net proceeds of at least $10,000,000, we will grant to ThinkEquity an irrevocable 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 offering during the twelve (12) month period immediately following the closing of such offering for us, or any successor to or any subsidiary of ours, on terms customary to ThinkEquity. ThinkEquity shall have the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation.

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 securities offered hereby will be passed upon for us by Hogan Lovells US LLP, Houston, TX. Venable LLP, New York, NY has acted as counsel for the underwriters in connection with certain legal matters related to this public offering.

EXPERTS

The financial statements of Kiromic BioPharma, Inc. as of December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. 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.

We are subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, we currently 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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kiromic BioPharma, Inc. and subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Houston, Texas

April 8, 2022

We began serving as the Company's auditor in 2016. In 2022 we became the predecessor auditor.

KIROMIC BIOPHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 25,353,900	$ 10,150,500
Accounts receivable	16,200	—
Prepaid expenses and other current assets	1,699,400	588,800
Total current assets	27,069,500	10,739,300
Property and equipment, net	3,629,000	2,066,000
Other assets	31,100	24,400
Total Assets	$ 30,729,600	$ 12,829,700
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 2,214,300	$ 665,200
Accrued expenses and other current liabilities	741,000	334,200
Interest payable	—	200
Loan payable	—	105,600
Note payable	454,500	362,400
Total current liabilities	3,409,800	1,467,600
Total Liabilities	3,409,800	1,467,600
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Common stock, $0.001 par value: 300,000,000 shares authorized as of December 31, 2021 and 2020; 15,488,516 shares and 7,332,999 shares issued and outstanding as of December 31, 2021 and 2020, respectively	9,300	1,200
Additional paid-in capital	94,527,000	52,988,700
Accumulated deficit	(67,216,500)	(41,627,800)
Total Stockholders' Equity	27,319,800	11,362,100
Total Liabilities and Stockholders' Equity	$ 30,729,600	$ 12,829,700

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 11,367,800	$ 5,052,900
General and administrative	13,937,900	14,144,000
Impairment expense	430,000	—
Total operating expenses	25,735,700	19,196,900
Loss from operations	(25,735,700)	(19,196,900)
Other income (expense)		
Gain on loan extinguishment	105,800	—
Other income	53,400	—
Interest expense	(12,200)	(3,300)
Total other income (expense)	147,000	(3,300)
Net loss	$ (25,588,700)	$ (19,200,200)
Net loss per share, basic and diluted	$ (2.26)	$ (4.42)
Weighted average common shares outstanding, basic and diluted	11,417,083	4,505,867

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series A-1 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
Balance 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	—	—	—	692,700	—	—	(692,700)	—	—
Warrants underlying Series B Preferred Stock issuance	—	—	—	—	—	—	2,668,300	—	2,668,300
Exercise of warrants	—	—	—	—	1,399,921	—	4,900	—	4,900
Common stock issuance net of issuance costs and discount amortization	—	—	—	—	1,250,000	1,200	11,974,200	—	11,975,400
Warrants underlying common stock discount amortization	—	—	—	—	—	—	(19,700)	—	(19,700)
Warrants underlying common stock issuance	—	—	—	—	—	—	377,000	—	377,000
Series A-1 Preferred stock conversion to common stock and fractional shares adjustments from stock split and conversion	(21,822,301)	(9,134,700)	—	—	624,594	—	9,134,700	—	—
Series B Preferred Stock conversion to common stock and fractional shares adjustments from stock split and conversion	—	—	(16,391,397)	(2,331,300)	469,136	—	2,331,300	—	—
Common stock issuance to employees and non-employees	—	—	—	—	725,536	—	9,432,000	—	9,432,000
Stock compensation expense	—	—	—	—	—	—	3,813,700	—	3,813,700
Net loss	—	—	—	—	—	—		(19,200,200)	(19,200,200)
Balance at December 31, 2020	—	$ —	—	$ —	7,332,999	$ 1,200	$52,988,700	$(41,627,800)	$ 11,362,100
Common stock issuance net of issuance costs and discount amortization	—	—	—	—	8,000,000	8,000	36,280,900	—	36,288,900
Warrants underlying common stock issuances discount amortization	—	—	—	—	—	—	829,200	—	829,200
Exercised stock options	—	—	—	—	18,891	100	125,300	—	125,400
Released restricted stock units	—	—	—	—	53,260	—	—	—	—
Common shares issued for InSilico Solutions, LLC Membership Purchase Agreement	—	—	—	—	50,189	—	400,000	—	400,000
Restricted stock units issued for InSilico Solutions, LLC Membership Purchase Agreement	—	—	—	—	33,177	—	140,000	—	140,000
Stock compensation expense	—	—	—	—	—	—	3,762,900	—	3,762,900
Net loss	—	—	—	—	—	—	—	(25,588,700)	(25,588,700)
Balance at December 31, 2021	—	$ —	—	$ —	15,488,516	$ 9,300	$94,527,000	$(67,216,500)	$ 27,319,800

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (25,588,700)	$ (19,200,200)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	469,800	200,000
Stock compensation expense	3,762,900	13,245,700
Gain on loan extinguishment	(105,800)	—
Impairment expense	430,000	—
Non-cash interest	—	200
Inventory obsolescence impairment	—	22,200
Changes in operating assets and liabilities, net of effects from acquisition:		
Accounts receivable	9,800	—
Prepaid expenses and other current assets	(1,117,400)	(499,700)
Accounts payable	1,411,100	(7,700)
Accrued expenses and other current liabilities	406,800	112,900
Net cash used for operating activities	(20,321,500)	(6,126,600)
Cash flows from investing activities:		
Purchases of property and equipment, net of effects from acquisition	(1,894,800)	(1,457,600)
Cash received from acquisition	84,000	—
Net cash used for investing activities	(1,810,800)	(1,457,600)
Cash flows from financing activities:		
Proceeds from issuance of common stock	40,000,000	15,000,000
Issuance cost	(2,881,900)	(2,667,300)
Borrowings from note payable	665,900	540,500
Repayments of note payable	(573,700)	(178,100)
Exercise of stock options	125,400	—
Proceeds from warrant exercise	—	4,900
Proceeds from loan payable	—	115,600
Loan repayments	—	(10,000)
Proceeds from Series B Preferred Stock issuance	—	3,000,000
Net cash provided by financing activities	37,335,700	15,805,600
Net change in cash and cash equivalents	15,203,400	8,221,400
Cash and cash equivalents:		
Beginning of year	10,150,500	1,929,100
End of period	$ 25,353,900	$ 10,150,500
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	$ 138,000	$ 220,500
Cash paid for interest on note payable	$ 12,200	$ 3,100
Common stock issuance for acquisition	$ 400,000	$ —
Restricted stock units granted for acquisition	$ 140,000	$ —
Acquisitions net of cash acquired	$ 456,000	$ —

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION

Nature of Business

Kiromic BioPharma, Inc. and subsidiaries (the "Company") is a clinical stage fully integrated biotherapeutics 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 an artificial intelligence-driven, end-to-end Chimeric Antigen Receptor T cell ("CAR-T cell") and gene therapy company, developing the first multi-indication allogeneic CAR-T cell therapy, that exploits the natural potency of the Gamma Delta T cell ("GDT") to target solid cancers. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

The Company is developing its brand of CAR-T cell product candidates known as ALEXIS. The two product candidates are called ALEXIS-ISO-1 and ALEXIS-PRO-1. ALEXIS-ISO-1 is an allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin). ALEXIS-PRO-1 is an allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1. These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. We filed two investigational new drug ("IND") applications in May 2021 for ALEXIS-ISO-1 and ALEXIS-PRO-1. The Food and Drug Administration ("FDA") has placed these applications under a clinical hold as of June 2021. The Company is currently working on addressing the FDA's comments. The FDA asked the Company to address key components regarding the chemical manufacturing and control components of the applications. Those components included tracing of all reagents used in manufacturing, flow chart of manufacturing processes, and Certificate of Analysis. The Company is working to address each of the FDA's comments.

Going Concern — These consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flow from operations of $20,321,500 for the year ended December 31, 2021, and an accumulated deficit of $67,216,500 as of December 31, 2021. 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. The Company does not have sufficient cash on hand or available liquidity to meet its obligations through the twelve months following the date the consolidated financial statements are issued. This condition raises substantial doubt about the Company's ability to continue as a going concern.

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

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

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

complete Phase I by the NIH through August 2021. Starting after Phase 1 completion in 2021, Phase II of the grant covers reimbursements for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees of $1,384,000. The Company applied for another Phase I extension in August 2021, and the extension was not granted. The Company does not expect to be reimbursed for any of the amounts for Phase II.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All intercompany balances were eliminated upon consolidation. Operating results for the year ended December 31, 2021 are not necessarily indicative of results to be expected for any future year.

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, warrants to purchase common stock underlying shares of Series B Preferred Stock, fair value of purchase price allocations of intangible assets associated with acquisitions, and estimating services incurred by third-party service providers used to recognize research and development expense.

Cash and Cash Equivalents—As of December 31, 2021 and 2020 cash and cash equivalents consisted entirely of cash on hand and bank deposits. The Company considers all highly liquid instruments with remaining maturities at purchase of 90 days or less to be cash equivalents.

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

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

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

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.

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

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

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

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company capitalized software development costs of approximately $207,800 and $10,200 for the years ended December 31, 2021 and 2020, respectively.

Goodwill— In connection with the InSilico Solutions, LLC ("InSilico") acquisition, the Company recognized goodwill for the excess of the purchase price over the fair value of tangible and identifiable intangible net assets of the business acquired. The Company will review goodwill for impairment annually on November 30, and whenever events or circumstances in interim periods indicate that it is more likely than not that an impairment may have occurred.

The Company assessed events and circumstances as of December 31, 2021 which was primarily driven by a reduced stock price as of December 31, 2021. The carrying value of the Company's assets was in excess of the market value of equity as of December 31, 2021. After analyzing this quantitative circumstance along with other qualitative considerations, the Company's management determined that an impairment of the entire value of the goodwill was appropriate. Accordingly, the Company incurred an impairment expense on the statement of operations totaling $430,000. Since the Company records a full valuation allowance to offset any deferred tax assets, the Company does not believe this impairment would result in any material tax impact.

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 have been no impairment losses on the Company's long-lived assets since inception.

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

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

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

The Company records uncertain tax positions in accordance with Accounting Standard Codification ("ASC") 740, *Income Taxes*, on the basis of a two-step process in which (1) the Company determines whether it is more-likely-than-not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations. No such interest or penalties were recognized during the years ended December 31, 2021 and 2020.

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

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

Proceeds from Grants—During the years ended December 31, 2021 and 2020, the Company recognized $0 and $142,400, respectively, as reductions to research and development expense within the consolidated statements of operations pursuant to its grant from the NIH.

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

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

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

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

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

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

There were no changes in the fair value hierarchy levels during the years ended December 31, 2021 and 2020.

Nonvested Stock Options and Restricted Stock Units—Pursuant to the Company's 2017 Stock Incentive Plan (the "2017 Plan") and the Omnibus 2021 Equity Incentive Plan (the "2021 Plan"), the Company has the ability to issue a variety of share-based payments and incentives to board members, employees, and non-employees through grants of nonvested stock options and restricted stock units ("RSUs").

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

The vesting conditions for RSUs include cliff vesting conditions. Certain RSUs vest with a range of 6 to 12 months following the expiration of employee lock-up agreements. Certain RSUs vest based on the later of achievement of key milestones or the expiration of employee lock-up agreements. When nonvested RSUs are vested, they are released to the grantee within sixty days.

Stock-Based Compensation—The Company records stock compensation expense related to the 2017 Plan and the 2021 Plan in accordance with ASC 718, Compensation—Stock Compensation. The Company measures and recognizes stock compensation expense for all stock based awards, including stock options, based on estimated fair values recognized using cliff vesting or the straight line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black Scholes option valuation model (the "Black Scholes model"). The calculation of stock based compensation expense requires that the Company make assumptions and judgments about the variables used in the Black Scholes model, including the fair value of the Company's common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

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

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

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

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

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

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

Common Stock Valuations. During the years ended December 31, 2021 and 2020, the closing price listed on the Nasdaq Capital Market for the Company's common stock on the date of the grant was used as the common stock valuation. Prior to the Company's initial public offering ("IPO") on October 16, 2020, the Company's board of directors, with input from management and third-party valuations, determined the fair value of the common stock underlying all stock-based compensation grants. The Company believes that the Board had the relevant experience and expertise to determine the fair value of the Company's common stock before the Company's common stock became publicly traded. The Board exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the Company's common stock at each grant date. These factors include:

- valuations of the common stock performed by third-party specialists;
- the prices, rights, preferences, and privileges of the Company's Series A-1 Preferred Stock and Series B Preferred Stock relative to those of the Company's common stock;
- lack of marketability of the common stock;
- current business conditions and projections;
- hiring of key personnel and the experience of management;

- the Company's stage of development;
- likelihood of achieving a liquidity event, such as an IPO, 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 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 IPO, as well as non-IPO 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 IPO liquidity event and stay private outcomes, as well as the values the Company expects those outcomes could yield. From February 2018 to October 2020, 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 IPO, the fair value of each share granted by the Board will be equal to the closing price of the common stock on the date of grant.

