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

FORM 10-K

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

For the fiscal year ended December 31, 2023

or

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

For the transition period from _____ to

Commission File Number: 001-39169

Kiromic BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4762913**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
7707 Fannin Street, Suite 200, Houston, TX	**77054**
(Address of Principal Executive Offices)	Zip Code

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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

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

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

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

Large Accelerated Filer ☐	Accelerated Filer ☐
Non-accelerated Filer ☒	Smaller Reporting Company ☒
	Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the registrant's Common Shares held by non-affiliates of the registrant was approximately $3,175,902 based on the closing price of the Common Stock on the Nasdaq Stock Market on June 30, 2023.

As of March 18, 2024, there were 1,288,235 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of the Form 10-K incorporates by reference certain portions of the registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission ("SEC") not later than 120 days after the end of the fiscal year covered by this report.

Kiromic BioPharma, Inc.
Annual Report on Form 10-K
Year Ended December 31, 2023

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Various statements made in this Annual Report on Form 10-K are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- Our goals and strategies.
- 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.
- Our ability to obtain financing in amounts sufficient to fund our operations and continue as a going concern and avoid seeking protection under Chapters 7 or 11 of the United States Bankruptcy Code.
- Difficulties or delays in the product development process, including the results of preclinical studies or clinical trials.
- Difficulties or delays in the regulatory approval process.
- Manufacturing, sales, marketing and distribution of any of our products that may be successfully developed and approved for commercialization.
- 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.
- Our ability to raise capital when needed.
- Relevant government policies and regulations relating to our industry.
- The outcome of any pending or threatened litigation.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. 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".

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements:

- The effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data.
- Our expectations regarding the timing and clinical development of our product candidates.
- Our ability to achieve profitable operations and access to needed capital.
- Fluctuations in our operating results.
- The success of current and future license and collaboration agreements.
- Our dependence on contract research organizations, vendors and investigators.
- Effects of competition and other developments affecting development of products.
- Market acceptance of our products.
- Protection of intellectual property and avoiding intellectual property infringement.
- Product liability.
- Other factors described in our filings with the SEC.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and subsequent quarterly reports on Form 10-Q describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized, except as may be required by law.

RISK FACTOR SUMMARY

The risk factors summarized below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. For more information, see "Item 1A. Risk Factors" in this Annual Report on Form 10-K for the year ended December 31, 2023.

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

Risks Related to Our Financial Position

- We have incurred losses since inception and may never achieve or sustain profitability.
- We 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 some or all of our research programs, product development activities and commercialization efforts.
- Our financial situation creates doubt whether we will continue as a going concern.

Risks Related to our Business

- We have a limited operating history, which makes it difficult to evaluate our current business and future prospects.
- As a company, 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.
- Our governing documents could limit our stockholders' ability to obtain a favorable judicial forum for disputes.
- We are an emerging growth company, and we cannot be certain if the reduced reporting requirements make our shares less attractive to investors.
- We may be subject to securities laws claims regarding past disclosures.
- We face risks associated with increased political uncertainty.

Risks Related to our Product Candidates

- Our tumor-specific cancer 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 from other pharmaceutical and biotechnology companies.
- 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 for clinical trials, our research and development efforts and the receipt of necessary regulatory approvals could be significantly delayed or prevented.
- 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 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.
- Results from preclinical studies and early-stage clinical trials may not be predictive.

- Preliminary interim or "top-line" data that we announce may change as more data becomes available.
- 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.
- 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 U.S. Food and Drug Administration (the "FDA") regulatory approval process is lengthy and time-consuming, and we may continue to experience significant delays.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.
- 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 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.
- We may be unable to obtain orphan drug designation or to maintain the associated benefits.
- We may not be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- Our products will be subject to ongoing regulatory obligations and continued regulatory review.
- Healthcare reform measures may have a material adverse effect on our product candidates' commercial success.

Risks Related to Our Reliance on Third Parties

- We 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 Market for Our Common Stock

- Our common stock may be volatile or may decline regardless of our operating performance.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the market price for the shares and trading volume could decline.
- We do not expect to pay dividends in the foreseeable future.
- Our stockholders may experience substantial dilution if we issue additional shares of our capital stock.
- We may issue additional debt and equity securities, which could materially adversely affect the market price of our common stock.
- Failure to meet listing requirements of OTCQB Market, LLC ("OTCQB") 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.

Risks Related to Going Concern and Bankruptcy

- We may not be able to continue as a going concern and holders of our common stock could suffer a total loss of their investment.
- In the event we pursue Bankruptcy Protection, we will be subject to the risks and uncertainties associated with such proceedings.
- In the event we are unable to pursue Bankruptcy Protection under Chapter 11 of the United States Bankruptcy Code, or, if pursued, successfully emerge from such proceedings, it may be necessary to pursue Bankruptcy Protection under Chapter 7 of the United States Bankruptcy Code for all or a part of our businesses.

Risks Related to Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure

- We are increasingly dependent on our information technology systems and infrastructure for our business.
- Any security breach of other incident, whether real or perceived, could cause us to suffer reputational damage.

ITEM 1. BUSINESS.

Overview

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 maintains offices in Houston, Texas. The Company has not generated any revenue to date.

The Company is an allogeneic Gamma Delta T-cell therapy company featuring unique, proprietary end-to-end bioinformatic, AI targeting, and manufacturing technologies to address solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and on-site current good manufacturing practices ("cGMP"), which we believe will allow us to leverage a new framework for the next generation of cell therapies.

From a development standpoint, we utilize innovative non-engineered and engineered Gamma Delta T cell (GDT) technologies and are developing proprietary, virus-free cell engineering methods to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. Deltacel™ (Deltacel) is our first allogeneic, off-the-shelf GDT cell-based product in Phase 1 clinical stage. Our Procel™ ("Procel") and Isocel™ ("Isocel") product candidates consist of allogeneic, engineered, off-the-shelf CAR-GDT cells, and they 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 which we expand, enrich, and activate ex- vivo through a proprietary process, and it is intended to treat solid tumors regardless of the specific tumor antigen expression. Procel consists of engineered GDTs targeting PD-L1 positive tumors, while Isocel consists of engineered GDTs targeting solid tumors expressing a tumor-specific variant (Isoform) of Mesothelin ("Iso-Meso").

We currently have three product candidates: 1) Deltacel™, non-engineered GDTs, expanded and activated with proprietary technology; 2) Isocel™, GDTs engineered with an anti-Mesothelin isoform Chimeric Antigen Receptor; and 3) Procel™, GDTs engineered with a PD-1 switch receptor.

We have a total of five clinical programs to study our key product candidates:

1) Deltacel-01: This phase 1 clinical trial is evaluating Deltacel in combination with low-dose targeted radiation for patients with non-small cell lung cancer (NSCLC).

2) Isocel combination: This phase 1 clinical trial is expected to evaluate Isocel in combination with low-dose radiation for patients with Mesothelin Isoform 2 positive solid malignancies.

3) Alexis-ISO-1: This phase 1 clinical trial is expected to evaluate Isocel in patients with Mesothelin Isoform 2 positive solid malignancies.

4) Procel combination: This phase 1 clinical trial is expected to evaluate Procel in combination with low-dose radiation for patients with PD-L1 positive solid malignancies.

5) Alexis-PRO-1: This phase 1 clinical trial is expected to evaluate Procel in patients with PD-L1 positive solid malignancies.

The Company is developing a novel and virus-independent engineering method, which will result in the submission of new IND applications (clinical programs 2, 3, 4 and 5). These applications are expected to be ready for submission to the FDA in the first half of 2025, subject to sufficient financing to support the progression of the developments of those additional clinical trial candidates. Depending on evidence from preclinical studies, we may limit the new IND submission to two instead of four: one for Isocel and one for Procel.

We submitted the IND for the Deltacel trial on March 31, 2023, and we began the activation of the clinical trial process during the second quarter of 2023. In December 2023, we entered the enrollment phase and are currently conducting part 1 (dose escalation) of the study. On October 23, 2023, we entered into a clinical trial agreement with Beverly Hills Cancer Center (BHCC) to conduct our Deltacel-01 Phase 1 Study in patients with stage 4 Non-Small Cell Lung Cancer (NSCLC). Lung cancer counts more than 2 million new diagnoses globally each year and is almost three times as deadly as breast and ovarian cancers. On December 13, 2023, the first patient in the Deltacel-01 trial received the first dose of Deltacel at BHCC. We report no dose-limiting toxicities to date and a favorable preliminary outcome showing stabilization of disease at the 6-week follow-up, and a reduction of the tumor lesion at the two-month follow-up. As we continue to monitor this patient, we enrolled two additional patients at BHCC. On February 28, 2024, we activated a second clinical trial site with Virginia Oncology Associates, PC in our Deltacel-01 Phase 1 Study, where patient enrollment is expected to begin in April 2024. Also, we plan to open the study at one additional clinical site by the end of March 2024.

We plan to continue the development of Isocel and Procel, and we expect to be able to be beginning the activation process for clinical programs 2 to 5 by the first half of 2025, subject to obtaining sufficient financing to support the progression of the development of these additional clinical trial candidates.

From a target discovery standpoint, our proprietary target discovery engine is called "Diamond." The Diamond platform is a suite of data mining algorithms that identify cancer-specific immunotherapy targets and AI models that evaluate the quality of potential targets. We believe that Diamond dramatically accelerates the development of live drug technologies by quickly locating rare cancer-specific targets in vast databases of billions of genomic datapoints and by applying the latest in machine learning methods to eliminate targets likely to fail prior to costly laboratory validation and development. From a development standpoint, Kiromic utilizes innovative engineered GDT manufacturing technologies and is developing proprietary, virus-free engineering tools, to develop novel therapies for solid tumors that will be effective and

cost-efficient. Our Allogeneic Lead Exogenous Isoforms ("ALEXIS") platform consists of allogeneic cell therapy products, currently in the pre-Investigational New Drug development stage. Investigational New Drug ("IND") application enabling, non-clinical pharmacology studies are supportive for the GDT-based therapy.

Our ALEXIS-PRO-1 trial candidate is our allogeneic GDT therapy product targeting PD-L1. Our ALEXIS-ISO-1 trial candidate is our allogeneic GDT therapy product targeting an isoform of Mesothelin that is preferentially present on tumor cells, namely Mesothelin Isoform 2 ("Isomeso").