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

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

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

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

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

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

Common Stock Valuations. The fair value of common stock when the warrants were issued is equal to the IPO common stock issuance price of $12.00 per share, and July 2021 offering issuance price of $5.00 per share.

Exercise Price. The representative warrants' exercise price to purchase common stock is $15.00 per share, and $6.25 per share for the IPO common stock issuance and July 2021 offering issuance, respectively.

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

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

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, Leases ("Topic 842"), which requires lessees to recognize the following for all leases (with the exception of short term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right of use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On October 16, 2019, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. Accordingly, Topic 842 is effective for the Company beginning in the first quarter of 2022. Modified retroactive transition approach will be required for operating leases existing at or entered into after the beginning of the earliest comparative period presented. Though the Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows, the Company expects that adopting the new standard will result in recording a material lease liability and right-of-use asset associated with the Company's facility lease agreement and subsequent amendments thereto.

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

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other ("Topic 350"), which simplifies the test for goodwill impairment. The FASB determined this update was needed because of concern expressed by private companies and their stakeholders about the cost and complexity of the goodwill impairment test. The FASB simplified how an entity is required to test

goodwill for impairment by eliminating Step 2 from the goodwill impairment test in this update. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill.

In computing the implied fair value of goodwill under Step 2, an entity had to perform procedures to determine the fair value at the impairment testing date of its assets and liabilities (including unrecognized assets and liabilities) following the procedure that would be required in determining the fair value of assets acquired and liabilities assumed in a business combination.

Instead, under the amendments in this update, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. This update was effective for public entities for any annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Accordingly, the Company has adopted this guidance as of December 31, 2021.

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 and RSUs, have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average common shares outstanding used to calculate both basic and diluted loss per common shares are the same. The following table illustrates the computation of basic and diluted loss per share:

	Year Ended December 31,	
	2021	2020
Net loss	$ (25,588,700)	$ (19,200,200)
Less: Series B Preferred Stock discount amortization	—	(692,700)
Less: Initial Public Offering Common Stock discount amortization	(100,000)	(19,700)
Less: Public Offering Common Stock discount amortization	(122,000)	—
Net loss attributable to common shareholders, basic and diluted	$ (25,810,700)	$ (19,912,600)
Weighted average common shares outstanding, basic and diluted	11,417,083	4,505,867
Net loss per common share, basic and diluted	$ (2.26)	$ (4.42)

For the years ended December 31, 2021 and 2020, potentially dilutive securities excluded from the computations of diluted weighted-average common shares outstanding were (in shares):

	December 31, 2021	December 31, 2020
Options to purchase	—	1,647
Restricted Stock Units	73,405	95,815
Total	73,405	97,462

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at:

	December 31, 2021	December 31, 2020
Equipment	$ 1,593,100	$ 780,500
Leasehold improvements	1,464,700	1,229,700
Office furniture, fixtures, and equipment	16,600	16,600
Software	359,500	151,700
Construction in progress	1,226,600	449,200
	4,660,500	2,627,700
Less: Accumulated depreciation	(1,031,500)	(561,700)
Total	$ 3,629,000	$ 2,066,000

Depreciation expense was $469,800 and $200,000 for the years ended December 31, 2021 and 2020, respectively. Depreciation expense is allocated between research and development and general and administrative operating expenses on the consolidated statements of operations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31, 2021	December 31, 2020
Accrued consulting and outside services	$ 467,100	$ 143,200
Accrued compensation	273,900	191,000
Total	$ 741,000	$ 334,200

6. LOAN PAYABLE

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

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

As the legal form of the Note is a debt obligation, the Company accounts for it as debt under ASC 470, Debt, and recorded $105,600 as of December 31, 2020, in the consolidated balance sheet. During the year ended December 31, 2020, the Company received initial proceeds of $115,600 and made a repayment of $10,000 on the SBA Loan, bringing the balance to $105,600 as of December 31, 2020. The Company accrued interest over the term of the loan and did not impute additional interest at a market rate because the guidance on imputing interest in ASC 835-30, Interest, excludes transactions where interest rates are prescribed by a government agency.

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

forgiveness, the principal and accrued interest totaled $105,800. The forgiveness was classified as a gain on loan extinguishment in the consolidated statement of operations.

7. NOTE PAYABLE

In November 2020, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of December 31, 2020, the remaining payable balance on the financed amount was $362,400. As of December 31, 2021, this financing arrangement was paid in its entirety.

In November 2021, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $665,900 with an annual interest rate of 4.59%, to be paid over a period of ten months. As of December 31, 2021, the remaining payable balance on the financed amount was $454,500.

8. ACQUISITIONS

InSilico

On July 26, 2021, the Company completed its previously announced acquisition of InSilico pursuant to the Membership Interest Purchase Agreement (the "Purchase Agreement") with InSilico and Michael Ryan (the "Seller").

Pursuant to the terms of the Purchase Agreement, the Company acquired 100% of the membership interest of InSilico by delivering 50,189 shares to the Seller, and granting 33,177 RSUs to the employees of InSilico under the Company's 2021 Plan (the "Acquisition"). At the closing of the Acquisition, InSilico became a wholly-owned subsidiary of the Company. InSilico, based in Fairfax, VA, is a world class bioinformatics and artificial intelligence services company.

The Company determined fair values for the assets purchased, liabilities assumed, and purchase consideration as of the date of acquisition in the following table. The determination of the estimated fair value required management to make significant estimates and assumptions. See below for the fair value of purchase consideration and fair value of net assets acquired.

	Estimated Fair Value at Acquisition Date
Fair value of purchase consideration	
Fair value of common stock issued to Seller	$ 400,000
Fair value of restricted stock units granted	140,000
Fair value of purchase consideration	$ 540,000
Fair value of net assets acquired	
Cash	$ 84,000
Accounts receivable	26,000
Fixed asset	1,000
Goodwill (a)	430,000
Other current liabilities	(1,000)
Fair value of net assets acquired	540,000

(a) Goodwill represents the excess of the purchase price over the fair value of tangible and identifiable intangible net assets of the business acquired. This amount also includes intangible assets that do not qualify for separate recognition, combined with synergies expected from integrating InSilico processes with the Company's.

After assessing certain events and circumstances, the Company incurred a Goodwill impairment expense of $430,000 for the year ended December 31, 2021.

9. COMMITMENTS AND CONTINGENCIES

Facility Lease Agreements— The Company leases its premises in Houston, Texas under an operating lease which was renewed on November 19, 2020. This renewed lease agreement will commence under an operating lease agreement that is noncancelable from commencement until May 1, 2024.

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

Two further amendments were executed in 2021. The agreements commenced on November 1, 2021, and December 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 3,684 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation.

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

The total lease payments per month are $51,700 beginning March 1, 2022, and $52,300 beginning May 1, 2023. The Company records rent expense as incurred over the term of the lease. As of December 31, 2021, future minimum commitments under the facility lease agreement are as follows:

	Amount
2022	616,157
2023	624,825
2024	523,939
Total	$ 1,764,921

Annual rent expense for the facility lease agreement was $420,500 and $262,900 for the years ended December 31, 2021 and 2020, 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, 2021 and 2020, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Legal Proceedings— On March 22, 2021, Jason Terrell ("Terrell"), a former consultant former director of the Company, commenced an action against us in the Court of Chancery of the State of Delaware, C.A. No. 2021-0248-MTZ (the "Action"). In the Action, Terrell seeks a declaratory judgment that the Company is obligated to issue him (i) options to purchase 500,000 shares of common stock at a price of $0.50 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 500,005 shares of common stock at a price of $0.17 per share pursuant to an alleged January 2017 non-employee director options agreement. In his complaint, Terrell also claimed that, pursuant to the operative certificate of incorporation, he is entitled to indemnification from us for attorneys' fees and costs he incurs in connection with the Action because the Action arises in connection with his position as a former director.

The Company disputes Terrell's claims and allegations in the Action and intends to vigorously defend against them. On May 21, 2021, the Company filed a motion to dismiss Terrell's claims in the actions with prejudice, arguing that (i) Terrell's options-related claims fail because his 2014 and January 2017 agreements were explicitly superseded by a later options agreement, under which Terrell relinquished his prior options; and (ii) Terrell is not entitled to indemnification because the Action relates to contracts between the Company and Terrell in his personal capacity, and not in connection with any activities or duties of Terrell in his official capacity as former director. In response to the motion, filed on June 21, 2021, Terrell withdrew his claim for indemnification, but opposed the

portion seeking dismissal of his declaratory judgment claim. The motion was fully briefed with the filing of the Company's reply brief on July 7, 2021.

Oral argument was held before the Vice Chancellor on October 20, 2021. During oral argument, the Vice Chancellor invited the parties to submit supplemental letter briefs on the question of whether the Court of Chancery even had the authority to adjudicate the Action in light of the delegation of authority in Terrell's most recent stock option agreement with the Company (the "SOA") to the Company's Compensation Committee to resolve all disputes regarding the interpretation of the SOA. The parties submitted simultaneous supplemental letters briefs on this issue on November 15, 2021.

In a separate matter, on or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board, submitted substantially identical reports (the "Complaints") through the Company's complaint hotline. These Complaints, alleged, among other topics, risks associated with the Company's public disclosures in securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the FDA authorization of the IND applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained an independent counsel to assist it in conducting the Internal Review.

On February 2, 2022, following the conclusion of the Internal Review, the Company's Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that the Company had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing the IND applications that the Company submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17 FDA Communications"). On July 13, 2021, the Company received the FDA's formal clinical hold letters, which asked the Company to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, the Company issued a press release disclosing that it had received comments from the FDA on the two INDs, but did not use the term "clinical hold." The Company then consummated a public offering of $40 million of its common stock pursuant to the Registration Statement on July 2, 2021. On August 13, 2021, the Company issued a press release announcing that these INDs were placed on clinical hold. The Company did not disclose the June 16 and 17, 2021 FDA Communications in (i) the Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) the Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021.

As a result of the disclosure omission of the June 16 and 17 FDA Communications, the Company has concluded that it is reasonably possible that unasserted claims exist for future litigation and losses as of December 31, 2021. However, the Company is unable to estimate any possible range of loss attributed to these unasserted claims at this time. See Note 14 for additional information regarding loss contingencies associated with these unasserted claims transpiring after December 31, 2021.

The Company regularly assesses all contingencies and believes, based on information presently known, the Company is not involved in any other matters that would have a material effect on the Company's financial position, results of operations and cash flows.

10. STOCKHOLDERS' EQUITY

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

Accordingly, unless otherwise noted, all share and per share information has been restated to retroactively show the effect of these stock splits during the years ended December 31, 2021 and 2020.

As of December 31, 2021 and 2020, the Company was authorized to issue 300,000,000 shares of common stock and 60,000,000 shares and of Preferred Stock, of which 24,000,000 shares were designated as Series A-1 Preferred Stock. Additionally, 16,500,000 shares and 14,130,435 shares were designated as Series B Preferred Stock as of December 31, 2021 and 2020, respectively.

Common Stock—As of December 31, 2021 and 2020, the Company has a single class of common stock.

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

On July 2, 2021, the Company received net proceeds of $37,118,100 from a public offering, after deducting underwriting discounts and commissions of $2,424,900 and other offering expenses of $457,000 incurred. The Company issued and sold 8,000,000 shares of common stock in the public offering at a price of $5.00 per share.