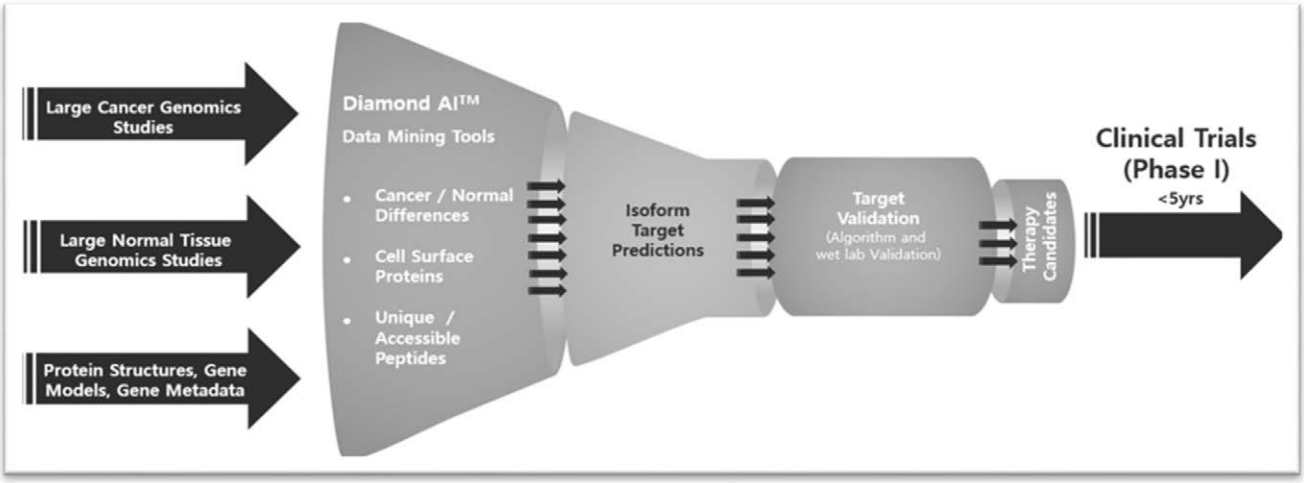
From a manufacturing standpoint, Kiromic uses in-house R&D laboratory facilities, current good manufacturing practices ("cGMP") production facilities for cell manufacturing with dedicated on-site quality control and environmental monitoring laboratories, which we believe will ensure rapid discovery, 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.

Target Discovery: Diamond (Identify, Screen, Prioritize)

Diamond addresses the main challenges in today's clinical pipeline: target identification, patient stratification, and donors' selection.

Successful development of precision immunotherapies requires 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.

Kiromic's Diamond does just that. 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 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.

We believe that the Diamond data mining tools drive discovery by sifting these billions of data points to identify rare cancer-specific immunotherapy targets. Diamond AI predictions then validate targets to find those that are most likely to be stably presented on the surface of tumor cells and that have strong immunological binding properties. We believe that the predictions speed development and reduce costs by quickly eliminating targets that would likely fail later in laboratory validation or development.

Most damaged cells are quickly identified and eliminated by the immune system. Damaged cells that become cancer are those that acquire changes, allowing them to evade the immune system and to proliferate. One common change of this type is an alteration of messenger RNA ("mRNA") splicing patterns. Changes in mRNA splicing lead to altered proteins (isoforms) that provide selective advantages to the tumor cells but also provide potential as cancer-specific immunotherapy targets.

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

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

Diamond analyzes tens of thousands of isoforms from 10,000+ tumor samples and 7,000+ normal samples to create a rank order list of isoforms that are strongly expressed in tumor but not in normal samples. It supports identification of targets for specific tumor types, sub-populations of patients, or cross-tumor type targets. In each case, tumor expression is compared to all profiled normal tissues. Diamond can distinguish splicing alterations that lead to unique protein regions or unique protein sequence junctions. The unique regions are the basis for identification of a target peptide. Diamond can also refine results to focus on just proteins that are presented on the surface of cells.

After a prioritized list of cancer-specific protein isoforms is developed by our data mining tools, a specific target peptide must be selected and targets must be vetted with in-silico methods to quickly eliminate those likely to fail later in development. The Diamond platform includes a suite of AI, machine learning models that assist in selection of the most promising targets. These include:

Transmembrane prediction. Immunotherapies like CAR-T cell therapies work optimally on proteins with cancer-specific alterations of cell surface proteins. Generally, cell surface proteins have a portion that stays inside the cell (cytoplasmic), a portion that crosses the cell membrane (transmembrane), and a portion that is outside on the cell's surface (extracellular). A good target for CAR-T cells needs to be on the extracellular portion of a protein that is altered by cancer but that is not so dramatically altered that it is no longer a transmembrane protein. A Diamond machine learning model trained on the properties of transmembrane proteins is used to ensure that these criteria are met.

Protein Structure prediction. Diamond leverages the latest advances in 3D protein folding / structure prediction using deep neural networks to model the shape of cancer-specific protein alterations. The predicted structure is used to evaluate the stability of the altered protein and the accessibility of potential targets.

Proteomic validation. Diamond includes a database of mass spectrometry proteomic data that was reprocessed to broadly identify protein fragments from alternative gene isoforms. This data can in some cases be used to validate that cancer-specific alterations present in the transcriptome do in-fact result in production of altered proteins by the tumor cells.

Research assistant. Even with many AI tools assisting in target selection, skilled human researchers still need to perform detailed investigation of potential targets. Many of these tasks are repetitive and time consuming so Diamond includes an automated assistant that speeds up this research by gathering relevant publications, figures, gene annotations, and connections to useful external tools.

The Diamond platform is now developed entirely by Kiromic's in-house bioinformatics group who interact regularly with Kiromic researchers selecting targets and designing therapies. This close, responsive collaboration allows for rapid evolution and improvement of the system in meeting research needs. Further, the system has been reconstructed to have a modular, pluggable architecture that is able to quickly accommodate advances in scientific or computational methods as well as new immunotherapy designs.

We have made significant progress in the use of bioinformatics data to develop a simple test which will allow us to pre-screen donors with the goal to identify those whose GDT cells have the most efficient expansion and activation potential. This will further reduce the costs of manufacturing by making our proprietary process more efficient.

In addition, we are developing a third module of the Diamond platform to predict which patients will best respond to our GDT cell therapies. This will allow us to personalize the treatment approach depending on the patient's tumor features.

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 tumor-specific iso-antigens ("TSIAs"), generate an immunological response and therefore eradicate cancer cells.

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.

Next Generation Allogeneic Therapy Summary

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

1. Addressing 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.

2. Targeting 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 trial candidate can effectively treat most solid cancers.

3. Exploitation of GDT's Natural Potency: Further, by using GDT, we believe that our trial candidates can achieve superior safety and superior efficacy based on our pre-clinical results.

We are developing our brand of CAR cell product candidates designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. These products are in the pre-IND stage of the FDA clinical trial process.

The following presents a detailed explanation of each component listed above:

Addressing a Growing Target Market

CAR-T cell therapy, a form of cancer immunotherapy, has recently emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers. In 2017, two autologous anti-CD19 CAR-T cell therapies, Kymriah, developed by Novartis International AG, and Yescarta, developed by Kite Pharma, Inc., (now part of Gilead), were approved by the FDA for the treatment of relapsed/recurrent B cell precursor acute lymphoblastic leukemia and relapsed/recurrent large B cell lymphoma, respectively. Autologous CAR-T cell therapies are manufactured individually for the patient's use by modifying the patient's own T cells outside the body, causing the T cells to express CARs. The entire manufacturing process is dependent on the viability of each patient's T cells and takes approximately three to four weeks.

It's important to note that the aforementioned therapies were for only hematological indications. Currently, these indications represent about 10% of new cases, while solid cancers comprise approximately 90% of new cases.

Further, we believe that the overall global CAR-T cell therapy market could expand to more than $33 billion by 2027. Additionally, by focusing on an allogeneic approach, we believe that we can provide a simplified and efficient supply chain with improved product availability compared to the autologous therapies. Allogeneic CAR-T cell therapies involve engineering healthy donor T cells, which we believe will allow for the creation of an inventory of OTS products that can be delivered to a larger portion of eligible patients throughout the world.

Allogeneic engineered T cells are manufactured in a similar manner as autologous, but with two key differences: (i) allogeneic T cells are derived from healthy donors, not cancer patients, and (ii) allogeneic T cells have a decreased risk of GvHD, a condition where T cells recognize the patient's normal tissues as foreign and cause damage to the patient.

First, we plan to study non-engineered T-cells in the Deltacel clinical trial. This will allow us to better establish the efficacy and tolerability of our unique GDT cells, which are derived from healthy donors and are expanded and activated in vitro through a proprietary methodology. Moreover, Deltacel will allow us to move into the clinical arena faster than Procel and Isocel, considering the following advantages of non-engineered GDT cells:

Deltacel targets are shared by multiple solid tumors; simplified manufacturing due to absence of T cell engineering; reduced risk of on-target off-tumor tox; allogeneic and off-the-shelf (cryopreserved).

In addition, Deltacel development will allow us to acquire manufacturing and clinical experience to support more complex products, such as Procel and Isocel.

Thwarting Antigen Escape by Targeting PD-L1

To further boost the potency of our effector cells, we have developed an off the shelf chimeric gamma delta PD1 T cell switch receptor therapy that interferes with the inhibitory "checkpoint" protein, PD-L1, found on most tumor cells and cells of the tumor microenvironment ("TME"). We believe that most solid cancers such as lung, melanoma, gastric, esophagus, colorectal, breast, prostate, liver, urothelial, renal, cervical, and head and neck can potentially now be effectively treated by targeting the checkpoint inhibitor PD-L1. By converting what is normally an inhibitory signal into an activating signal, we predict that this will overcome the resistance of the TME and mitigate the issue of antigen loss typically seen with solid malignancies.

We believe our engineered GDTs significantly enhance the immune response. First, it blocks the ability of checkpoint like PD-L1 from inactivating a T cell (similar to checkpoint inhibitors). Second, engineered GDTs are now able to kill cancer cells with enhanced potency upon binding with the PD-L1 receptor.

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

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

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

Although this chimeric PD1 GDT can effectively lyse both hematologic and solid tumors expressing PD-L1, the focus of the first related IND submission will focus on solid malignancies that express PD-L1 as this represents one of the greatest needs in oncology at this time. This IND submission is supported by strong in vitro and in vivo tumor cytotoxicity data, and thus far no significant adverse effects have been noted in the animal models tested, which has included the testing of multiple types of solid malignancies.

Development Plan

Deltacel will be studied in a Phase 1, First-in-Human, Open-label, Dose Escalation Study Subjects with metastatic and refractory non-small cell lung cancer (NSCLC). In this trial, the product candidate, KB-GDT-01, will be studied in combination with low dose radiotherapy.

The primary goal will be to assess safety, tolerability, and preliminary efficacy of KB-GDT-01 at increasing dose levels in order to estimate the recommended Phase 2 dose (RP2D) which will serve as the dose for up to additional 12 subjects in the expansion phase.

We submitted the IND for the Deltacel trial in March 2023, obtained FDA authorization in April 2023, and we began the activation of clinical trial process in May 2023. The study is conducted in two parts.

In Part 1 (Dose Escalation), the study will attempt to identify the best dose with the lowest incidence of adverse effects. In Part 2 (Expansion) the best dose will be further investigated in up to 12 additional participants. In December 2023, we entered the enrollment phase, and we are currently evaluating the first dose level of the dose-escalation part of the trial.

Isocel will be studied alone or in combination with low-dose radiation for subjects with Mesothelin Positive Metastatic or Progressive Locally Advanced Solid Malignancies.

Procel will be studied in a Phase 1, First-in-Human, Open-label, Dose Escalation Study of an Allogeneic Gamma Delta PD1 T Cell Switch Receptor Therapy (KB-PD1) for subjects with PD-L1 Positive Metastatic or Progressive Locally Advanced Solid Malignancies.

The primary goal of these studies will be to assess safety, tolerability, and preliminary efficacy of Kiromic's cell therapy products at increasing dose levels in order to estimate the maximum tolerated dose (MTD) which will serve as the dose for an expansion cohort.