Below is a table that outlines the initial value of issuances allocated to the IPO and public offering of common stock and the IPO and public offering common stock discount amortization, during the year ended December 31, 2021:

	2021	2020
Common Stock		
Balance at January 1,	$ 11,975,400	$ —
Common stock issuance from public offering, net of underwriting discounts and commissions and other offering expenses	37,118,100	—
Common stock public offering discount	(1,051,200)	—
Common stock issuance from Initial Public Offering, net of underwriting discounts and commissions and other offering expenses	—	12,332,700
Common stock Initial Public Offering discount	—	(377,000)
Common stock Initial Public Offering discount amortization	100,000	19,700
Common stock public offering discount amortization	122,000	—
Balance at December 31,	$ 48,264,300	$ 11,975,400

On June 8, 2020, the Company agreed to amend the warrant vesting schedule such that the warrants became immediately exercisable for each warrant holder. On June 8, 2020, warrant holders exercised their option to purchase 335,982 shares of common stock for proceeds of $1,200. Then, on June 10, 2020, warrant holders exercised their option to purchase an additional 1,063,939 shares of common stock for proceeds of $3,700.

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

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

The Company has never paid dividends and has no plans to pay dividends on common stock. As of December 31, 2017, the Company adopted the 2017 Plan. On September 25, 2019, the Board approved an additional 10,000,000 shares to be reserved and authorized under the 2017 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 approved an additional 850,000 shares to be reserved and authorized under the 2017 Plan. This approval increased the total number of authorized shares from 858,615 to 1,708,615.

As of June 25, 2021, the Company adopted the 2021 Plan. Under the 2021 Plan, the Board approved an additional 200,000 shares to be reserved and authorized under the 2021 Plan plus any unallocated shares from the 2017 Plan.

There were 433,895 shares and 270,933 shares available for issuance as of December 31, 2021 and 2020, respectively.

Series B Preferred Stock—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.

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

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

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

Accordingly, in connection with the IPO, all shares of the Company's Series B Preferred Stock were converted into 469,136 shares of common stock on October 15, 2020.

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

	2020
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	692,700
Series B Preferred Stock conversion to common stock	(2,331,300)
Balance at December 31,	$ —

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.

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

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

On June 8, 2020, the Company agreed to amend the warrant vesting schedule such that the warrants became immediately exercisable for each warrant holder. Prior to that amendment, the Company had sold 16,391,397 shares of Series B Preferred Stock, which contained 1,399,921 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 $5,533,000 was reflected as additional paid-in capital.

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. As of June 30, 2021, there were no warrants underlying Series B Preferred.

The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions for the year ended December 31, 2020:

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

Representative's Warrants— In connection with the IPO on October 15, 2020, the Company granted the underwriters warrants (the "Underwriters' Warrants") to purchase an aggregate of 62,500 shares of common stock at an exercise price of $15.00 per share, which is 125% of the IPO price. The Underwriters' Warrants have a five-year term and are not exercisable prior to April 13, 2021. All of the Underwriters' Warrants were outstanding at December 31, 2021.

These warrants were equity classified. As of December 31, 2021 and 2020, the warrant fair values of $257,300 and $357,300, respectively, is reflected as additional paid-in capital. On the issuance date, the Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions on October 15, 2020:

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

In connection with the public offering on July 2, 2021, the Company granted the underwriters warrants to purchase an aggregate of 400,000 shares of common stock at an exercise price of $6.25 per share, which is 125% of the IPO price. The Underwriters' Warrants have a five-year term and are not exercisable prior to January 2, 2022. All of the Underwriters' Warrants were outstanding at December 31, 2021.

These warrants were equity classified. As of December 31, 2021, the warrants contained a fair value of $929,300 and is reflected as additional paid-in capital. On the issuance date, the Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions on July 2, 2021:

Risk-free interest rate	0.40 %
Expected volatility	98.27 %
Expected life (years)	2.75
Expected dividend yield	0 %

11. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan— Stock Options

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

	December 31, 2021	December 31, 2020
Risk-free interest rate	1.09 %	0.15% - 2.92 %
Expected volatility	83.34 %	72.29% - 82.52 %
Expected life (years)	6.22	4.93 - 6.07
Expected dividend yield	0 %	0 %

In the year ended December 31, 2021, the fair value of the shares of common stock underlying the stock options was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

Prior to the Company's IPO, the fair value of the shares of common stock underlying the stock options had historically been determined by the Board, with input from management. Because there was no public market for the Company's shares of common stock prior to October 15, 2020, the Board determined the fair value of the shares of common stock 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 shares of common stock, among other factors.

The following table summarizes the activity for all stock options outstanding at December 31 under the 2017 Plan:

	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	489,718	$ 10.03	598,083	$ 11.04
Granted	147,038	8.47	86,536	17.95
Exercised	(18,891)	6.64	—	—
Cancelled and forfeited	(236,956)	11.68	(194,901)	15.06
Balance at December 31	380,909	$ 8.57	489,718	$ 10.03
Options exercisable at December 31:	372,533	$ 8.49	441,430	$ 9.50
Weighted average grant date fair value for options granted and expected to be vested during the year:		$ 8.47		$ 17.43

The intrinsic value of the options exercised during the year ended December 31, 2021 was $33,000. There were no options exercised during the year ended December 31, 2020.

The following table summarizes additional information about stock options outstanding and exercisable at December 31, 2021 and 2020, under the 2017 Plan:

	Options Outstanding				Options Exercisable		
As of December 31,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2021	380,909	5.45	8.57	—	372,533	8.49	—
2020	489,718	6.37	10.03	554,900	441,430	9.50	—

Total stock compensation expense recognized from stock-based compensation awards classified as stock options were recognized in the consolidated statements of operations for the years ended December 31, 2021 and 2020, as follows:

	Year Ended December 31,	
	2021	2020
Research and development	$ 176,600	$ 1,008,000
General and administrative	274,600	332,000
Total	$ 451,200	$ 1,340,000

On August 20, 2020, the Board canceled and terminated 15,792 stock options, granted during the quarter ended June 30, 2020, to four non-employees. Thereafter, on August 20, 2020, the Board granted 21,112 stock options to the same individuals with a grant date fair value of $12.81 per share. There were 3,959 stock option grants that were considered vested on the grant date. The effects of the stock option modifications resulted in $34,900 and $65,900 of stock compensation expense allocable to general and administrative for the years ended December 31, 2021, and 2020, respectively. Included in that amount were $16,000 and $34,800 of incremental compensation costs resulting from the modifications for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, total unrecognized stock compensation expense is $79,909, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 1.01 years.

2017 Stock Incentive Plan—Restricted Stock Units

In January 2017, the Board approved the adoption of the 2017 Plan. The 2017 Plan permitted 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 2017 Plan and are available for grant in conjunction with the issuance of new common stock awards. RSUs vest over a specified amount of time or when certain performance metrics are achieved by the Company.

In the year ended December 31, 2021, the fair value of the shares of common stock underlying RSUs was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

Prior to the Company's IPO, the fair value of the shares of common stock underlying the stock options had historically been determined by the Board, with input from management. As there was no public market for Company's shares of common stock prior to October 15, 2020, the Board determined the fair value of the shares of common stock 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 shares of common stock, among other factors.

The following table summarizes the activity for all RSUs outstanding under the 2017 Plan at:

	2021		2020	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	946,245	$ 12.81	—	$ —
Granted	166,660	7.98	1,655,579	12.84
Vested	(37,802)	6.51	—	—
Cancelled and forfeited	(208,145)	12.79	(709,334)	12.87
Nonvested RSUs at December 31,	866,958	$ 12.16	946,245	$ 12.81

Total stock compensation expense recognized from stock-based compensation awards classified as RSUs were recognized in the consolidated statements of operations for the years ended December 31, 2021 and 2020, as follows:

	Year Ended December 31,	
	2021	2020
Research and development	$ 2,070,600	$ 748,400
General and administrative	1,053,900	1,725,300
Total	$ 3,124,500	$ 2,473,700

On August 20, 2020, the Board canceled and terminated 709,334 RSUs, granted during the quarter ended June 30, 2020. The cancelled RSUs were originally granted to five individuals with a grant date fair value of $12.87 per share. Thereafter, on August 20, 2020, the Board granted 946,245 RSUs to the same individuals with a grant date fair value of $12.81 per share. None of the RSU grants were considered vested on the grant date. The RSU grants were modified for three employees and two non-employees.

The effects of the RSU modifications resulted in $598,900 and $1,286,800 of stock compensation expense allocable to research and development and general and administrative, respectively, during year ended December 31, 2021. Included in those amounts were incremental compensation costs of $52,500 and $115,200 of stock compensation expense allocable to research and development and general and administrative, respectively, year ended December 31, 2021.

The effects of the RSU modifications resulted in $748,400 and $1,725,300 of stock compensation expense allocable to research and development and general and administrative, respectively, during the year ended December 31, 2020. Included in those amounts were incremental compensation costs of $166,900 and $402,700 of stock compensation expense allocable to research and development and general and administrative, respectively, during the year ended December 31, 2020.

2021 Stock Incentive Plan—Restricted Stock Units

In June 2021, the Company's board of directors approved the adoption of the 2021 Plan. The 2021 Plan permits the Company to grant up to 217,292 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 2021 Plan and are available for grant in conjunction with the issuance of new common stock awards. RSUs vest over a specified amount of time or when certain performance metrics are achieved by the Company.

In year ended December 31, 2021, the fair value of the shares of common stock underlying RSUs was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

The following table summarizes the activity for all RSUs outstanding at December 31, 2021 under the 2021 Plan:

	2021	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	—	$ —
Granted	102,613	5.20
Vested	(37,900)	4.75
Cancelled and forfeited	(2,664)	4.22
Nonvested RSUs at December 31,	62,049	$ 5.52

Total stock compensation expense recognized from stock-based compensation awards classified as RSUs were recognized in the consolidated statements of operations for year ended December 31, 2021, as follows:

	Year Ended December 31, 2021
Research and development	34,300
General and administrative	152,900
Total	$ 187,200

12. INCOME TAXES

For the years ended December 31, 2021 and 2020, 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, 2021 and 2020.

	2021	2020
Federal income tax at statutory rates	21.00 %	21.00 %
Federal income tax rate reduction		
Change in valuation allowance	(21.00)	(21.00)
Effective income tax rate	— %	— %

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. The Company recorded a valuation allowance to fully offset the net deferred tax asset, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets as of December 31, 2021 and 2020 due to the significant uncertainty about the realization of the deferred tax asset until the Company can operate profitably.

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

	2021	2020
Deferred tax assets (liabilities):		
Net operating loss carryforward	8,135,900	3,842,900
Stock compensation expense	4,169,200	3,379,000
Research and development tax credit	874,400	—
Intangible assets	95,300	23,600
Total gross deferred tax assets	13,274,800	7,245,500
Valuation allowance	(13,274,100)	(7,061,600)
Property and equipment	(700)	(183,900)
Net deferred tax assets (liabilities)	—	—

As of December 31, 2021 and 2020, the Company has a U.S. net operating loss ("NOL") carryforward of $38,742,400 and $18,299,500, 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.

Under Section 382, a corporation that undergoes an "ownership change" is subject to an annual limitation on its ability to utilize its pre-change NOL, tax credits or other tax attributes to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own greater than

5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. The Company recently performed a Section 382 study to determine whether any of our existing NOLs, tax credits, or other tax attributes would be subject to such limitation. The Company determined, based on that study, that it underwent an "ownership change" during the years ended December 31, 2021 and 2020. The Company believes that the annual limitation will not result in the expiration of any NOLs prior to utilization. However, the annual limitation would result in the expiration of a portion of the research and development tax credit as of December 31, 2021.

As of December 31, 2021and 2020, 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, 2021, the Company is not currently under audit by any income tax authority.

13. RELATED PARTY TRANSACTIONS

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

Beginning in the year ended December 31, 2014, the Company entered into its first consulting agreement with the CSIO. Pursuant to the amended agreement dated July 20, 2018, the CSIO 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 CSIO will provide a leadership role for the Company's business development strategies. The consulting fees paid to the CSIO totaled $579,700 in the year ended December 31, 2020. In addition, the Company issued the CSIO 320,000 shares of common stock on June 19, 2020, in exchange for services rendered and no cash considerations.

Beginning in the year ended December 31, 2018, the Company entered into its first consulting agreement with the CFO and COO. Initially, his title was "Consultant", and the Company changed his title to CFO and COO on October 25, 2019. The CFO and COO was elected as a director of the Company on January 17, 2020. Pursuant to the agreement on April 18, 2018 and amended on September 4, 2019, the CFO and COO is entitled to a consulting fee of $2,500 per month amended to $10,000 per month plus discretionary bonuses approved by management. The consulting fees paid to the CFO and COO totaled $140,000 in the years ended December 31, 2020. 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.

After the Company completed the IPO on October 15, 2020, the CFO and COO and the CSIO became full time employees, at which time their consulting agreements were terminated.

There were no related party transactions during the year ended December 31, 2021.

14. SUBSEQUENT EVENTS

Legal Complaint Filed Against the Company

Sabby Volatility Warrant Master Fund Ltd., et al. v. Kiromic BioPharma, Inc. et al., Case No. 22-cv-1927 (SDNY). On March 7, 2022, entities related to Sabby Management LLC (the "Sabby Entities") and Empery Asset Management, LP (the "Empery Entities") filed a complaint in the District Court for the Southern District of New York alleging claims against the Company and certain current and former officers and directors of the Company for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021. The plaintiffs seek unspecified damages; rescission to the extent they still hold the Company's securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The Company expects to vigorously defend against this claim. The Company has evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000. Similarly, the Company has evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, the Company is unable to estimate any possible range of loss attributed to other unasserted claims at this time.

KIROMIC BIOPHARMA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 15,123,100	$ 25,353,900
Accounts receivable	—	16,200
Prepaid expenses and other current assets	1,607,900	1,699,400
Total current assets	16,731,000	27,069,500
Property and equipment, net	6,900,400	3,629,000
Operating lease right-of-use asset	2,227,300	—
Other assets	31,100	31,100
Total Assets	$ 25,889,800	$ 30,729,600
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 2,302,600	$ 2,214,300
Accrued expenses and other current liabilities	1,036,600	741,000
Note payable	285,700	454,500
Operating lease liability - short term	480,300	—
Total current liabilities	4,105,200	3,409,800
Deferred rent	5,500	—
Operating lease liability - long term	1,747,000	—
Total Liabilities	5,857,700	3,409,800
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.001 par value: 300,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 15,585,587 shares and 15,488,516 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	9,300	9,300
Additional paid-in capital	94,607,100	94,527,000
Accumulated deficit	(74,584,300)	(67,216,500)
Total Stockholders' Equity	20,032,100	27,319,800
Total Liabilities and Stockholders' Equity	$ 25,889,800	$ 30,729,600

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 2,925,800	$ 1,885,600
General and administrative	4,439,200	2,071,000
Total operating expenses	7,365,000	3,956,600
Loss from operations	(7,365,000)	(3,956,600)
Other income (expense)		
Gain on loan extinguishment	—	105,800
Interest expense	(2,800)	(3,700)
Total other income (expense)	(2,800)	102,100
Net loss	$ (7,367,800)	$ (3,854,500)
Net loss per share, basic and diluted	$ (0.48)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	15,542,444	7,332,999

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Three Months Ended March 31, 2022				
	Common Stock				
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance January 1, 2022	15,488,516	$ 9,300	$94,527,000	$(67,216,500)	$27,319,800
Common stock discount amortization	—	—	85,100	—	85,100
Warrants underlying common stock issuance	—	—	(85,100)	—	(85,100)
Released restricted stock units	97,071	—	—	—	—
Stock compensation expense	—	—	80,100	—	80,100
Net loss	—	—	—	(7,367,800)	(7,367,800)
Balance at March 31, 2022	15,585,587	$ 9,300	$94,607,100	$(74,584,300)	$20,032,100

	Three Months Ended March 31, 2021				
	Common Stock				
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at January 1, 2021	7,332,999	$ 1,200	$ 52,988,700	$(41,627,800)	$11,362,100
Common stock discount amortization	—	—	24,700	—	24,700
Warrants underlying common stock issuance	—	—	(24,700)	—	(24,700)
Stock compensation expense	—	—	945,200	—	945,200
Net loss	—	—	—	(3,854,500)	(3,854,500)
Balance at March 31, 2021	7,332,999	$ 1,200	$ 53,933,900	$(45,482,300)	$ 8,452,800

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (7,367,800)	$ (3,854,500)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	182,800	95,600
Stock compensation expense	80,100	945,200
Gain on loan extinguishment	—	(105,800)
Changes in operating assets and liabilities		
Accounts receivable	16,200	—
Prepaid expenses and other current assets	91,500	75,400
Operating lease right-of-use asset	(2,227,300)	—
Accounts payable	(882,800)	273,600
Accrued expenses and other current liabilities	295,600	(65,400)
Deferred rent	5,500	—
Operating lease liability	2,227,300	—
Net cash used for operating activities	(7,578,900)	(2,635,900)
Cash flows from investing activities:		
Purchases of property and equipment	(2,483,100)	(44,700)
Net cash used for investing activities	(2,483,100)	(44,700)
Cash flows from financing activities:		
Repayments of note payable	(168,800)	(134,600)
Net cash used for financing activities	(168,800)	(134,600)
Net change in cash and cash equivalents	(10,230,800)	(2,815,200)
Cash and cash equivalents:		
Beginning of year	25,353,900	10,150,500
End of period	$ 15,123,100	$ 7,335,300
Supplemental disclosures of non-cash investing and financing activities:		
Accounts payable and accruals for property and equipment	$ 971,100	$ 264,400
Cash paid for interest on note payable	$ 2,800	$ 3,700

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 subsidiaries (the "Company") is a clinical stage fully integrated biotherapeutics company formed under the Texas Business Organizations Code in December 2012.

The Company is an artificial intelligence-driven, end-to-end CAR-T and gene therapy company, developing the first multi-indication allogeneic CAR-T cell therapy, that exploits the natural potency of Gamma Delta T-cells to target solid cancers. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

The Company is developing its brand of CAR-T cell product candidates known as ALEXIS. The two product candidates are called ALEXIS-PRO-1 and ALEXIS-ISO-1. ALEXIS-PRO-1 is an allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1. ALEXIS-ISO-1 is an allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin). These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. We filed two investigational new drug ("IND") applications in May 2021 for ALEXIS-PRO-1 and ALEXIS-ISO-1. The Food and Drug Administration ("FDA") placed these applications under a clinical hold in June 2021. On July 13, 2021, the Company received the FDA's formal clinical hold letters, which asked the Company to address key components regarding the chemical, manufacturing, and control components of the IND applications. Those components included tracing of all reagents used in manufacturing, flow chart of manufacturing processes, and certificate of analysis. The Company is currently working on addressing the FDA's comments.

Going Concern— These condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flow from operations of $7,578,900 for the three months ended March 31, 2022, and an accumulated deficit of $74,584,300 as of March 31, 2022. 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. The Company does not have sufficient cash on hand or available liquidity to meet its obligations through the twelve months following the date the condensed consolidated financial statements are issued. This condition raises substantial doubt about the Company's ability to continue as a going concern.

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

The 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.

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 with 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.

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, warrants to purchase common stock underlying shares of Series B Preferred Stock and public offering common stock, and estimating services incurred by third-party service providers used to recognize research and development expense.

Cash and Cash Equivalents—As of March 31, 2022 and December 31, 2021, cash and cash equivalents consisted entirely of cash on hand and bank deposits. The Company considers all highly liquid instruments with remaining maturities at purchase of 90 days or less to be cash equivalents.

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

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

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.

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

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

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

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company did not capitalize any software development costs during the three months ended March 31, 2022 and 2021.

Goodwill— In connection with the InSilico Solutions, LLC ("InSilico") acquisition, the Company recognized goodwill for the excess of the purchase price over the fair value of tangible and identifiable intangible net assets of the business acquired. The Company will review goodwill for impairment annually on November 30, and whenever events or circumstances in interim periods indicate that it is more likely than not that an impairment may have occurred.

The Company assessed events and circumstances as of December 31, 2021 which was primarily driven by a reduced stock price as of December 31, 2021. The carrying value of the Company's assets was in excess of the market value of equity as of December 31, 2021. After analyzing this quantitative circumstance along with other qualitative considerations, the Company's management determined that an impairment of the entire value of the goodwill was appropriate. Accordingly, the Company incurred an impairment expense on the statement of operations totaling $430,000 during the year ended December 31, 2021. Since the Company records a full valuation allowance to offset any deferred tax assets, the Company does not believe this impairment would result in any material tax impact.

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 have 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 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*, 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 months ended March 31, 2022 and 2021.

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 clinical development activities including costs of outside consultants and contractors, the submission and maintenance of regulatory filings, equipment and supplies used in developing products prior to market approval and an allocation of certain overhead costs such as facility and related expenses.

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

Fair Value Measurements—The carrying value of the Company's cash and cash equivalents, accounts receivable, 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 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 three months ended March 31, 2022 and 2021.

Nonvested Stock Options and Restricted Stock Units—Pursuant to the Company's 2017 Stock Incentive Plan (the "2017 Plan") and the Omnibus 2021 Equity Incentive Plan (the "2021 Plan"), the Company has the ability to issue a variety of share-based payments and incentives to board members, employees, and non-employees. The Company has issued grants of nonvested stock options and restricted stock units under the 2017 Plan and 2021 Plan.

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

The vesting conditions for restricted stock units include cliff vesting conditions. Certain restricted stock units vest with a range of 6 to 12 months following the expiration of employee lock-up agreements. Certain restricted stock units vest based on the later of achievement of key milestones or the expiration of employee lock-up agreements. When nonvested restricted stock units are vested, they are released to the grantee within sixty days.

Stock-Based Compensation—The Company records stock compensation expense related to the 2017 Plan and the 2021 Plan in accordance with ASC 718, *Compensation—Stock Compensation*. The Company measures and recognizes stock compensation expense for all stock-based awards, including stock options, based on estimated fair values recognized using cliff vesting or the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model (the "Black-Scholes model"). The calculation of stock-based compensation expense requires that the Company make assumptions and judgments about the variables used in the Black-Scholes model, including the fair value of the Company's common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

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

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

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

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

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

Common Stock Valuations. During the three months ended March 31, 2022 and 2021, the closing price listed on the Nasdaq Capital Market for the Company's common stock on the date of the grant was used as the common stock valuation. 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.

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, 2022. Accordingly, the Company has adopted Topic 842 beginning in the first quarter of 2022. Modified retroactive transition approach will be required for operating leases existing at or entered into after the beginning of the earliest comparative period

presented. The Company notes that adopting the new standard resulted in recording a lease liability and right-of-use asset associated with the Company's facility lease agreement and subsequent amendments thereto totaling $2,067,000 and $2,063,400, respectively as of January 1, 2022.

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 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 SHARE OF COMMON STOCK

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

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (7,367,800)	$ (3,854,500)
Less: initial public offering Common Stock discount amortization	(24,700)	(24,700)
Less: public offering Common Stock discount amortization	(60,400)	—
Net loss attributable to common shareholders, basic and diluted	$ (7,452,900)	$ (3,879,200)
Weighted average common shares outstanding, basic and diluted	15,542,444	7,332,999
Net loss per common share, basic and diluted	$ (0.48)	$ (0.53)

For the three months ended March 31, 2022 and 2021, potentially dilutive securities excluded from the computations of diluted weighted-average shares of common stock outstanding were:

	March 31, 2022	March 31, 2021
Stock options	—	677
Restricted stock units	—	32,000
Total	—	32,677

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of March 31, 2022 and December 31, 2021:

	March 31, 2022	December 31, 2021
Equipment	$ 1,651,800	$ 1,593,100
Leasehold improvements	2,936,200	1,464,700
Office furniture, fixtures, and equipment	109,500	16,600
Software	359,500	359,500
Construction in progress	3,057,700	1,226,600
	8,114,700	4,660,500
Less: Accumulated depreciation	(1,214,300)	(1,031,500)
Total	$ 6,900,400	$ 3,629,000

Depreciation expense was $182,800 and $95,600 for the three months ended March 31, 2022 and 2021, 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 as of March 31, 2022 and December 31, 2021:

	March 31, 2022	December 31, 2021
Accrued consulting and outside services	$ 742,900	$ 467,100
Accrued compensation	293,700	273,900
Total	$ 1,036,600	$ 741,000

6. LOAN PAYABLE

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

As the legal form of the Note is a debt obligation, the Company accounts for it as debt under ASC 470, *Debt*, and recorded $105,600 as of December 31, 2020, in the condensed consolidated balance sheet. During the year ended December 31, 2020, the Company received initial proceeds of $115,600 and made a repayment of $10,000 on the SBA Loan, bringing the balance to $105,600 as of December 31, 2020. The Company accrued interest over the term of the loan and did not impute additional interest at a market rate because the guidance on imputing interest in ASC 835-30, *Interest*, excludes transactions where interest rates are prescribed by a government agency.