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

Exploitation of GDT's Natural Potency

We have two simple claims with respect to our allogeneic AI driven GDT engineering approach.

1. We believe that our GDTs are safer than other CAR-T cell approaches;
2. We believe that our GDTs are more efficacious than other CAR-T cell approaches.

Below, safety and efficacy are discussed in greater detail.

Safety

Deltacel

We conducted a pivotal IND-enabling Toxicology and Pharmacology study of Deltacel in tumor-bearing NSG mice (N=120).

Deltacel was given at the human equivalent dose of 12 billion cells (24 billion cumulative dose), which is 7.5x the human equivalent dose (with respect to the highest planned IND dose).

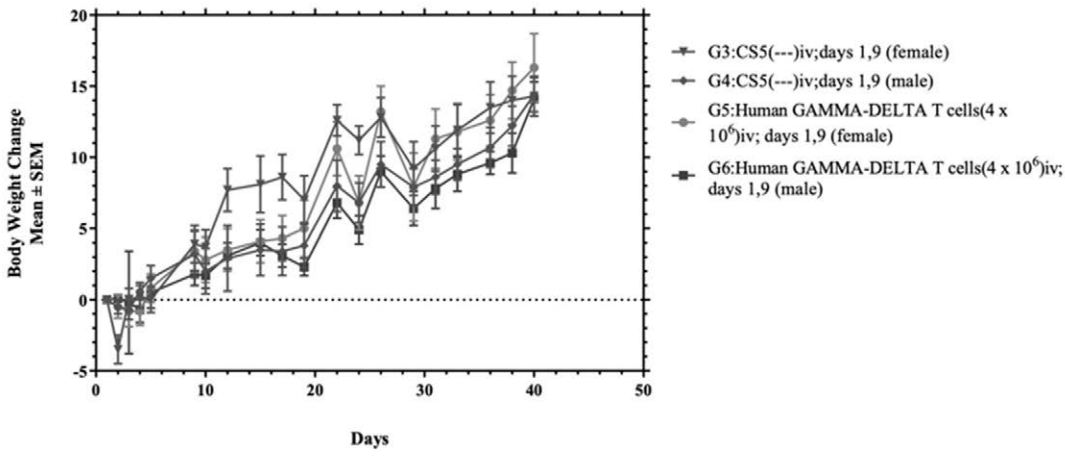
It was well tolerated with no incidence on mice weight or impact on survival (both overall and event-free).

Clinical Pathology did not evidence any significant Deltacel-induced abnormalities in blood chemistry, with the exception of a minor increase in Alanine Aminotransferase in female mice receiving Deltacel compared with controls. This was not associated to any defect in liver function.

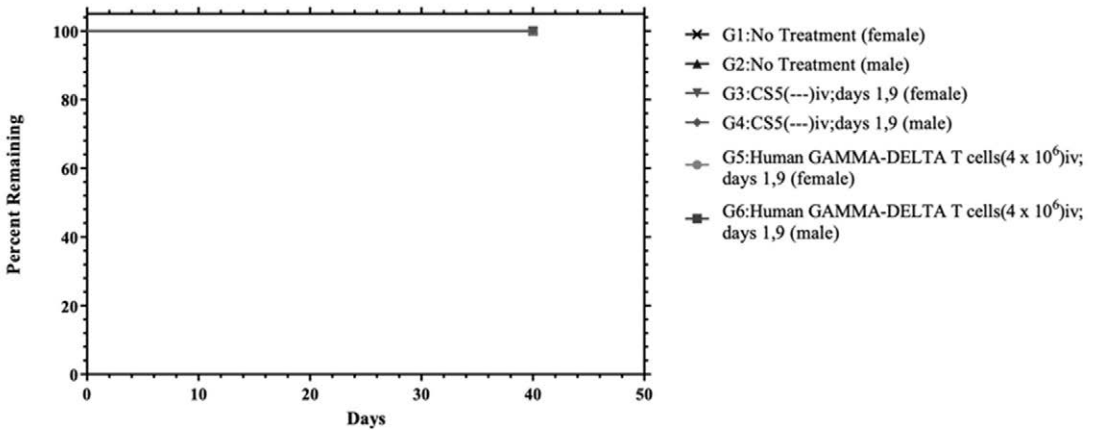
Histopathology examination on multiple organs did not evidence any abnormalities after Deltacel administration.

The graphics below show that Deltacel did not cause significant changes in mice's body weight, did not affect survival, and did not alter metabolic functions.

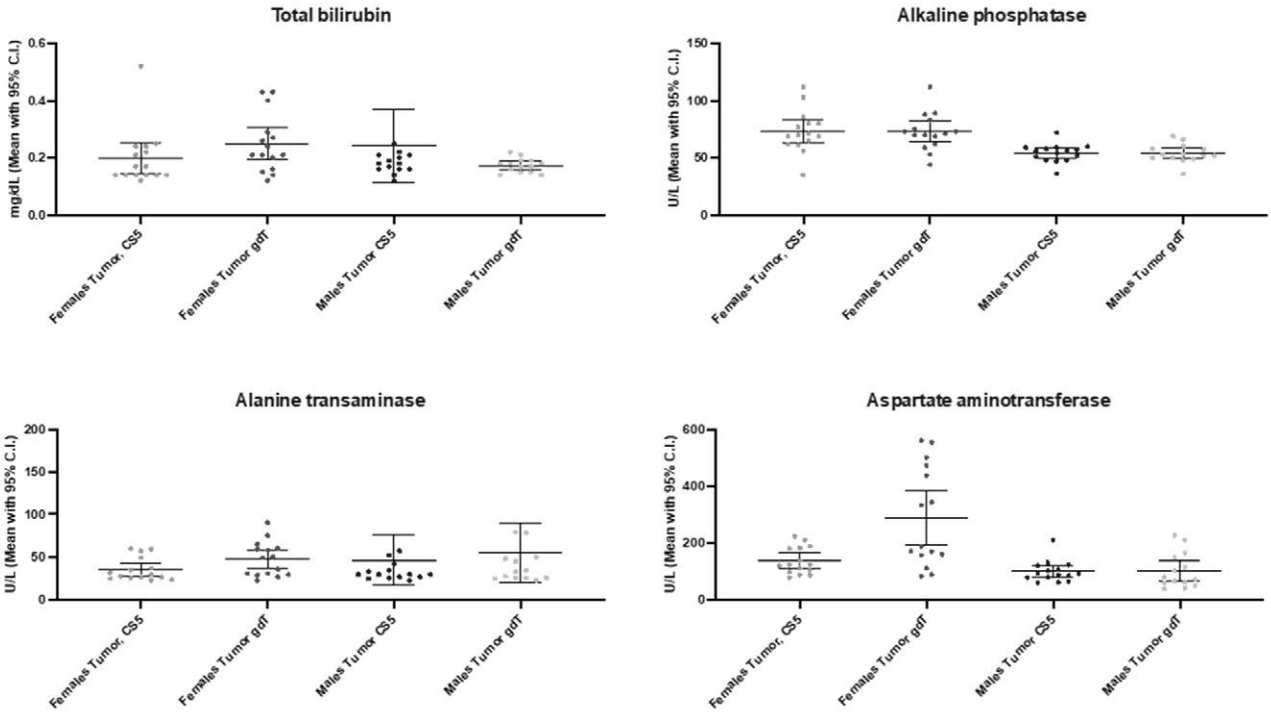
Percent Group Mean Body Weight Changes from Day 1.

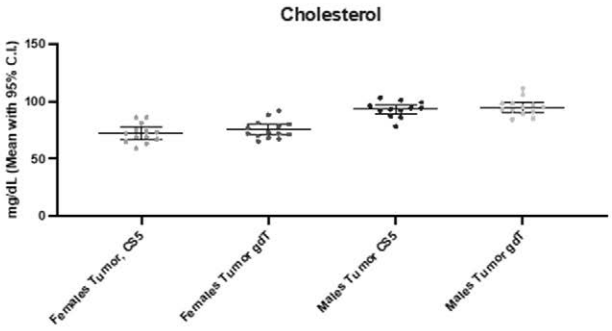


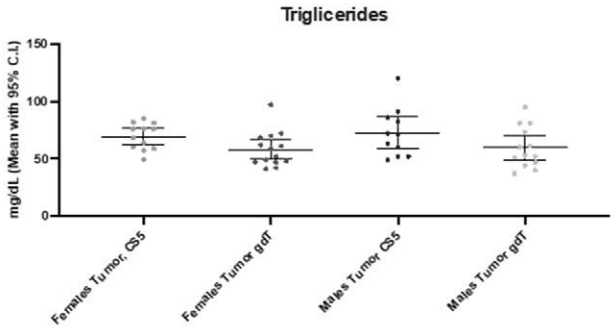
Survival rates.

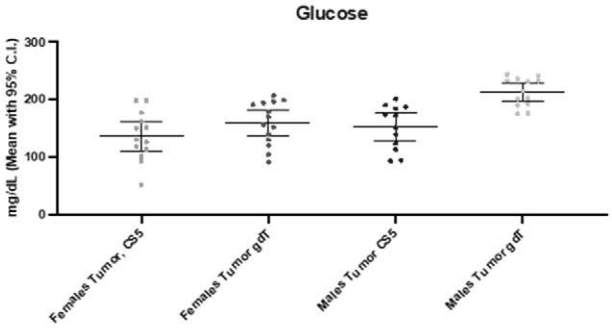


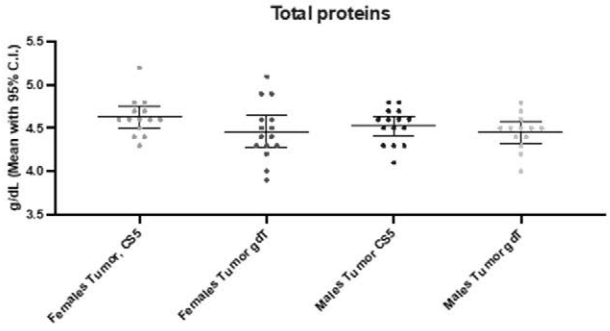
Complete metabolic panel.