During the year ended December 31, 2020, the Company applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. On February 16, 2021, the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,800. The forgiveness was classified as a gain on loan extinguishment in the condensed consolidated statement of operations.

7. NOTE PAYABLE

In November 2020, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of December 31, 2021, this financing arrangement was paid in its entirety.

In November 2021, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $665,900 with an annual interest rate of 4.59%, to be paid over a period of ten months. As of March 31, 2022 and December 31, 2021, the remaining payable balance on the financed amount was $285,700 and $454,500, respectively.

8. COMMITMENTS AND CONTINGENCIES

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 March 31, 2022 and December 31, 2021, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Strategic Alliance Agreement with Leon Office (H.K.) — On January 28, 2021, the Company executed a strategic alliance agreement with Leon Office (H.K.) ("Leon") a company established under existing laws of Hong Kong. It is intended that Leon acts as an independent business development advisor on behalf of the Company. Leon will seek to introduce organizations and individuals that will create business development opportunities for the Company, to expand the Company's reach to international markets with a focus on certain Asian markets and to increase brand recognition and exposure through developing liaisons, collaborations, branches and subsidiaries. They will also use commercially reasonable efforts to research the Asian market, with a primary, but not exclusive, focus on determining the most suitable structures for the development of medical partnerships or joint ventures with scientific partners in the Asian market with a mission to test products to be created by the joint venture resulting from such partnership and to develop validation programs for any products produced by such joint venture, including programs for clinical trials and human testing and, ultimately, for product certification. The cost of the agreement is $360,000 annually, payable in four quarterly installments. The Company did not renew this agreement as of March 31, 2022 and there are no further estimated payments associated with the agreement.

Legal Proceedings— On March 22, 2021, Jason Terrell ("Terrell"), a former consultant former director of the Company, commenced an action against us in the Court of Chancery of the State of Delaware, C.A. No. 2021-0248-MTZ (the "Action"). In the Action, Terrell seeks a declaratory judgment that the Company is obligated to issue him (i) options to purchase 500,000 shares of common stock at a price of $0.50 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 500,005 shares of common stock at a price of $0.17 per share pursuant to an alleged January 2017 non-employee director options agreement. In his complaint, Terrell also claimed that, pursuant to the operative certificate of incorporation, he is entitled to indemnification from us for attorneys' fees and costs he incurs in connection with the Action because the Action arises in connection with his position as a former director.

The Company disputes Terrell's claims and allegations in the Action and intends to vigorously defend against them. On May 21, 2021, the Company filed a motion to dismiss Terrell's claims in the actions with prejudice, arguing that (i) Terrell's options-related claims fail because his 2014 and January 2017 agreements were explicitly superseded by a later options agreement, under which Terrell relinquished his prior options; and (ii) Terrell is not entitled to indemnification because the Action relates to contracts between the Company and Terrell in his personal capacity, and not in connection with any activities or duties of Terrell in his official capacity as former director. In response to the motion, filed on June 21, 2021, Terrell withdrew his claim for indemnification, but opposed the portion seeking dismissal of his declaratory judgment claim. The motion was fully briefed with the filing of the Company's reply brief on July 7, 2021.

Oral argument was held before the Vice Chancellor on October 20, 2021. During oral argument, the Vice Chancellor invited the parties to submit supplemental letter briefs on the question of whether the Court of Chancery even had the authority to adjudicate the Action in light of the delegation of authority in Terrell's most recent stock option agreement with the Company (the "SOA") to the Company's Compensation Committee to resolve all disputes regarding the interpretation of the SOA. The parties submitted simultaneous supplemental letters briefs on this issue on November 15, 2021. On January 20, 2022, the Vice Chancellor issued her decision on our motion to dismiss, ruling that the Action is stayed until the Compensation Committee itself resolves whether it has sole authority to resolve the parties' contract interpretation dispute.

Subsequently, the parties agreed upon a process for coordinating submissions and/or presentations to the Compensation Committee. The parties made their respective written submissions to the Compensation Committee on March 31, 2022 and are awaiting the Compensation Committee's determination(s).

In the interim, as noted, the Action is stayed and no further proceedings are taking place.

In a separate matter, on or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board, submitted substantially identical reports (the "Complaints") through the Company's complaint hotline. These Complaints, alleged, among other topics, risks associated with the Company's public disclosures in securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the FDA authorization of the IND applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained an independent counsel to assist it in conducting the Internal Review.

On February 2, 2022, following the conclusion of the Internal Review, the Company's Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that the Company had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing the IND applications that the Company submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17 FDA Communications"). On July 13, 2021, the Company received the FDA's formal clinical hold letters, which asked the Company to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, the Company issued a press release disclosing that it had received comments from the FDA on the two INDs, but did not use the term "clinical hold." The Company then consummated a public offering of $40 million of its common stock pursuant to the Registration Statement on July 2, 2021. On August 13, 2021, the Company issued a press release announcing that these INDs were placed on clinical hold. The Company did not disclose the June 16 and 17, 2021 FDA Communications in (i) the Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) the Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021.

As a result of the disclosure omission of the June 16 and 17 FDA Communications, on March 7, 2022, entities related to Sabby Management LLC (the "Sabby Entities") and Empery Asset Management, LP (the "Empery Entities") filed a complaint in the District Court for the Southern District of New York alleging claims against the Company and certain current and former officers and directors of the Company for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021. The plaintiffs seek unspecified damages; rescission to the extent they still hold the Company's securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The parties have agreed that the Defendants' shall respond to the complaint on June 30, 2022. The Company has evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000.

Similarly, the Company has evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, the Company is unable to estimate any possible range of loss attributed to other unasserted claims at this time.

The Company regularly assesses all contingencies and believes, based on information presently known, the Company is not involved in any other matters that would have a material effect on the Company's financial position, results of operations and cash flows.

9. ACQUISITIONS

InSilico

On July 26, 2021, the Company completed its previously announced acquisition of InSilico pursuant to the Membership Interest Purchase Agreement (the "Purchase Agreement") with InSilico and Michael Ryan (the "Seller").

Pursuant to the terms of the Purchase Agreement, the Company acquired 100% of the membership interest of InSilico by delivering 50,189 shares to the Seller, and granting 33,177 restricted stock units to the employees of InSilico under the Company's 2021 Plan (the "Acquisition"). At the closing of the Acquisition, InSilico became a wholly-owned subsidiary of the Company. InSilico, based in Fairfax, VA, is a world class bioinformatics and artificial intelligence services company.

The Company determined fair values for the assets purchased, liabilities assumed, and purchase consideration as of the date of acquisition in the following table. The determination of the estimated fair value required management to make significant estimates and assumptions. See below for the fair value of purchase consideration and fair value of net assets acquired.

	Estimated Fair Value at Acquisition Date
Fair value of purchase consideration	
Fair value of common stock issued to Seller	$ 400,000
Fair value of restricted stock units granted	140,000
Fair value of purchase consideration	$ 540,000
Fair value of net assets acquired	
Cash	$ 84,000
Accounts receivable	26,000
Fixed asset	1,000
Goodwill[(a)]	430,000
Other current liabilities	(1,000)
Fair value of net assets acquired	540,000

(a) Goodwill represents the excess of the purchase price over the fair value of tangible and identifiable intangible net assets of the business acquired. This amount also includes intangible assets that do not qualify for separate recognition, combined with synergies expected from integrating InSilico processes with the Company's.

The Company assessed events and circumstances as of December 31, 2021 which was primarily driven by a reduced stock price as of December 31, 2021. The carrying value of the Company's assets was in excess of the market value of equity as of December 31, 2021. After analyzing this quantitative circumstance along with other qualitative considerations, the Company's management determined that an impairment of the entire value of the goodwill was appropriate. Accordingly, the Company recorded impairment expense of $430,000 during the year ended December 31, 2021.

10. LEASES

The Company adopted FASB ASU No. 2016-02, Leases (Topic 842) on January 1, 2022, using the modified retrospective method, in which it did not restate prior periods. Upon adoption, the Company elected the package of practical expedients permitted under the transition guidance within Topic 842 which, among other things, allowed the Company to carry forward the historical lease classification.

In our implementation of ASU No. 2016-02 the Company elected to discount lease obligations using our incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of lease payments. The

Company's incremental borrowing rate represents the rate of interest that it would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment. The Company considers publicly available data for instruments with similar terms and characteristics when determining its incremental borrowing rates. In addition, we elected the practical expedient to account for the lease and non-lease components on a combined basis. The Company intends to use the full lease term under the existing lease agreement as the lease term, which is currently set to expire on April 30, 2026. As of March 31, 2022, the Company is not able to determine if any renewal options will be exercised.

The Company leases its premises in Houston, Texas under an operating lease which was renewed on November 19, 2020. This renewed lease agreement will commence under an operating lease agreement that is noncancelable from commencement until May 1, 2024.

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

Two further amendments were executed in 2021. The agreements commenced on November 1, 2021, and December 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 3,684 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation.

An amendment to the lease agreement was executed in January 2022 and commenced May 1, 2022. The amendment will add approximately 9,352 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation. In year one and two monthly rent is $4,800 per month, in year three and four monthly rent is $4,896 per month, and in year five monthly rent is $5,000 per month.

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

The following table indicates the balance sheet line items that include the right-of-use assets and lease liabilities for our operating lease:

	March 31, 2022
	Operating lease
Right-of-Use Asset	
Operating lease	$ 2,227,300
Total right-of use asset	2,227,300
Lease Liabilities	
Operating lease - short term	$ (480,300)
Operating lease - long term	(1,747,000)
Deferred rent	(5,500)
Total lease liabilities	(2,232,800)

For the three months ended March 31, 2022, the components of lease expense were as follows:

	2022
Operating lease cost allocated to research and development expense	$ 82,300
Operating lease cost allocated to general and administrative expense	68,100
Total lease expense	$ 150,400
Weighted-average remaining lease term	4.08
Weighted-average discount rate	7.12 %

As of March 31, 2022 the maturities of the Company's operating lease liabilities were as follows:

Maturity of Lease Liabilities	Operating lease
2022	$ 465,300
2023	626,100
2024	628,900
2025	634,600
2026	212,500
Total lease payments	2,567,400
Less: imputed interest	(334,600)
Present value of lease payments	2,232,800

The Company maintains a month to month lease in Arlington, VA, which is considered a short term lease. The Company elected to exclude this lease from the determination of the right-of-use asset and lease liability, as permitted under ASC 842. The Company will recognize the lease payments in profit or loss in the statement of operations on a straight-line basis over the term of the lease.

Under ASC 840, rent expense recognized under the leases was $69,000 for the three months ended March 31, 2021.

Future minimum lease payments under noncancellable operating leases were:

	As of December 31, 2021
2022	$ 616,157
2023	624,825
2024	523,939
Total lease payments	1,764,921

11. STOCKHOLDERS' EQUITY

As of March 31, 2022 and December 31, 2021, the Company was authorized to issue 300,000,000 shares of common stock and 60,000,000 shares of Preferred Stock, of which 24,000,000 shares were designated as Series A-1 Preferred Stock and 16,500,000 shares were designated as Series B Preferred Stock.

Common Stock—As of March 31, 2022 and December 31, 2021, the Company has a single class of common stock.

On October 15, 2020, the Company received net proceeds of $12,332,700 from its initial public offering ("IPO"), after deducting underwriting discounts and commissions of $1,275,000 and other offering expenses of $1,392,300 incurred. The Company issued and sold 1,250,000 shares of common stock in the IPO at a price of $12.00 per share.

On July 2, 2021, the Company received net proceeds of $37,118,100 from its public offering, after deducting underwriting discounts and commissions of $2,494,900 and other offering expenses of $457,000 incurred. The Company issued and sold 8,000,000 shares of common stock in the public offering at a price of $5.00 per share.

Below is a table that outlines the initial value of issuances allocated to the IPO and public offering of common stock and the IPO and public offering common stock discount amortization, during the three months ended March 31:

	2022	2021
Common Stock		
Balance at January 1,	$ 48,264,300	$ 11,975,400
Common stock initial public offering discount amortization	24,700	24,700
Common stock public offering discount amortization	60,400	—
Balance at March 31,	$ 48,349,400	$ 12,000,100

The Company has never paid dividends and has no plans to pay dividends on common stock. As of December 31, 2017, the Company adopted the 2017 Plan.

As of June 25, 2021, the Company adopted the 2021 Plan. Under the 2021 Plan, the Board approved an additional 200,000 shares to be reserved and authorized under the 2021 Plan plus any unallocated shares from the 2017 Plan.

There were 880,785 shares and 433,895 shares available for issuance as of March 31, 2022, and December 31, 2021, respectively.

Representative's Warrants—In connection with the IPO on October 15, 2020, the Company granted the underwriters warrants (the "Underwriters' Warrants") to purchase an aggregate of 62,500 shares of common stock at an exercise price of $15.00 per share, which is 125% of the initial public offering price. The Underwriters' Warrants have a five-year term and are not exercisable prior to April 13, 2021. All of the Underwriters' Warrants were outstanding at March 31, 2022.

These warrants were equity classified. As of March 31, 2022 and December 31, 2021, the warrant fair values of $232,600 and $257,300, respectively, is reflected as additional paid-in capital. On the issuance date, the Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions on October 15, 2020:

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

In connection with the public offering on July 2, 2021, the Company granted the underwriters warrants (the "Additional Underwriters' Warrants") to purchase an aggregate of 400,000 shares of common stock at an exercise price of $6.25 per share, which is 125% of the initial public offering price. The Additional Underwriters' Warrants have a five-year term and are not exercisable prior to January 2, 2022. All of the Additional Underwriters' Warrants were outstanding at March 31, 2022.

These warrants were equity classified. As of March 31, 2022 and December 31, 2021, the fair value of the warrants was $868,900 and $929,300, respectively, and is reflected as additional paid-in capital.. On the issuance date, the Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions on July 2, 2021:

Risk-free interest rate	0.40 %
Expected volatility	98.27 %
Expected life (years)	2.75
Expected dividend yield	0 %

12. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan— Stock Options

The Black-Scholes option-pricing model has been used previously to estimate the fair value of stock options. However, there were no options granted during the three months ended March 31, 2022 and 2021.

The following table summarizes the activity for all stock options outstanding at March 31 under the 2017 Plan:

	2022		2021	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	380,909	$ 10.03	489,718	$ 10.03
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled and forfeited	(42,037)	9.19	(57,149)	17.88
Balance at March 31	338,872	$ 8.49	432,569	$ 8.99
Options exercisable at March 31:	332,674	$ 8.44	408,306	$ 8.75
Weighted average grant date fair value for options granted and expected to be vested during the period:		$ —		$ —

The following table summarizes additional information about stock options outstanding and exercisable at March 31, 2022 and 2021 under the 2017 Plan:

	Options Outstanding				Options Exercisable		
As of March 31,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2022	338,872	5.76	8.49	—	332,674	8.44	—
2021	432,569	6.72	8.99	839,700	408,306	8.75	269,514

Total stock compensation expense recognized from stock-based compensation awards classified as stock options were recognized in the condensed consolidated statements of operations for the three ended March 31, 2022 and 2021 as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 49,000	$ 19,000
General and administrative	8,000	102,000
Total	$ 57,000	$ 121,000

On August 20, 2020, the board of directors canceled and terminated 15,792 stock options, granted during the quarter ended June 30, 2020 to four non-employees. Thereafter, on August 20, 2020, the board of directors granted 21,112 stock options to the same individuals with a grant date fair value of $12.81 per share. There were 3,959 stock option grants that were considered vested on the grant date. The effects of the stock option modifications resulted in $20,900 of stock compensation expense allocable to general and administrative for the three months ended March 31, 2021. Included in that amount were $9,600 of incremental compensation costs resulting from the modifications for the three months ended March 31, 2021.

As of March 31, 2022, total unrecognized stock compensation expense is $61,815 related to unvested stock options to be recognized over the remaining weighted-average vesting period of 0.79 years.

2017 Stock Incentive Plan—Restricted Stock Units

The 2017 Plan permits the Company to grant equity awards for 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 2017 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.

In the three months ended March 31, 2022 and 2021, the fair value of the shares of common stock underlying restricted stock units was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

The following table summarizes the activity for all RSUs outstanding at March 31 under the 2017 Plan:

	2022		2021	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year, as restated	510,851	$ 12.48	946,245	$ 12.81
Granted	—	—	6,019	9.00
Vested	(2,947)	8.71	—	—
Cancelled and forfeited	(334,271)	12.81	—	—
Nonvested RSUs at March 31,	173,633	$ 11.91	952,264	$ 12.79

Subsequent to the issuance of the December 31, 2021 consolidated financial statements, the Company identified an error related to the calculation of the number of vested shares of restricted stock units related to the Company's 2017 Equity Incentive Plan. The Company used an incorrect number of vested shares of restricted stock units for the year ended December 31, 2021. Accordingly, the Company restated the number of vested shares of restricted stock units for the year ended December 31, 2021 from 37,802 shares to 393,909 shares, and the resulting total non-vested restricted stock units at December 31, 2021 from 866,958 shares to 510,851 shares. Additionally, the weighted average grant date fair value of vested shares for the year ended December 31, 2021 was restated from $6.51 per share to $11.21 per share, and the weighted average grant date fair value for total nonvested restricted stock units as of December 31, 2021 was restated from $12.16 per share to $12.48 per share. This change did not have any impact on our earnings per share calculations, nor did it have any impact on any previous disclosures related to potentially dilutive securities excluded from the computations of diluted weighted-average shares of common stock outstanding. The Company has evaluated the materiality of this error and concluded that it is not material to the December 31, 2021 consolidated financial statements. Further, the Company will also prospectively restate the previously reported financial information for the related error in future and annual filings for the year ending December 31, 2022.

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021, as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 12,000	$ 267,700
General and administrative	(7,100)	556,600
Total	$ 4,900	$ 824,300

On August 20, 2020, the board of directors canceled and terminated 709,334 RSUs, granted during the quarter ended June 30, 2020. The cancelled RSUs were originally granted to five individuals with a grant date fair value of $12.87 per share. Thereafter, on August 20, 2020, the board of directors granted 946,245 RSUs to the same individuals with a grant date fair value of $12.81 per share. None of the RSU grants were considered vested on the grant date. The RSU grants were modified for three employees and two non-employees. The effects of the RSU modifications did not result in any stock compensation expense during the three months ended March 31, 2022. The effects of the RSU modifications resulted in $267,700 and $556,600 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended March 31,

2021. Included in those amounts were incremental compensation costs of $20,400 and $44,700 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended March 31, 2021.

2021 Stock Incentive Plan—Restricted Stock Units

The 2021 Plan permits the Company to grant equity awards for up to 217,292 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 2021 Plan and are available for grant in conjunction with the issuance of new common stock awards. RSUs vest over a specified amount of time or when certain performance metrics are achieved by the Company.

In the three months ended March 31, 2022, the fair value of the shares of common stock underlying restricted stock units was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

The following table summarizes the activity for all RSUs outstanding at March 31, 2022 under the 2021 Plan:

	2022	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	62,049	$ 5.52
Granted	—	—
Vested	—	—
Cancelled and forfeited	(2,090)	4.22
Nonvested RSUs at March 31,	59,959	$ 5.57

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three months ended March 31, 2022, as follows:

	Three Months Ended March 31, 2022
Research and development	$ 8,300
General and administrative	9,900
Total	$ 18,200

13. INCOME TAXES

The Company's effective tax rate from continuing operations was 0% for the three months ended March 31, 2022 and 2021. The Company recorded no income tax provision for the three months ended March 31, 2022 and 2021.

The provision for income taxes during the interim reporting periods is calculated by applying an estimate of the annual effective tax rate 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.

Table of Contents

Up to Shares of Common Stock

Warrants to Purchase Shares of Common Stock
Pre-Funded Warrants to Purchase up to Shares of Common Stock

Kiromic BioPharma, Inc.

PRELIMINARY PROSPECTUS

ThinkEquity

, 2022

Through and including , 2022 (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.

PART II—INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of common shares being registered. All amounts, other than the SEC registration fee and FINRA filing fee, are estimates.

	Amount
SEC registration fee	$ 2,655
FINRA fee	8,500
Accounting fees and expenses	300,000
Legal fees and expenses	125,000
Transfer agent fees and expenses	1,000
Printing and related fees	37,000
Miscellaneous fees	4,845
Total	$ 479,000

Item 14. Indemnification of Directors and Officers.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement in connection with specified actions, suits and proceedings whether civil, criminal, administrative, or investigative, other than a derivative action by or in the right of the corporation, if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification extends only to expenses, including attorneys' fees, incurred in connection with the defense or settlement of such action and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation, bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our Fourth Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws provide for indemnification of directors and officers to the fullest extent permitted by law, including payment of expenses in advance of resolution of any such matter.

We have entered into separate indemnification agreements with our directors and officers. Each indemnification agreement will provide, among other things, for indemnification to the fullest extent permitted by law and our certificate of incorporation and bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements will provide for the advancement or payment of all expenses to the indemnitee and for reimbursement to us if it is found that such indemnitee is not entitled to such indemnification under applicable law and our certificate of incorporation and bylaws.

We maintain standard policies of insurance under which coverage is provided (a) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act, and (b) to us with respect to payments which we may make to such officers and directors pursuant to the above indemnification provision or otherwise as a matter of law.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities.

During the past three years, we issued the following securities, which were not registered under the Securities Act.

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, 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 the convertible promissory note, 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.

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, the Company issued an additional 1,739,130 shares of Series B Preferred Stock for $800,000.

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

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

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

Item 16. Exhibits.

(a) Exhibits.

Exhibit No.	Description
1.1**	Form of Underwriting Agreement
3.1	Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K that was filed on October 21, 2021)
3.2	Second Amended and Restated Bylaws of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.5 of the Company's Amendment No. 1 to Form S-1 that was filed on June 26, 2020)
4.1**	Form of Common Stock Warrants
4.2**	Form of Pre-Funded Warrant
4.3**	Form of Representative's Warrant
5.1**	Opinion of Hogan Lovells US LLP
10.1#	License Agreement, dated December 1, 2016, between Mercer University and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.2#	License Agreement, dated September 14, 2018, between CGA 369 Intellectual Holdings, Inc. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.3#	Amendment to License Agreement, dated October 16, 2019, between CGA 369 Intellectual Holdings, Inc. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.4#	Amended and Restated License Agreement dated as of November 30, 2020 by and between Longwood University and Kiromic Biopharma, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K that was filed on January 29, 2021)
10.5#	Collaboration Agreement, dated February 6, 2020, between University of Texas MD Anderson Cancer Center and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.14 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.6	Strategic Alliance Agreement by and between Kiromic BioPharma, Inc. and Leon Office (H.K.) Ltd, effective as of January 28, 2021 (incorporate by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K that was filed on February 12, 2021)
10.7#	Joint venture agreement, dated April 6, 2020, between Molipharma S.R.L. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.28 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.8	Lease Agreement, dated October 9, 2015, between Timothy L. Sharma d/b/a Cambridge Properties and Kiromic, Inc. (incorporated by reference to Exhibit 10.15 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.9	Second Amendment to Lease Agreement, dated May 6, 2016, between Cambridge Properties and Kiromic, Inc. (incorporated by reference to Exhibit 10.16 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.10	Third Amendment to Lease Agreement, dated November 7, 2018, between Cambridge Properties and Kiromic, Inc. (incorporated by reference to Exhibit 10.17 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.11	Fourth Amendment to Lease Agreement, dated October 8, 2019, between Cambridge Properties and Kiromic, Inc. (incorporated by reference to Exhibit 10.18 of the Company's Registration Statement on Form S-1 that was filed on May 11, 2020)
10.12	Fifth Amendment to Lease Agreement, dated December 2, 2020, between Cambridge Properties and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 that was filed on June 25, 2021)
10.13	Sixth Amendment to Lease Agreement, dated March 22, 2021, between Cambridge Properties and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 that was filed on June 25, 2021)

Exhibit No.	Description
10.14†	Executive Employment Agreement by and between the Company and Pietro Bersani, effective as of January 27, 2022 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K that was filed on February 2, 2022)
10.15†	Executive Employment Agreement effective as of February 14, 2022, by and between Kiromic BioPharma, Inc. and Daniel Clark (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K that was filed on February 16, 2022)
10.16†	Employment Agreement dated January 1, 2020 between Kiromic BioPharma, Inc and Scott Dahlbeck (incorporated by reference to Exhibit 10.19 of the Company's Amendment No. 1 to Form S-1 that was filed on June 26, 2020)
10.17†	Modification to Employment Agreement effective as of February 9, 2022, by and between Kiromic BioPharma, Inc. and Scott Dahlbeck (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K that was filed on February 16, 2022)
10.18†	Executive Employment Agreement by and between the Company and Dr. Michael Ryan, effective as of July 1, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K that was filed on July 8, 2021)
10.19†	Form of Director Services Agreement between Kiromic BioPharma, Inc. and all independent directors (incorporated by reference to Exhibit 10.24 of the Company's Amendment No. 1 to Form S-1 that was filed on June 26, 2020)
10.20†	Form of Director Indemnification Agreement between Kiromic BioPharma, Inc. and all independent directors (incorporated by reference to Exhibit 10.25 of the Company's Amendment No. 1 to Form S-1 that was filed on June 26, 2020)
10.21*†	Form of Confidential Information, Inventions, Non-Solicitation and Non-Competition Agreement
10.22†	Kiromic BioPharma, Inc 2021 Omnibus Equity Incentive Plan (incorporate by reference to Appendix A to Schedule 14A filed on April 30, 2021)
10.23	First Amendment to Executive Employment Agreement effective as of May 10, 2022, by and between Kiromic BioPharma, Inc. and Pietro Bersani (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K that was filed on May 11, 2022)
10.24	First Amendment to Executive Employment Agreement effective as of May 10, 2022, by and between Kiromic BioPharma, Inc. and Daniel Clark (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K that was filed on May 11, 2022)
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of the Company's Annual Report on Form 10-K that was filed on April 8, 2022)
23.1**	Consent of Hogan Lovells US LLP (included in Exhibit 5.1)
23.2*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included in the signature page)
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
107*	Fee Table

* Filed herewith.