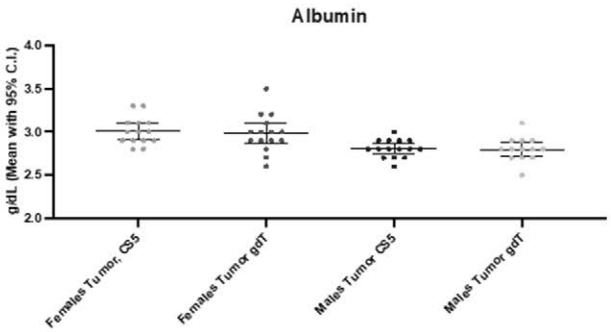


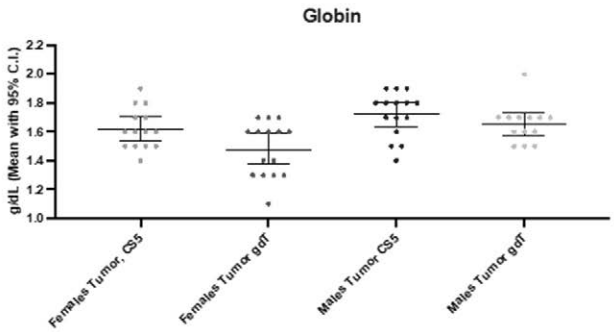

Cholesterol
mg/dL (Mean with 95% C.I.)
150
100
50
0
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT

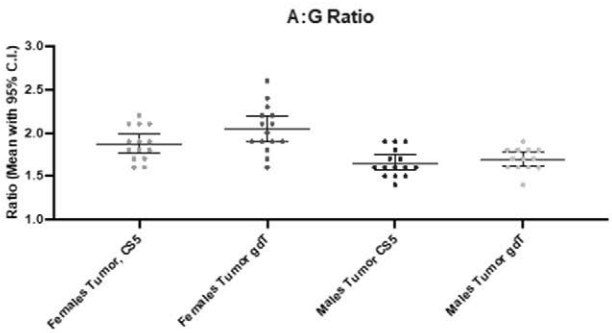

Triglicerides
mg/dL (Mean with 95% C.I.)
150
100
50
0
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT

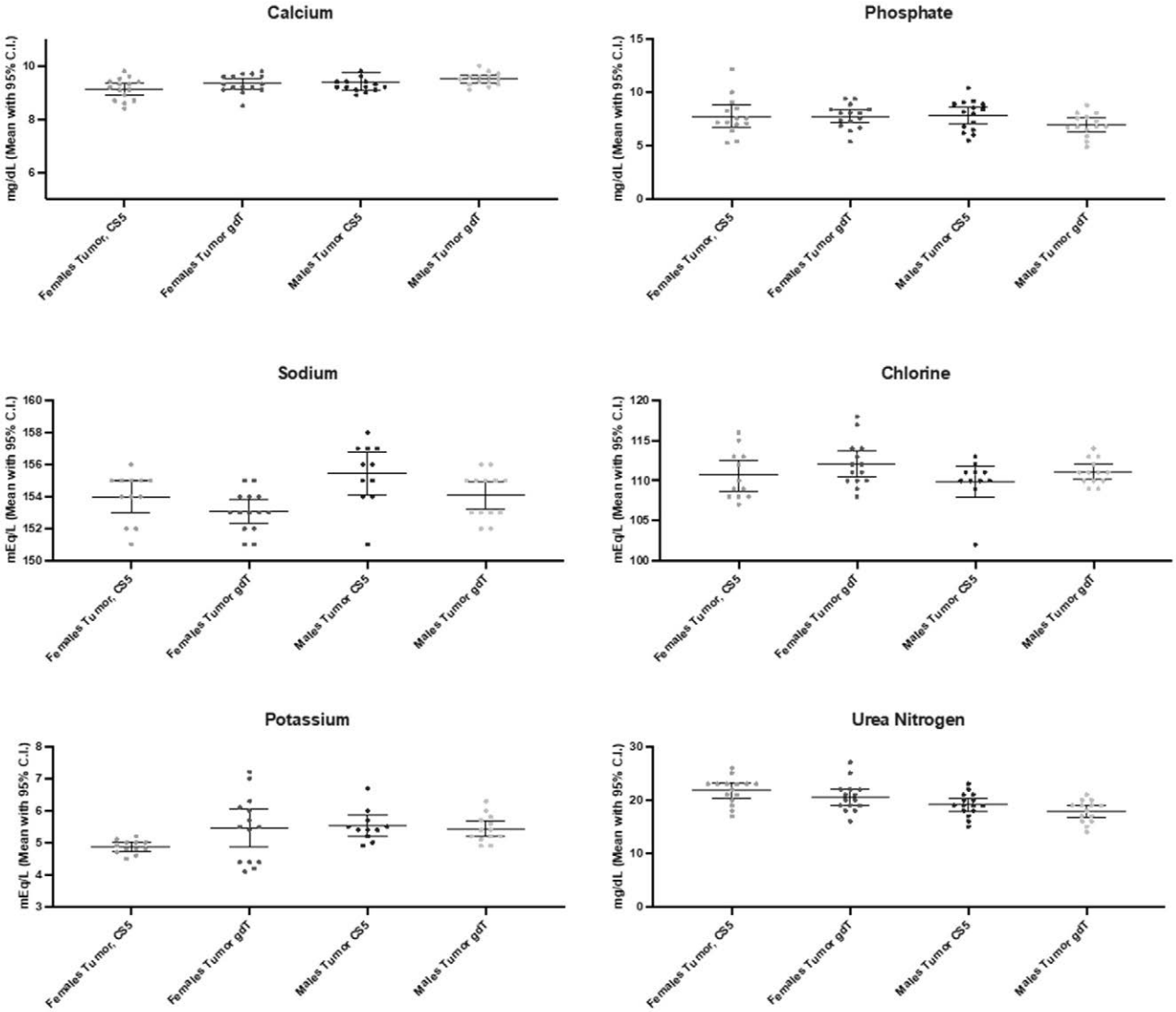

Glucose
mg/dL (Mean with 95% C.I.)
300
200
100
0
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT


Total proteins
g/dL (Mean with 95% C.I.)
5.5
5.0
4.5
4.0
3.5
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT


Albumin
g/dL (Mean with 95% C.I.)
4.0
3.5
3.0
2.5
2.0
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT


Globin
g/dL (Mean with 95% C.I.)
2.2
2.0
1.8
1.6
1.4
1.2
1.0
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT

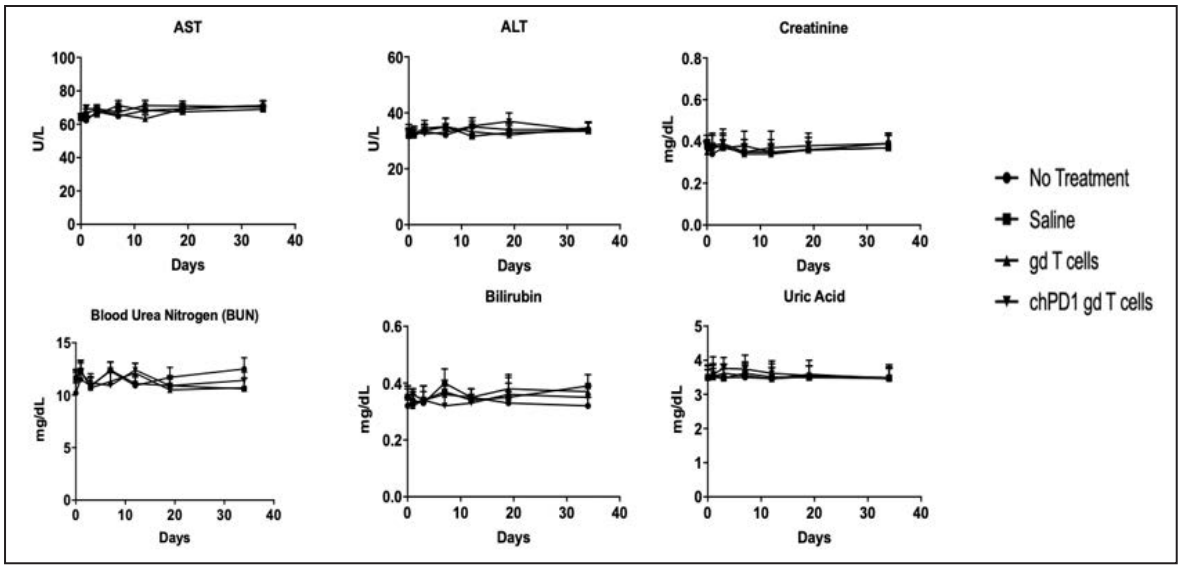

A:G Ratio
Ratio (Mean with 95% C.I.)
3.0
2.5
2.0
1.5
1.0
Females Tumor, CS5
Females Tumor gdT
Males Tumor CS5
Males Tumor gdT



Procel

Current FDA approved CAR-T cell therapy products carry a high risk of side effects including the Cytokine Release Syndrome ("CRS") and Immune Cell Associated Neurotoxicity Syndrome ("ICANS"). We believe that GDTs contain minimal to no CRS or ICANS, or GvHD between donors and patients.

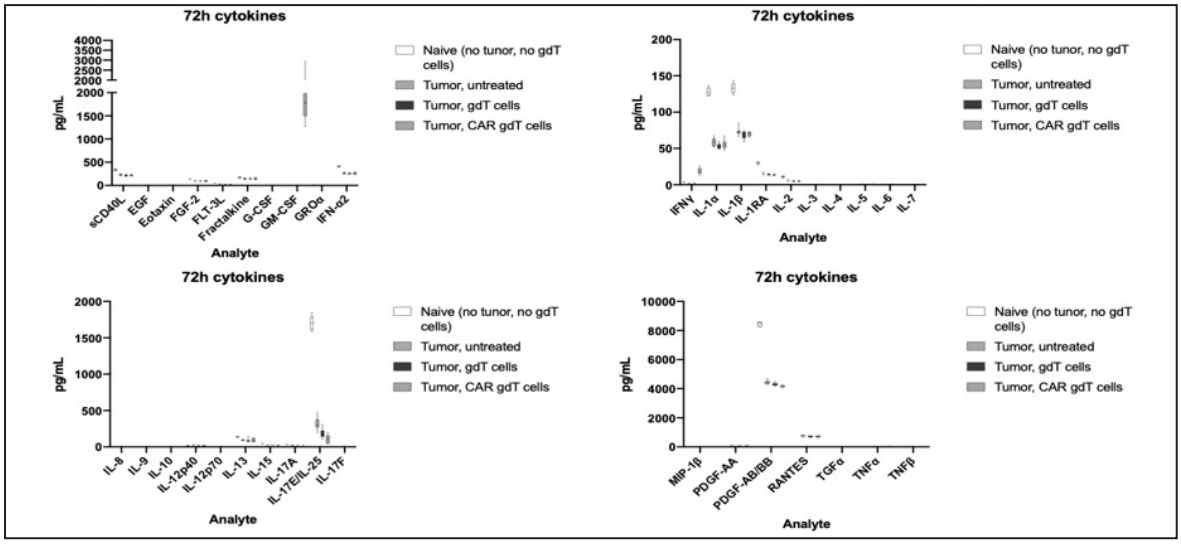
The graphic below demonstrates that our GDTs for checkpoint PD-L1 are shown to be safe in animal testing. The graphs demonstrate serological tests of organ damage biomarkers. In the experiment, the athymic Balb/c Nude mice were subcutaneously implanted with NCI-H226 and were treated intravenously with checkpoint PD-L1 GDTs. Serum biomarkers were measured. Graphs show the means out of 5 mice per group, while error bars indicate standard deviations.



The safety laboratory analyses and safety monitoring visits conducted so far on our first subject enrolled in the Deltacel-01 clinical trial confirmed such a safety profile and revealed that the treatment was and continues to be well tolerated.

Isocel

We also performed preclinical experiments on safety on our ALEXIS-ISO-1 clinical candidate, which contains allogeneic GDTs expressing the isoform of mesothelin. The experiments tested for inflammatory cytokines in mice. The cytokines in panel were not significantly different in CAR GDT treated mice compared with untreated or non-transduced GDT treated mice. In effect, our scientific team drew the conclusion that there was no significant difference in inflammatory markers with our engineered GDTs.



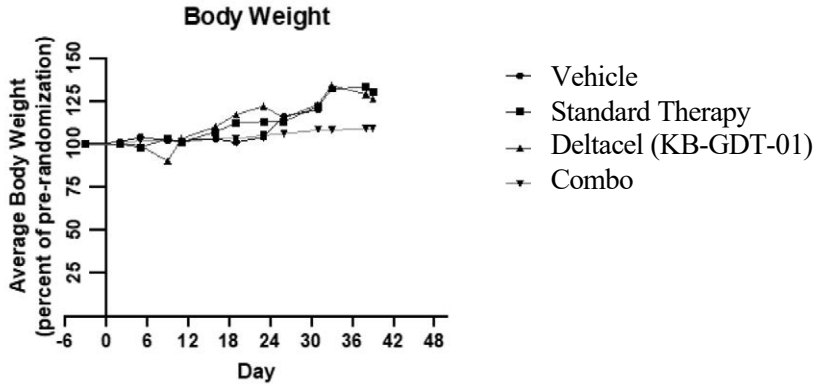
Efficacy

Deltacel

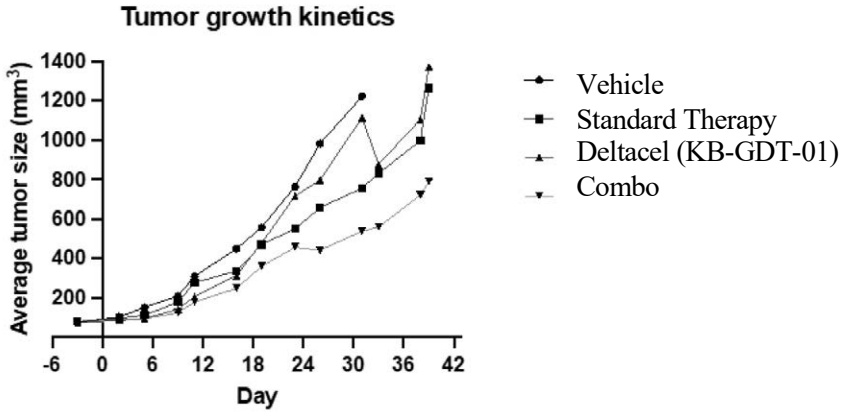
We conducted an IND-enabling pivotal Efficacy study in mice (N=80, 40 females and 40 males), where Deltacel was given alone or in combination to a standard anti-tumor therapy to animals bearing advanced lung cancer tumors implanted sub-cutaneously.

Adding the standard tumor therapy treatment to the Delatcel (KB-GDT-01) injections prolonged the duration and the magnitude of the benefit afforded by the cell treatment alone, and it was superior to the standard therapy when compared

with the untreated control group (vehicle). These effects were not associated to any effect on multi-organ functions and metabolism as evidenced by a clinical chemistry analysis. Based on the mRNA profile by NanoString analysis, adding the standard anti-tumor therapy to KB-GDT-01 appeared to favor a pro-inflammatory tumor microenvironment. A unique gene expression signature was identified in mice treated with the combination therapy that could not be obtained with either monotherapies and could represent a set of biomarkers that may be associated to Deltacel in patients.



Changes of average tumor size in each group during the in-life observation period. No statistically significant differences were observed.



Changes of average tumor size in each group during the in-life observation period. Combination therapy versus cell monotherapy. The combination therapy significantly reduced the size of tumors compared with those from mice in the cell monotherapy group. The average size of the combination therapy group's tumors remained smaller than that of the cell monotherapy group.

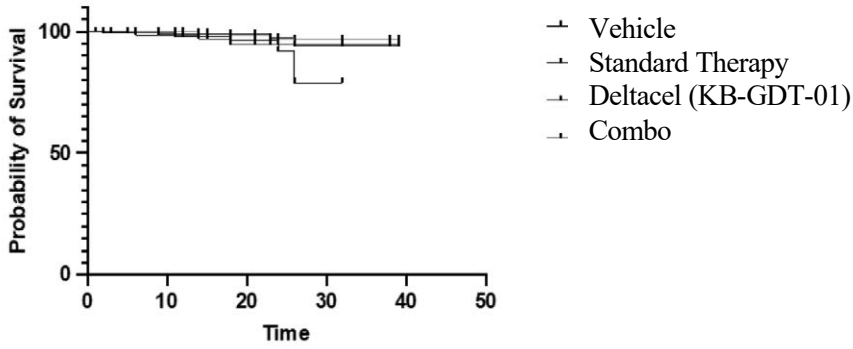
Combination therapy versus standard therapy alone. Except for a temporary effect from day 9 until day 11 (included), where the combination therapy group mean tumor volume was significantly smaller than that of the standard therapy alone, the mean tumor volume of mice in the combination therapy group was not significantly different from that of mice in the standard therapy alone group. However, on average, from day 16 until the end of the experiments, it remained 24% smaller than that of the standard therapy group.

Combination therapy versus vehicle control. The combination therapy significantly reduced the size of tumors compared with those from mice in the vehicle control group starting from day 5, i.e., around 48 hours after the injection of the first cell dose.

Cells monotherapy versus standard therapy or vehicle. During the 39-day observation window after the administration of the second dose of cells, the cells monotherapy was never better than standard therapy in controlling tumor growth, while

it significantly reduced tumor size compared with the vehicle control group starting from day 5, i.e., around 48 hours after the injection of the first cell dose.

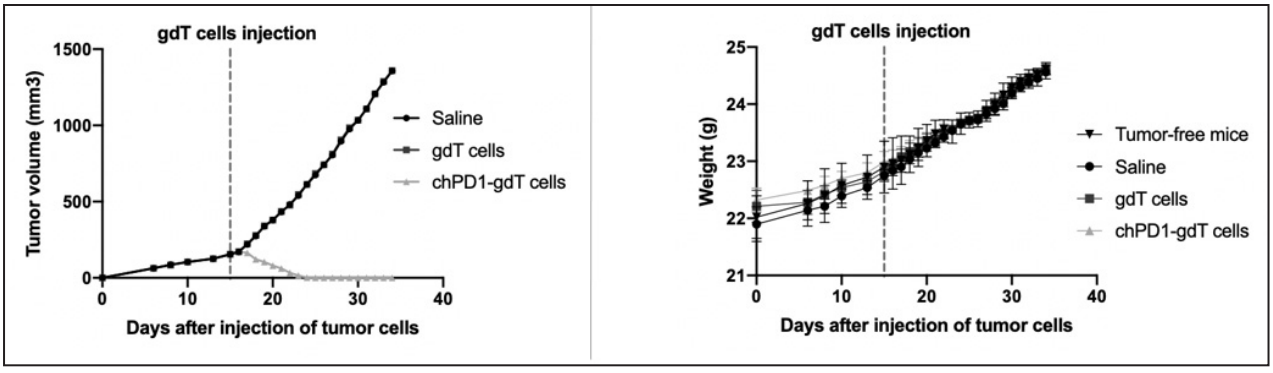
Standard therapy versus vehicle. Tumor growth in the mice from the standard therapy group was not significantly different from that of mice from the vehicle group, except for a temporary effect observed only on day 5.



Probability of survival for each treatment group: no statistically significant differences in survival rates among groups were observed (Log-rank test and Gehan-Breslow-Wilcoxon test p>0.05). There was no statistically significant difference among groups.

Procel

We believe that our engineered checkpoint PD-L1 GDT approach is potentially more efficacious than non-engineered GDT approaches. The figures below demonstrate our experimentation of that hypothesis. The results indicate the in vivo efficacy and tolerability of GDTs (5 x 106 cells) in athymic Balb/c Nude mice subcutaneously implanted with the PD-L1+ cell line, NCI-H226 (10 (6) cells). The dotted vertical line indicates the day when the GDTs were administered (day +15). Graphs show the average (A) tumor volumes and (B) weights of 10 mice (Saline, GDTs, chPD1 GDTs), or five mice (tumor-free), with a 95% confidence interval.

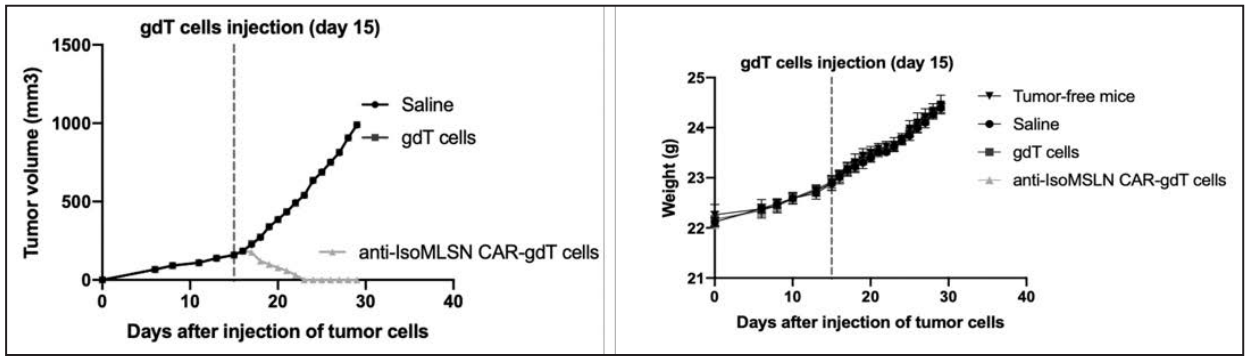


In summation, our GDT therapy reduced tumor size to zero within approximately eight days in mice, while showing no weight loss. Conversely, mice treated intravenously with either non-engineered GDTs or untreated (saline) experienced statistically significant tumor growth.

Isocel

Similarly, we believe that our engineered GDTs targeting the isoform of mesothelin are potentially more efficacious than non-engineered GDT approaches. The figures below demonstrate our experimentation of that hypothesis. We tested the in vivo efficacy and tolerability of a high dose of GDT in Balb/c nude mice sub-cutaneously implanted with the mesothelioma cell line, NCI-H226. Fifteen days after tumor cell implantation, mice with comparable tumor volumes were then divided into three groups (n=10 mice/group) and were (i) injected with our CAR GDTs, (ii) injected with non-engineered GDTs, iii) injected with saline solution. Tumor volumes and mice weight were measured daily for an additional 30 days. The dotted vertical line indicates the day when the GDTs were administered. Graphs show the tumor growth/reduction and

body weight from the ten tested mice (Saline, our CAR GDTs, non-engineered GDTs), or five mice (tumor-free), with a 95% confidence interval.



In summation, our GDT therapy reduced tumor size to zero within approximately eight days in mice, while showing no weight loss. Conversely, mice treated intravenously with either non-engineered GDTs or untreated (saline) experienced statistically significant tumor growth.

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

These cells are stimulated to proliferate, then purified and cryopreserved. In the case of Procel and Isocel, they are transfected with a virus-free methodology.

These cells can be propagated in cell culture bags until sufficient cells are available. The GDTs are then washed, frozen, and shipped to the clinical sites.