** To be filed by amendment.

† Executive Compensation Plan or Agreement.

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

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information called for is not required or is shown either in the consolidated financial statements or in the notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes as follows:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining any liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or our securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the undersigned pursuant to the foregoing provisions, or otherwise, the undersigned has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the undersigned of expenses incurred or paid by a director, officer or controlling person of the undersigned in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the undersigned will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Houston, State of Texas, on June 27, 2022.

KIROMIC BIOPHARMA, INC.

By: /s/ Pietro Bersani
Name: Pietro Bersani
Title: Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Pietro Bersani and Daniel Clark as his or her true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement and to file a new registration statement under Rule 461, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Pietro Bersani Pietro Bersani	Chief Executive Officer (principal executive officer) and Director	June 27, 2022
/s/ Daniel Clark Daniel Clark	Chief Financial Officer (principal financial and accounting officer)	June 27, 2022
/s/ Americo Cicchetti Americo Cicchetti	Director	June 27, 2022
/s/ Michael Nagel Michael Nagel	Director	June 27, 2022
/s/ Karen Reeves Karen Reeves	Director	June 27, 2022
/s/ Frank Tirelli Frank Tirelli	Director	June 27, 2022

CONFIDENTIAL INFORMATION, INVENTIONS, NON-SOLICITATION AND NON-COMPETITION AGREEMENT

In consideration of my employment by **Kiromic Biopharma Inc.**, and its subsidiaries, parents, affiliates, successors and assigns (together, "***Kiromic"*** or the "***Company***") and the compensation now and later paid to me, I hereby enter into this Employee Confidential Information, Inventions, Non Solicitation and Non-Competition Agreement (the "***Agreement***") and agree as follows:

1. CONFIDENTIAL INFORMATION PROTECTIONS.

1.1 Recognition of Company's Rights; Nondisclosure. I understand and acknowledge that my employment by Company creates a relationship of confidence and trust with respect to Company's Confidential Information (as defined below) and that Company has a protectable interest therein. At all times during and after my employment, I will hold in confidence and will not disclose, use, lecture upon or publish any of Company's Confidential Information, except as such disclosure, use or publication may be required in connection with my work for Company, or unless an officer of Company expressly authorizes such disclosure in writing. I will obtain Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that discloses and/or incorporates any Confidential Information. I hereby assign to Kiromic any rights I may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole and exclusive property of Kiromic and its assigns. I will take all reasonable precautions to prevent the inadvertent or accidental disclosure of Confidential Information. Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

1.2 Confidential Information. The term "Confidential Information" shall mean any and all confidential knowledge, data or information of Company. By way of illustration but not limitation, "***Confidential Information***" includes (a) trade secrets, inventions, mask works, ideas, processes, formulas, software in source or object code versions, data, programs, other works of authorship, know how, improvements, discoveries, developments, designs and techniques and any other proprietary technology and all Intellectual Property Rights therein (collectively, "***Inventions***"); (b) information regarding research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, margins, discounts, credit terms, pricing and billing policies, quoting procedures, methods of obtaining business, forecasts, future plans and potential strategies, financial projections and business strategies, operational plans, financing and capital raising plans, activities and agreements, internal services and operational manuals, methods of conducting Company business, suppliers and supplier information, and purchasing; (c) information regarding customers and potential customers of Company, including customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by Company,

proposals, bids, contracts and their contents and parties, the type and quantity of products and services provided or sought to be provided to customers and potential customers of Company and other non public information relating to customers and potential customers; (d) information regarding any of Company's business partners and their services, including names; representatives, proposals, bids, contracts and their contents and parties, the type and quantity of products and services received by Company, and other non public information relating to business partners; (e) information regarding personnel, employee lists, compensation, and employee skills; and (f) any other non public information which a competitor of Company could use to the competitive disadvantage of Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which was known to me prior to employment with Company or which is generally known in the trade or industry through no breach of this Agreement or other act or omission by me. Notwithstanding the foregoing or anything to the contrary in this Agreement or any other agreement between Company and me, nothing in this Agreement shall limit my right to discuss my employment or report possible violations of law or regulation with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, or other federal government agency or similar state or local agency or to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act or to the extent that such disclosure is protected under the applicable provisions of law or regulation, including but not limited to "whistleblower" statutes or other similar provisions that protect such disclosure.

1.3 Third Party Information. I understand, in addition, that Company has received and in the future will receive from third parties their confidential and/or proprietary knowledge, data or information ("***Third Party Information***") subject to a duty on Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During my employment and thereafter, I will hold Third Party Information in confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for Company) or use, except in connection with my work for Company, Third Party Information unless expressly authorized by an officer of Company in writing.

1.4 Term of Nondisclosure Restrictions. I understand that Confidential Information and Third Party Information is never to be used or disclosed by me, as provided in this Section 1. If a temporal limitation on my obligation not to use or disclose such information is required under applicable law, and the Agreement or its restriction(s) cannot otherwise be enforced, I agree and Company agrees that the two (2) year period after the date my employment ends will be the temporal limitation relevant to the contested restriction, provided, however, that this sentence will not apply to trade secrets protected without temporal limitation under applicable law.

1.5 No Improper Use of Information of Prior Employers and Others. During my employment by Company, I will not improperly use or disclose confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person.

2. ASSIGNMENTS OF INVENTIONS

2.1 Definitions. As used in this Agreement, the term "***Intellectual Property Rights***" means all trade secrets, Copyrights, trademarks, mask work rights, patents and other intellectual property rights recognized by the laws of any jurisdiction or country; the term "***Copyright***" means the exclusive legal right to reproduce, perform, display, distribute and make derivative works of a work of authorship (as a literary, musical, or artistic work) recognized by the laws of any jurisdiction or country; and the term "***Moral Rights***" means all paternity, integrity, disclosure, withdrawal, special and any other similar rights recognized by the laws of any jurisdiction or country.

2.2 Excluded Inventions and Other Inventions. Attached hereto as **Exhibit A** is a list describing all existing Inventions, if any, that may relate to Company's business or actual or demonstrably anticipated research or development and that were made by me or acquired by me prior to the commencement of my employment with, and which are not to be assigned to, Company ("***Excluded Inventions***"). If no such list is attached, I represent and agree that it is because I have no rights in any existing Inventions that may relate to Company's business or actual or demonstrably anticipated research or development. For purposes of this Agreement, "***Other Inventions***" means Inventions in which I have or may have an interest, as of the commencement of my employment, other than Company Inventions (defined below) and Excluded Inventions. I acknowledge and agree that if I use any Excluded Inventions or any Other Inventions in the scope of my employment, or if I include any Excluded Inventions or Other Inventions in any product or service of Company, or if my rights in any Excluded Inventions or Other Inventions may block or interfere with, or may otherwise be required for, the exercise by Company of any rights assigned to Company under this Agreement, I will immediately so notify Company in writing. Unless Company and I agree otherwise in writing as to particular Excluded Inventions or Other Inventions, I hereby grant to Company, in such circumstances (whether or not I give Company notice as required above), a non exclusive, perpetual, transferable, fully paid and royalty free, irrevocable and worldwide license, with rights to sublicense through multiple levels of sublicensees, to reproduce, make derivative works of, distribute, publicly perform, and publicly display in any form or medium, whether now known or later developed, make, have made, use, sell, import, offer for sale, and exercise any and all present or future rights in, such Excluded Inventions and Other Inventions. To the extent that any third parties have rights in any such Other Inventions, I hereby represent and warrant that such third party or parties have validly and irrevocably granted to me the right to grant the license stated above.

2.3 Assignment of Company Inventions. Inventions assigned to Kiromic, or to a third party as directed by Kiromic pursuant to Section 2.6, are referred to in this Agreement as "***Company Inventions***." Subject to Section 2.4 (Unassigned or Nonassignable Inventions) and except for Excluded Inventions set forth in **Exhibit A** and Other Inventions, I hereby assign to Kiromic all my right, title, and interest in and to any and all Inventions (and all Intellectual Property Rights with respect thereto) made, conceived, reduced to practice, or learned by me, either alone or with others, during the period of my employment by Company. To the extent required by applicable Copyright laws, I agree to assign in the future (when any copyrightable Inventions are first fixed in a tangible medium of expression) my Copyright rights in and to such Inventions. Any assignment of Company Inventions (and all Intellectual Property Rights with respect thereto) hereunder includes an assignment of all Moral Rights. To the extent such Moral

Rights cannot be assigned to Kiromic and to the extent the following is allowed by the laws in any country where Moral Rights exist, I hereby unconditionally and irrevocably waive the enforcement of such Moral Rights, and all claims and causes of action of any kind against Company or related to Company's customers, with respect to such rights. I further acknowledge and agree that neither my successors in interest nor legal heirs retain any Moral Rights in any Company Inventions (and any Intellectual Property Rights with respect thereto).

2.4 Unassigned or Nonassignable Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that I developed entirely on my own time without using Company's equipment, supplies, facilities, trade secrets or Confidential Information, except for those Inventions that either (i) relate to Company's actual or anticipated business, research or development, or (ii) result from or are connected with work performed by me for Company. In addition, this Agreement does not apply to any Invention which qualifies fully for protection from assignment to Company under any specifically applicable state law, regulation, rule or public policy ("***Specific Inventions Law***").

2.5 Obligation to Keep Company Informed. During the period of my employment and for one (1) year after termination of my employment, I will promptly and fully disclose to Company in writing all Inventions authored, conceived, or reduced to practice by me, either alone or jointly with others. In addition, I will promptly disclose to Company all patent applications filed by me or on my behalf within one (1) year after termination of employment. At the time of each such disclosure, I will advise Company in writing of any Inventions that I believe fully qualify for protection under the provisions of any applicable Specific Inventions Law; and I will at that time provide to Company in writing all evidence necessary to substantiate that belief. Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any Confidential Information disclosed in writing to Company pursuant to this Agreement relating to Inventions that qualify fully for protection under a Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under a Specific Inventions Law.

2.6 Government or Third Party. I agree that, as directed by Company, I will assign to a third party, including without limitation the United States, all my right, title, and interest in and to any particular Company Invention.

2.7 Ownership of Work Product.

(a) I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by Copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

(b) I agree that Kiromic will exclusively own all work product that is made by me (solely or jointly with others) within the scope of my employment, and I hereby irrevocably and unconditionally assign to Kiromic all right, title, and interest worldwide in and to such work product. I understand and agree that I have no right to publish on, submit for publishing, or use for any publication any work product protected by this Section, except as necessary to perform services for Company.

2.8 Enforcement of Intellectual Property Rights and Assistance. I will assist Company in every proper way to obtain, and from time to time enforce, United States and foreign Intellectual Property Rights and Moral Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Intellectual Property Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Intellectual Property Rights to Kiromic or its designee, including the United States or any third party designated by Kiromic. My obligation to assist Company with respect to Intellectual Property Rights relating to such Company Inventions in any and all countries will continue beyond the termination of my employment, but Company will compensate me at a reasonable rate after my termination for the time actually spent by me at Company's request on such assistance. In the event Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in this paragraph, I hereby irrevocably designate and appoint Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Intellectual Property Rights assigned under this Agreement to Kiromic.