Manufacturing Operations

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

Our product candidates are designed and manufactured via a platform comprised of defined unit operations and technologies. The process is gradually developed from small to larger scales, incorporating compliant procedures to create current cGMP conditions. Although we have a platform-based manufacturing model, each product is unique and for each new product candidate, a developmental phase is necessary to individually customize each engineering step and to create a robust procedure that can later be implemented in a cGMP environment to ensure the production of clinical batches. This work is performed in our research and development environment to evaluate and assess variability in each step of the process in order to define the most reliable production conditions.

Our headquarters in Houston, Texas, support clinical manufacturing 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 processes 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.

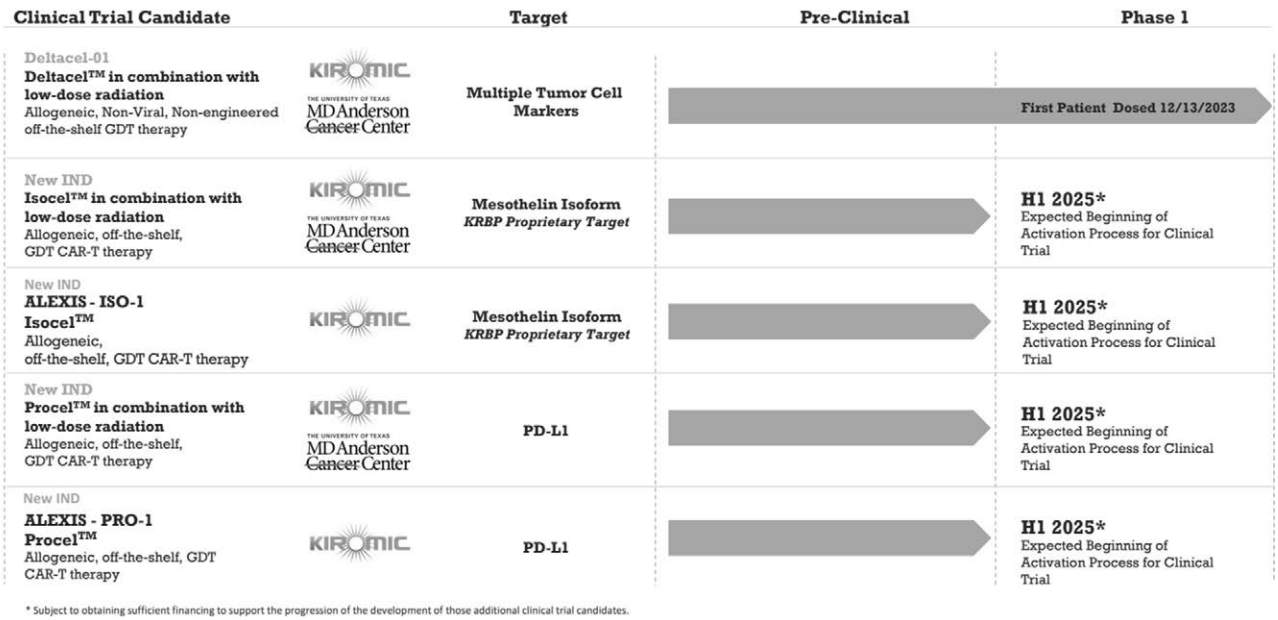
2. Outpatient Treatment – This means reduced hospitalization and other treatment-related costs. Current hospitals struggle to break even if CAR-T cell therapies are administered in the inpatient setting.

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, non-engineered, and engineered GDTs to be used for specific patients as treatments for metastatic or progressive locally advanced solid malignancies.

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)*:



If we achieve preliminary proof of efficacy from our patients in the Deltacel-01 phase 1 clinical trial, we plan to apply for a breakthrough designation in the summer of 2024.

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 continue building an intellectual property portfolio around our product candidates and our discovery programs, based on intellectual property we own as well as licensed intellectual property. We are the owners of, co-owners of, or the licensee of multiple patents and patent applications in the U.S. and worldwide. Our patent portfolio includes patent applications having claims directed to aspects of our lead product candidates, Deltacel, Procel, and Isocel, as well as other research-stage candidates and our Bioinformatics discovery platform. Our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward: (1) manufacturing processes, (2) methods of treatment for therapeutic indications, (3) antigen binding domains directed to the targets of our product candidates, (4) CAR constructs and engineered molecules.

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 U.S., patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (the "USPTO") in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the U.S., the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

License Agreements

Longwood University

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

Our Research and Development Collaborations

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 U.S. will transfer to us. Molipharma agreed 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.

On February 28, 2024, we notified Molipharma of the Company's intent not to renew, allowing the Joint Venture to expire on April 2, 2025.

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, Gilead (acquired Kite), Novartis International AG, Celgene (acquired Juno), Tmunity Therapeutics, Inc. and Unum Therapeutics Inc.

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

- *GDT cell therapy competition:* Adicet Bio, Inc., Lava Therapeutics N.V., IN8 Bio, Inc. TC Biopharm Limited, Acepodia Inc., GammaDelta Therapeutics Limited (acquired by Takeda), ImCheck Therapeutics SAS, Immatics/BMS NV.

We believe to be unique in our position to target multiple solid malignancies with a combination of non-engineered and engineered, but not gene-edited, allogeneic off-the-shelf GDT cells and to be the first to use an innovative low-dose radiation protocol in combination with our cell products.

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.

Corporate Information

Our principal executive office is 7707 Fannin, Suite 200, Houston, TX 77054. Our telephone number is (832) 968-4888. Our website is www.kiromic.com. The information contained on our website is not a part of this annual filing, nor is such

content incorporated by reference herein, and should not be relied upon in determining whether to make an investment in our common stock.

GreenPlanet Pharma

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

This business has not generated any revenues nor other income for Kiromic during the years ended December 31, 2023 or 2022.

InSilico Solutions, LLC

Our wholly owned subsidiary, InSilico Solutions, LLC ("InSilico"), operated a world class bioinformatics and AI services company. The Company completed its acquisition of InSilico on July 26, 2021, which was fully absorbed into Kiromic as of December 31, 2022, and no longer operates as an entity.

This business has not generated any revenues nor other income for Kiromic during the years ended December 31, 2023 or 2022.

Government Regulation

As a company that operates in the U.S., we are subject to extensive regulation. Biological products, such as our clinical trial candidates, are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("the FDCA"), the Public Health Service Act (the "PHSA"), the FDA regulations under Title 21 of the Code of Federal Regulations (21 CFR), as well as other federal, state and local statutes and regulations.

Government authorities in the U.S. (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, safety, efficacy 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 U.S. 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 U.S., 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 U.S., the FDA regulates pharmaceutical and biological products under the FDCA, 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 U.S. generally involves the following:

- Completion of nonclinical laboratory tests and animal studies according to good laboratory practices ("GLPs") and applicable requirements for the humane use of laboratory animals, such as the Animal Welfare Act, 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 institutional review board ("IRB") or ethics committee at each clinical site before the trial is commenced at that site.
- Performance of adequate and well-controlled human clinical trials according to the FDA's good clinical practice requirements ("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 Biologics License Application (BLA) for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials, as well as detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product candidate.
- Consideration by an FDA Advisory Committee, if applicable.
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product candidate 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 ("cGTPs") for the use of human cellular and tissue products.
- Satisfactory completion of potential FDA audits of the nonclinical study and clinical trial sites that generated the data in support of the BLA.
- FDA review and approval, or licensure, of the BLA, including agreement on post-marketing commitments, if applicable.

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 and the Animal Welfare Act. 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 an IND at any time before or during clinical trials for a biological product candidate 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 and GCP requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety, and well-being are protected. GCP requirements also include 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 ("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 or RNA molecules. IBCs are typically assigned certain review responsibilities relating to the use of recombinant DNA or RNA 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 ("DSMB"), 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 trials and clinical trials 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 candidate is initially introduced into healthy human subjects and tested for safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions, determine side effects associated with increasing doses, and, if possible, gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product candidate 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 candidate 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 candidate 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 DSMB 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 product candidates, 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 nonclinical 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.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as ClinicalTrials.gov. Additionally, a manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

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, as amended ("PDUFA"), 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. FDA performance goals generally provide for action on a BLA within 10 months of the 60-day filing date, which would be within 12 months of its submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to six months of the 60-day filing date, or eight months after submission, for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. 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 consideration, discussion and a vote on specific questions relevant to the approval decision. 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 ("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 a medication guide, communication plan, or elements to assure safe use, such as required healthcare provider or pharmacy certification, a patient registry and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS, and the FDA will not approve a BLA without a REMS.

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 ("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. 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 may take for the FDA to consider the application. 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 REMS, 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 U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. 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 U.S. 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 development and review of 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. For a fast track-designated 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. Fast track designation may be rescinded if the FDA determines the program no longer meets the qualifying criteria for the fast-track program.

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, breakthrough therapy designation, and accelerated approval. A product is eligible for priority review if is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. 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 on a 6 month, rather than the standard 10-month, timeline. 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 accelerated approval, the FDA will 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 requires as a condition for accelerated approval that promotional materials be submitted in advance of initial dissemination, which could adversely impact the timing of the commercial launch of the product. Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by the 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 the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. Breakthrough Therapy designation may be rescinded if the FDA determines the program no longer meets the qualifying criteria for breakthrough therapy. Regenerative Medicine Advanced Therapy ("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 may include more frequent meetings with the 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 will be 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 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 deem 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 (“BPCIA”) 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. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively by relying to some extent on the data generated by the reference product's sponsor, and the FDA's previous review and approval of the reference product. Under the BPCIA, a biosimilar sponsor's ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted by the FDA to the holder of the reference product's BLA. In general, no biosimilar application may be accepted by the FDA for review until 4 years after the date the reference product was first licensed by the FDA, and no biosimilar application, once accepted, may receive final approval until 12 years after the reference product was first licensed by the FDA.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., 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 Centers for Medicare and Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services ("HHS") (e.g., the Office of Inspector General, the U.S. Department of Justice ("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 of 1996 ("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, and its implementing regulations, imposes requirements on covered entity health care providers, health plans, and health care clearinghouses, as well as their “business associates” – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA, and other privacy and data security and consumer protection laws, and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, and subject to other civil and/or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. 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. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health data, which may be subject to additional protections. The landscape of federal and state laws regulating personal data is constantly evolving, and compliance with these laws requires a flexible privacy framework and substantial resources, and compliance efforts will likely be an increasing and substantial cost in the future. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation, and/or adverse publicity. Federal regulators, state attorneys general, and plaintiffs’ attorneys have been active in this space.

The Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices

in violation of Section 5(a) of the Federal Trade Commission Act ("FTC Act"). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

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 U.S. 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 U.S., 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 European Union (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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 ("AMP") for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the 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 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 (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.
- Created a licensure framework for follow on biologic products.

There have been legal challenges and legislative changes to certain aspects of the Affordable Care Act. For example, in December 2017, Congress repealed, effective January 1, 2019, 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 (the "Tax Act").

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. It is unclear how efforts to modify or challenge the Affordable Care Act or its implementing regulations, or portions thereof, will affect our business. Additional legislative and regulatory changes, and further judicial challenges, related to the Affordable Care Act remain possible. Any such changes or challenges could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates.