2.9 Incorporation of Software Code. I agree that I will not incorporate into any Company software or otherwise deliver to Company any software code licensed under the GNU General Public License or Lesser General Public License or any other license that, by its terms, requires or conditions the use or distribution of such code on the disclosure, licensing, or distribution of any source code owned or licensed by Company except in strict compliance with Company's policies regarding the use of such software.

3. RECORDS. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by Company) of all Confidential Information developed by me and all Company Inventions made by me during the period of my employment at Company, which records will be available to and remain the sole property of Company at all times.

4. DUTY OF LOYALTY DURING EMPLOYMENT. I agree that during the period of my employment by Company I will not, without Company's express written consent, directly or indirectly engage in any employment or business activity which is directly or indirectly competitive with, or would otherwise conflict with, my employment by Company.

5. NO SOLICITATION OF EMPLOYEES, CONSULTANTS, CONTRACTORS, OR CUSTOMERS OR POTENTIAL CUSTOMERS. I agree that during the period of my employment and for the one (1) year period after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by Company, I will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, except on behalf of Company:

5.1 solicit, induce, encourage, or participate in soliciting, inducing or encouraging any person known to me to be an employee, consultant, or independent contractor of Company to terminate his or her relationship with Company, even if I did not initiate the discussion or seek out the contact;

5.2 solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any person known to me to be an employee, consultant, or independent contractor of Company to terminate his or her relationship with Company to render services to me or any other person or entity that researches, develops, markets, sells, performs or provides or is preparing to develop, market, sell, perform or provide Conflicting Services (as defined in Section 6 below);

5.3 hire, employ, or engage in a business venture with as partners or owners or other joint capacity, or attempt to hire, employ, or engage in a business venture as partners or owners or other joint capacity, with any person then employed by Company or who has left the employment of Company within the preceding three (3) months to research, develop, market, sell, perform or provide Conflicting Services;

5.4 solicit, induce or attempt to induce any Customer or Potential Customer (as defined below), to terminate, diminish, or materially alter in a manner harmful to Company its relationship with Company;

5.5 solicit or assist in the solicitation of any Customer or Potential Customer to induce or attempt to induce such Customer or Potential Customer to purchase or contract for any Conflicting Services; or

5.6 perform, provide or attempt to perform or provide any Conflicting Services for a Customer or Potential Customer.

The parties agree that for purposes of this Agreement, a "***Customer or Potential Customer***" is any person or entity who or which, at any time during the one (1) year period prior to my contact with such person or entity as described in Sections 5.4 5.6 above if such contact occurs during my employment or, if such contact occurs following the termination of my employment, during the one (1) year period prior to the date my employment with Company ends: (i) contracted for, was billed for, or received from Company any product, service or process with which I worked directly or indirectly during my employment by Company or about which I acquired Confidential Information; or (ii) was in contact with me or in contact with any other employee, owner, or agent of Company, of which contact I was or should have been aware, concerning the sale or purchase of, or contract for, any product, service or process with which I worked directly or indirectly during my employment with Company or about which I acquired Confidential Information; or (iii) was solicited by Company in an effort in which I was involved or of which I was aware.

6. NON COMPETE PROVISION. I agree that for (i) the six (6) month period if I am employed by the Company for less than six (6) months or (ii) the one (1) year period if I am employed by the Company for six (6) months or longer, both after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by Company, I will not, directly or indirectly, as an officer, director, employee,

consultant, owner, partner, or in any other capacity solicit, perform, or provide, or attempt to perform or provide Conflicting Services anywhere in the Restricted Territory (as defined below), nor will I assist another person to solicit, perform or provide or attempt to perform or provide Conflicting Services anywhere in the Restricted Territory.

The parties agree that for purposes of this Agreement, "***Conflicting Services"*** means any product, service, or process or the research and development thereof, of any person or organization other than Company that directly competes with a product, service, or process, including the research and development thereof, of Company with which I worked directly or indirectly during my employment by Company or about which I acquired Confidential Information during my employment by Company.

The parties agree that for purposes of this Agreement, "***Restricted Territory***" means the one hundred (100) mile radius of any of the following locations: (i) any Company business location at which I have worked on a regular or occasional basis during the preceding year; (ii) my home if I work from home on a regular or occasional basis; (iii) any potential business location of Company under active consideration by Company to which I have traveled in connection with the consideration of that location; (iv) the primary business location of a Customer or Potential Customer; or (v) any business location of a Customer or Potential Customer where representatives of the Customer or Potential Customer with whom I have been in contact in the preceding year are based.

7. REASONABLENESS OF RESTRICTIONS.

7.1 I agree that I have read this entire Agreement and understand it. I agree that this Agreement does not prevent me from earning a living or pursuing my career. I agree that the restrictions contained in this Agreement are reasonable, proper, and necessitated by Company's legitimate business interests. I represent and agree that I am entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

7.2 In the event that a court finds this Agreement, or any of its restrictions, to be ambiguous, unenforceable, or invalid, I and Company agree that the court will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

7.3 If the court declines to enforce this Agreement in the manner provided in subsection 7.2, I and Company agree that this Agreement will be automatically modified to provide Company with the maximum protection of its business interests allowed by law and I agree to be bound by this Agreement as modified.

7.4 Furthermore, the parties agree that the market for Company's products is the entire United States. If, however, after applying the provisions of subsections 7.2 and 7.3, a court still decides that this Agreement or any of its restrictions is unenforceable for lack of reasonable geographic limitation and the Agreement or restriction(s) cannot otherwise be enforced, the parties hereby agree that the fifty (50) mile radius from any location at which I worked for Company on either a regular or occasional basis during the one (1) year

immediately preceding termination of my employment with Company shall be the geographic limitation relevant to the contested restriction.

8. NO CONFLICTING AGREEMENT OR OBLIGATION. I represent that my performance of all the terms of this Agreement and as an employee of Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by Company. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict with this Agreement.

9. RETURN OF COMPANY PROPERTY. When I leave the employ of Company, I will deliver to Company any and all drawings, notes, memoranda, specifications, devices, formulas and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Confidential Information of Company. I agree that I will not copy, delete, or alter any information contained upon my Company computer or Company equipment before I return it to Company. In addition, if I have used any personal computer, server, or e mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide Company with a computer useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on Company's premises and owned by Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company's personnel at any time with or without notice. Prior to leaving, I will cooperate with Company in attending an exit interview and completing and signing Company's termination statement if required to do so by Company.

10. LEGAL AND EQUITABLE REMEDIES.

10.1 I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to Company and Company will have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Company may have for a breach or threatened breach of this Agreement.

10.2 I agree that if Company is successful in whole or in part in any legal or equitable action against me under this Agreement, Company will be entitled to payment of all costs, including reasonable attorneys' fees, from me.

10.3 In the event Company enforces this Agreement through a court order, I agree that the restrictions of Sections 5 and 6 will remain in effect for a period of twelve (12) months from the effective date of the order enforcing the Agreement.

11. NOTICES. Any notices required or permitted under this Agreement will be given to Company at its headquarters location at the time notice is given, labeled "Attention Chief Operating Officer," and to me at my address as listed on Company payroll, or at such other address as Company or I may designate by written notice to the other. Notice will be effective

upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five (5) business days after it was mailed, as evidenced by the postmark. If delivered by courier or express mail service, notice will be considered to have been given on the delivery date reflected by the courier or express mail service receipt.

12. PUBLICATION OF THIS AGREEMENT TO SUBSEQUENT EMPLOYER OR BUSINESS ASSOCIATES OF EMPLOYEE.

12.1 If I am offered employment or the opportunity to enter into any business venture as owner, partner, consultant or other capacity while the restrictions described in Sections 5 and 6 of this Agreement are in effect I agree to inform my potential employer, partner, co-owner and/or others involved in managing the business with which I have an opportunity to be associated of my obligations under this Agreement and also agree to provide such person or persons with a copy of this Agreement.

12.2 I agree to inform Company of all employment and business ventures which I enter into while the restrictions described in Sections 5 and 6 of this Agreement are in effect and I also authorize Company to provide copies of this Agreement to my employer, partner, co-owner and/or others involved in managing the business with which I am employed or associated and to make such persons aware of my obligations under this Agreement.

13. GENERAL PROVISIONS.

13.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of Texas as such laws are applied to agreements entered into and to be performed entirely within Houston between Houston residents. I hereby expressly consent to the personal jurisdiction and venue of the state and federal courts located in Houston for any lawsuit filed there against me by Company arising from or related to this Agreement.

13.2 Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained in this Agreement. If moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

13.3 Successors and Assigns. This Agreement is for my benefit and the benefit of Company, its successors, assigns, parent corporations, subsidiaries, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives.

13.4 Survival. The provisions of this Agreement will survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by Company to any successor in interest or other assignee.

13.5 At-Will Employment; No Oral Agreements. The Company and I acknowledge and agree that this Agreement does not affect the ability of either party to terminate their employment relationship, which relationship, unless otherwise agreed to in writing signed by an authorized representative of the Company, may be terminated at any time, for any or no reason. No supervisor, manager or other Company representative has the authority to make any verbal promises, commitments, or statements of any kind regarding the Company's policies, procedures or any other issues or terms of employment that are legally binding on the Company.

13.6 Waiver. No waiver by Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by Company of any right under this Agreement will be construed as a waiver of any other right. Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

13.7 Export. I agree not to export, re-export, or transfer, directly or indirectly, any U.S. technical data acquired from Company or any products utilizing such data, in violation of the United States export laws or regulations.

13.8 Advice of Counsel. I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.

13.9 Entire Agreement. The obligations pursuant to Sections 1 and 2 (except Subsections 2.4 and 2.7(a)) of this Agreement will apply to any time during which I was previously engaged, or am in the future engaged, by Company as a consultant if no other agreement governs nondisclosure and assignment of Inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter of this Agreement and supersedes and merges all prior discussions between us. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

This Agreement will be effective as of [Date].

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS.

	ACCEPTED AND AGREED TO: KIROMIC BIOPHARMA INC.
_____	By: _____
Name:	Name:

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement on Form S-1 of our report dated April 8, 2022, relating to the financial statements of Kiromic BioPharma, Inc. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ Deloitte & Touche LLP

Houston, Texas

June 27, 2022

Exhibit 107

Calculation of Filing Fee Table

Form S-1
(Form Type)

Kiromic Biopharma, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price(1)	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Common Stock, par value $0.001 per share (2)	457(o)	—	—	$28,750,000.00	0.0000927	$2,665.13
Fees to Be Paid	Equity	Warrants to purchase common stock (3)(4)	Other	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock, par value $0.001 per share(5)	457(o)	—	—	$35,937,500	0.0000927	$3,331.41
Fees to Be Paid	Equity	Pre-Funded Warrants to purchase common stock (2) (3)	Other	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock, par value $0.001 per share (2)(6)	457(o)	—	—	—	—	—
Fees to Be Paid	Equity	Underwriter's Warrants to purchase common stock (3) (7)	Other	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock, $0.001 par value (8)	457(o)	—	—	$1,796,875.00	0.0000927	$166.57
				Total Offering Amounts		$66,484,375.00	—	$6,163,11
						Total Fees Previously Paid		—
						Total Fee Offsets		—
						Net Fee Due		$6,163.11

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to Rule 416(a) under the Securities Act, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.
(2) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any common stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $28,750,000.
(3) No registration fee is required pursuant to Rule 457(g) under the Securities Act.
(4) Represents warrants to purchase common stock issued together with the shares of common stock sold and issued in this offering on a one-for-one basis that are exercisable at a price equal to 125% of the combined public offering price per share of common stock (the "Common Stock Warrants").
(5) Represents shares of common stock issuable upon exercise of the Common Stock Warrants.
(6) Represents shares of common stock issuable upon exercise of the pre-funded warrants.
(7) Represents warrants issuable to ThinkEquity LLC, or its designees, to purchase a number of shares of common stock equal to 5.0% of the aggregate number of shares of common stock and shares of common stock issuable upon exercise of the pre-funded warrants being offered at an exercise price equal to 125% of the combined public offering price per share of common stock (the "Underwriter Warrants").
(8) Represents shares of common stock issuable upon exercise of the Underwriter Warrants.