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 adopted 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, on average, 2% per fiscal year, which went into effect beginning on April 1, 2013, and, due to subsequent legislation, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through May 31, 2022, due to the COVID-19 pandemic. The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. 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, regulatory and enforcement interest in the U.S. with respect to specialty and other drug pricing practices. Among other things, there have been several U.S. Congressional inquiries and federal

and state legislative and regulatory activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare and other government programs, examine the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, at the federal level, 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. 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 those regarding price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. 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 U.S. to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use. The General Data Protection Regulation (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 EU, 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.

The GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the EU, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for violations of the data protection obligations. Specifically regarding the transfer of personal data outside of the EU, while there are legal mechanisms available to lawfully transfer personal data outside of the EU, including to the United States, there are certain unsettled legal issues regarding such data transfers, the resolution of which may adversely affect our ability to transfer personal data or otherwise may cause us to incur significant costs to come into compliance with applicable data transfer impact assessments and implementation of legal data transfer mechanisms. On July 16, 2020, the European Court of Justice ruled the EU-US Privacy Shield to be an invalid data transfer mechanism and confirmed that the Model Clauses remain valid, and in June 2021, the European Commission published updated versions of the Model Clauses, which must be incorporated into new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside of the EU. Data protection authorities from the different EU member states, as well as in the United Kingdom and Switzerland, have promulgated national privacy laws that impose additional requirements, which add to the complexity of processing and transferring EU personal data, with the United Kingdom and Switzerland following the EU with the publication of new Model Clauses to be incorporated in all applicable contracts within a specified timeframe in order to legitimize data transfers from those jurisdictions. Our ability to continue to transfer personal data outside of the EU, United Kingdom, or Switzerland may become significantly more costly and may subject us to increased scrutiny and liability under the GDPR or similar local laws, and we may experience operating disruptions if we are unable to conduct these transfers in the future.

California Consumer Privacy Act

The California Consumer Privacy Act ("CCPA") 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. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA and its implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. We implemented processes to manage compliance with the CCPA and continue to assess the impact of the CPRA, and other state legislation, on our business as additional information and guidance becomes available. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in the area of consumer protection. These laws and regulations are evolving and may impose limitations on our business activities. The obligations to comply with new privacy laws may require us, among other things, to update our notices and develop new processes internally and with our service providers to facilitate consumer rights requests, and such laws may impose restrictions on our processing of personal information that may impact the way we operate our business. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

Human Capital

Our Employees. As of December 31, 2023, we had a total of 35 employees all located in the United States of America. 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.

Overseas Government Regulation

In addition to regulations in the U.S., 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 U.S. 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 U.S. 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.

EU General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation, or the GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S. 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.

ITEM 1A. RISK FACTORS.

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

Risks Related to Our 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, 2023, we incurred net losses of $20,949,300 and our net cash used in operating activities was $21,225,300. As of December 31, 2023, our accumulated deficit was $122,896,800. 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, 2024. Further, we anticipate that our expenses will increase substantially if and as we:

- Continue our current research and development programs, including conducting laboratory, preclinical and greenhouse studies for product candidates.
- Initiate clinical or field trials for product candidates.
- Seek to identify, assess, acquire or develop additional research programs or product candidates.

- Maintain, expand and protect our intellectual property portfolio.
- Seek marketing approvals for any product candidates that may successfully complete development.
- Establish a sales, marketing and distribution infrastructure to commercialize any products that may obtain marketing approval.
- Further develop and refine the manufacturing process for our product candidates.
- Change or add additional manufacturers or suppliers of biological materials or product candidates.
- Validate a commercial-scale manufacturing facility compliant with cGMP.
- Further develop our genome editing technology.
- Acquire or in-license other technologies.
- Seek to attract and retain new and existing personnel.
- 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 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.
- 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 and debt financing. 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.

We have not generated any revenues to date. For the years ended December 31, 2023 and 2022, we had a net loss of $20,949,300 and $34,731,000, 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.

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 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 and device 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, Brian Hungerford, our Chief Financial Officer, Leonardo Mirandola, our Chief Scientific Officer and Scott Dahlbeck, our Chief of Staff 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 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 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 product candidates, respectively, on clinical hold (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 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.

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

We face risks associated with increased political uncertainty.

The recent invasion of Ukraine by Russia and the sanctions, bans and other measures taken by governments, organizations and companies against Russia and certain Russian citizens in response thereto has increased the political uncertainty in Europe and has strained the relations between Russia and a significant number of governments, including the U.S. The duration and outcome of this conflict, any retaliatory actions taken by Russia and the impact on regional or global economies is unknown but could have a material adverse effect on our business, financial condition and results of our operations.

In the U.S., the change in the U.S. government to the Biden administration has resulted in uncertainty regarding potential changes in regulations, fiscal policy, social programs, domestic and foreign relations and international trade policies. In addition, potential changes in relationships among the U.S. and China and other countries including Taiwan could have significant impacts on global trade and regional economic conditions, among other things. In addition, changes in the relationships between the U.S. and its neighbors, such as Mexico, could have significant, potentially negative, impacts on commerce. Further, anti-American sentiment could harm the reputation and success of U.S. companies doing business abroad.

Our ability to respond to these developments or comply with any resulting new legal or regulatory requirements, including those involving economic and trade sanctions, could reduce our sales, increase our costs of doing business, reduce our financial flexibility and otherwise have a material adverse effect on our business, financial condition and results of our operations.

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.

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.
- 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 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 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.

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 cellular 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 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.
- 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 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.
- 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.
- 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.
- 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 Breakthrough Therapy Designation (BTD) and/or Orphan Drug Designation (ODD) for some 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.

- 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 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.

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

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

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

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

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

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

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

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

- The federal 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 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.

- 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 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 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 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 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 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 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.
- 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 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 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.
- 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 Market for Our Common Stock

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

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

- Quarterly variations in our operating results compared to market expectations.
- Adverse publicity about us, the industries we participate in or individual scandals.
- Announcements of new offerings or significant price reductions by us or our competitors.
- Stock price performance of our competitors.
- Fluctuations in stock market prices and volumes.
- Changes in senior management or key personnel.
- 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.
- The other factors listed in this ''Risk Factors'' section.

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 to 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.

Because a principal stockholder controls a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of March 18, 2024, a principal stockholder beneficially owns approximately 19.67% of our outstanding shares of common stock. As a result, this stockholder has the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, this stockholder has the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

● delaying, deferring or preventing a change in corporate control;

● impeding a merger, consolidation, takeover or other business combination involving us; or

● discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

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

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

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

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock, including in connection with the sale or issuance of our common stock.

Our charter allows us to issue up to a total of 300,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 60,000,000 shares of preferred stock. To raise additional capital, we may in

the future sell or issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders or in settlement of claims against us, which could result in substantial dilution to the interests of existing stockholders.

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.

Security breaches, cyber-attacks, or other disruptions or incidents could expose us to liability and affect our business and reputation.

We are increasingly dependent on our information technology systems and infrastructure for our business. We, our collaborators and our service providers collect, store, and transmit sensitive information including intellectual property, proprietary business information, clinical trial data and personal information in connection with our business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees, nation-state and nation-state supported actors, and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

We have implemented information security measures to protect our systems, proprietary information, and sensitive data against the risk of inappropriate and unauthorized external use and disclosure and other types of compromise. However, despite these measures, and due to the ever-changing information cyber-threat landscape, we cannot guarantee that these measures will be adequate to detect, prevent or mitigate security breaches and other incidents and we may be subject to data breaches through cyber-attacks, malicious code (such as viruses and worms), phishing attacks, social engineering schemes, and insider theft or misuse. Any such breach could compromise our networks and the information stored there could be accessed, modified, destroyed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion.

Any security breach of other incident, whether real or perceived, could cause us to suffer reputational damage. Such incidents could result in costs to respond to, investigate and remedy such incidents, notification obligations to affected individuals, government agencies, credit reporting agencies and other third parties, legal claims or proceedings, and liability under our contracts with other parties and federal and state laws that protect the privacy and security of personal information. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial

data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the California Consumer Privacy Act, or the CCPA, became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of 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. Although there are limited exemptions for clinical trial data and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Foreign data protection laws, including, without limitation, the European Union Directive 95/46/EC, or the Directive, and the European Union's General Data Protection Regulation, or the GDPR, that became effective in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union and the United Kingdom, including in relation to use, collection, analysis, and transfer (including cross-border transfer) of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibit, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR increases our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 1C. CYBERSECURITY.

We believe cybersecurity is critical to advancing our technological developments. As a biopharmaceutical company, we face a multitude of cybersecurity threats that range from attacks common to most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our business strategy, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Risk Management

We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. We have established cybersecurity security awareness training and ongoing monitoring.

In the event of an incident, we intend to follow our cybersecurity incident response plan, which outlines the steps to be followed from incident detection to mitigation, and notification. We contract with external firms that have extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks. As a biopharmaceutical company, we must comply with extensive regulations, including requirements imposed by the Federal Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. We believe we are positioned to meet the requirements of the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach. We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a clinical site, subcontractor, or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to us so that we can assess the direct impact of the incident.

Governance

The Audit Committee has oversight responsibility for risks and incidents relating to cybersecurity threats, including compliance with disclosure requirements, cooperation with law enforcement, and related effects on financial and other risks, and it reports any findings and recommendations, as appropriate, to the full Board for consideration. Senior management regularly discusses cyber risks and trends and, should they arise, any material incidents with the Audit Committee.

While we have not experienced any material cybersecurity threats or incidents in recent years, there can be no guarantee that we will not be the subject of future threats or incidents. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See “Risk Factors” for a discussion of cybersecurity risks.

ITEM 2. PROPERTIES.

We lease our corporate headquarters at 7707 Fannin Street, Suite 140 in Houston, Texas under a noncancelable operating lease expiring in April 2026. Our lease agreement contains approximately 34,400 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on April 30, 2026. The termination date is effective after a 90-day notice of cancellation.

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

ITEM 3. LEGAL PROCEEDINGS.

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

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 16,667 shares of common stock at a price of $15.00 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 16,667 shares of our common stock at a price of $5.10 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 on July 21, 2022, the Compensation Committee determined that (i) the Compensation Committee has sole authority under the SOA to resolve the parties' contract interpretation dispute, and (ii) Terrell's most recent options agreement superseded and nullified any option rights Terrell may have had under his prior agreements. On August 2, 2022, the Vice Chancellor issued an order dismissing the Action for lack of subject matter jurisdiction. No further proceedings are taking place.

On August 23, 2022, Terrell filed a notice of appeal of the Vice Chancellor's order of dismissal to the Delaware Supreme Court.

Oral argument on Terrell's appeal was held before the Delaware Supreme Court on February 8, 2023. On May 4, 2023, the Delaware Supreme Court issued a written opinion (the "Opinion") reversing the Vice Chancellor's order of dismissal and remanding to Chancery Court for further proceedings consistent with the Opinion. In its Opinion, the Delaware Supreme Court affirmed several of the Chancery Court's legal determinations on the motion to dismiss, but concluded that Chancery Court itself should independently review the Compensation Committee's determinations under Delaware law. The Delaware Supreme Court also rejected Terrell's argument that the waiver clause in the third options agreement (which, according to the Company, superseded and extinguished unexercised options under the prior options agreements) was unconscionable.

Pursuant to a stipulated scheduling order, the parties submitted supplemental letter briefs to the Chancery Court in mid-August 2023, addressing the impact of the Opinion on the Company's motion to dismiss. Thereafter, the Chancery Court notified the parties that it had received the supplemental letter briefs and would take the matter under advisement without holding oral argument.

On January 31, 2024, the Chancery Court issued a letter opinion that dismissed Terrell's claims based on the contract-interpretation grounds the Company originally advanced back in 2021, as well as the Delaware Supreme Court's determination that the third options agreement was not unconscionable. The parties are required to submit a stipulated final order to the Chancery Court, reflecting the outcome of the Chancery Court's letter opinion, for approval. Should Terrell appeal the dismissal to the Delaware Supreme Court, the Company intends to vigorously argue that the Chancery Court's dismissal should be affirmed. We have determined that it is not possible to estimate a potential range of loss at this time.

Karp Class Action

On August 5, 2022, Ronald H. Karp, filed a class action complaint in the United States District Court for the Southern District of New York (the "Karp Class Action") covering the same subject matter as the Sabby Entities' and Empery Entities' claims discussed below and asserting 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 and Section 10(b) of the Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the certain statements and acts made by the defendants between June 25, 2021 and August 13, 2021.

Podmore Class Action

On October 3, 2022, Joseph Podmore filed a class action complaint in the United States District Court for the Southern District of New York (the "Podmore Class Action") covering the same subject matter as the Sabby Entities' and Empery Entities' claim discussed below asserting claims against the Company and certain 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 through the Company's public offering that closed on July 2, 2021 and Section 10(b) of the Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the certain statements and acts made by the defendants between June 25, 2021 and August 13, 2021.

The Karp Class Action and the Podmore Class Action are collectively referred to as the "Class Action". Please refer to the Settlement of the Class Action described more fully below.

Settlement in Principle of the Class Action

On August 7, 2023, we entered into a term sheet with the plaintiffs in the Class Action, to settle in principle (and globally resolve) the Class Actions. In the Class Action, the plaintiffs have made allegations and asserted claims against the Company and certain current and former directors and officers, as well as the Company's former underwriter, including for alleged violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 as well as Section 10(b) (and Rule 10b-5 promulgated thereunder) and Section 20(a) of the Securities Exchange Act of 1934 in connection with a public offering by the Company that closed on or about July 2, 2021. We subsequently reached agreement with the plaintiffs in the Class Action on all settlement materials and terms including with respect to payment of up to $2,300,000 and, on September 29, 2023, counsel for plaintiffs submitted the proposed settlement materials to the Court for approval. Of this amount, insurance will cover $570,000, resulting in a net settlement of $1,730,000 owed by the Company. See Note 8 to the consolidated financial statements for more information.

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.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is traded on the OTCQB Capital Market under the symbol "KRBP."

Stockholders

As of December 31, 2023, there were 82 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividend Policy

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

Equity Compensation Plans

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

Issuer Purchases of Equity Securities

There have been no repurchases of our shares of common stock either on the open market or by private transaction during the year ended December 31, 2023.

ITEM 6. [RESERVED].

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

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

Overview

Kiromic BioPharma, Inc. and subsidiaries (the "Company") is an allogeneic Gamma Delta T-cell therapy company featuring unique, proprietary end-to-end bioinformatic, AI targeting, and manufacturing technologies to address solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and on-site current good manufacturing practices ("cGMP"), which we believe will allow us to leverage a new framework for the next generation of cell therapies.

From a development standpoint, we utilize innovative non-engineered and engineered GDT technologies and are developing proprietary, virus-free cell engineering tools to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. Deltacel™ (Deltacel) is our first allogeneic off-the-shelf non-engineered GDT cell-based product in Phase 1 clinical stage. Our Procel™ ("Procel") and Isocel™ ("Isocel") product candidates consist of allogeneic,

engineered, off-the-shelf GDT cells and they are currently in the preclinical development stage. Our Deltacel product candidate consists of non-engineered GDTs which we expand, enrich, and activate ex- vivo through a proprietary process, and it is intended to treat solid tumors regardless of the specific tumor antigen expression. Procel consists of engineered GDTs targeting PD-L1 positive tumors, while Isocel consists of engineered GDTs targeting solid tumors expressing a tumor-specific variant (Isoform) of Mesothelin ("Iso-Meso").

We currently have three product candidates: 1) Deltacel™, non-engineered GDTs, expanded and activated with proprietary technology; 2) Isocel™, GDTs engineered with an anti-Mesothelin isoform Chimeric Antigen Receptor; and 3) Procel™, GDTs engineered with a PD-1 switch receptor.

The Company is developing a novel and virus-independent engineering method, which will result in the submission of new IND applications (clinical trial candidates 2,3,4 and 5). These applications are expected to be ready for submission to the FDA in the first half of 2025, subject to sufficient financing to support the progression of the development of those additional clinical trial candidates. Depending on evidence from preclinical studies, we may limit the new IND submission to two instead of four: one for Isocel and one for Procel.

IND #1 named Deltacel-01 study, is evaluating Deltacel™ GDTs in combination with low-dose radiation. We submitted the IND for the Deltacel-01 trial on March 31, 2023. On April 28, 2023, the FDA authorized us to proceed with the first-in-human clinical trial of Deltacel (IND #1). We began the clinical trial activation process during the second quarter of 2023. We entered into a clinical trial agreement with Beverly Hills Cancer Center (BHCC) on October 23, 2023, to conduct our Deltacel-01 Phase 1 Study in patients with stage 4 Non-Small Cell Lung Cancer (NSCLC). On February 28, 2024, we activated a second clinical trial site with Virginia Oncology Associates, PC. in our Deltacel-01 Phase 1 Study, where patient enrollment is expected to begin in April 2024. Also, we plan to open the study at one additional clinical site by the end of March 2024.

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. As discussed in more detail below, the Company is currently in discussions with financing sources in an attempt to secure short-term financing to continue operations and fund other liquidity needs through the end of the year. In the absence of such financing, management anticipates that existing cash resources will not be sufficient to meet operating and liquidity needs beyond mid-June, 2024.

Recent Developments

Terminated Equity Offering

In June 2022, we filed a registration statement with the Securities and Exchange Commission (the "SEC"), pursuant to which we planned to conduct an underwritten public offering.

As discussed in more detail under *Part II. "Item 1. Legal Proceedings"*, on March 7, 2022, entities related to Sabby Management LLC and Empery Asset Management, LP filed a complaint in the United States 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. On July 22, 2022, the plaintiffs amended their complaint to, among other things, include the underwriter of our proposed public offering as a defendant. As a result, the underwriter suspended the public offering.. As discussed below, we are currently in discussions with financing sources in an attempt to secure short-term financing to continue operations and fund other liquidity needs through the end of the year. However, there is no assurance that we will be able to secure financing on acceptable terms, if at all.

Settlement Update

On October 10, 2022, we and certain current and former officers and directors (together with us, the "Defendants") entered into a Stipulation of Settlement and Mutual Release (the "Initial Settlement Agreements") with the Empery Entities and with the Sabby Entities (collectively, the "Plaintiffs"), respectively, in connection with a case filed by the Plaintiffs against the Defendants for alleged violations of Sections 11, 12, and 15 of the Securities Act in connection with the purchase of Company's common stock through the Company's public offering that closed on July 2, 2021. Pursuant to the Initial Settlement Agreements, the Plaintiffs and the Defendants agreed to dismiss the case with prejudice against all Defendants (including ThinkEquity, LLC) with no admission of liability. As part of the Settlement, the Company agreed to (a) make a $75,000 cash payment to each of the Empery Entities and Sabby Entities and (b) issue the Settlement Notes in the

aggregate principal amount of $1,656,720 to each of the Empery Entities and Sabby Entities. The Settlement Notes were convertible into shares of the Company's common stock (the "Conversion Shares") at an initial conversion price per share of $9.20 (the "Conversion Price"), subject to a beneficial ownership limitation equivalent to 9.99% ("Beneficial Ownership Limitation").

On November 2, 2022, the Court granted a joint motion, pursuant to which the Settlement Notes would be unrestricted and exempt from the registration requirements of the Securities Act, and the Conversion Shares, when issued upon conversion of the Settlement Notes in accordance with the terms set forth therein, would also be unrestricted and exempt from the registration requirements of the Securities Act.

As of December 31, 2023, the Settlement Notes were settled and converted into 329,086 shares of common stock, at the Conversion Price. See Note 8 to the Company's Consolidated Financial Statements, "Commitment and Contingencies" for further details.

Going Concern and Liquidity

We do not have sufficient cash on hand and available liquidity to meet our obligations through the twelve months following the date the consolidated financial statements are issued. 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. Therefore, this condition raises substantial doubt about the Company's ability to continue as a going concern. See Note 1 to the Company's Consolidated Financial Statements, "Going Concern" for further details.

The Company's cash and cash equivalents were $3,204,000 as of December 31, 2023. The Company is currently in discussions with financing sources in an attempt to secure short-term financing to continue operations and fund other liquidity needs through 12 months after the date of the filing of this Annual Report on Form 10-K. The Company has begun working with a financial advisor to assist it with its efforts to obtain financing. In the absence of such financing, management anticipates that existing cash resources will not be sufficient to meet operating and liquidity needs beyond mid-June 2024. However, management is currently evaluating various cost reduction actions, including additional reductions in the Company's workforce and suspending research and development expenditures on one or more product candidates, in order to reduce the Company's expenditures and preserve cash. We are not able to predict whether any such cost reduction actions will be successful.

As a result of the Company's current liquidity position, management can provide no assurance that the Company will be able to obtain financing on acceptable terms, if at all. If financing is available, it may not be on favorable terms and may have a significant dilutive effect on our existing stockholders. In the event we are unable to secure financing sufficient to allow us to meet our obligations as they become due, we may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation. See Part I, Item 1A. "Risk Factors" for further details.

Financing Update

On October 13, 2022, we entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, Ltd. (the "Investor"). Pursuant to the SEPA, we shall have the right, but not the obligation, to sell to the Investor up to $8,000,000 (the "Commitment Amount") of our shares of common stock, par value $0.001 per share ("Common Stock"), at our request any time during the commitment period commencing on October 13, 2022 and terminating on the earliest of (i) the first day of the month following the 24-month anniversary of the SEPA and (ii) the date on which the Investor shall have made payment of any advances requested pursuant to the SEPA for shares of the Common Stock equal to the Commitment Amount. Each sale that we request under the SEPA (an "Advance") may be for the greater of (i) an amount of shares of Common Stock equal to the average of the daily traded amount of the Common Stock during the five trading days immediately preceding the notice of an Advance or (ii) $1,000,000. The shares would be purchased at 95.0% of the Market Price (as defined below) and would be subject to certain limitations, including that the Investor could not purchase any shares that would result in it owning more than 9.99% of the outstanding Common Stock after such purchase (the "Ownership Limitation").

During the year 2023, the Company issued 197,000 shares under the SEPA for $659,100.

On April 2, 2023, the Company entered into an Exchange Agreement with the holder of promissory notes to exchange an aggregate principal amount of $8 million of the Company's 25% Senior Secured Convertible Promissory Notes for 8,000 shares of Series C Stock. The $8 million Senior Secured Convertible Promissory Notes is the aggregate of four promissory notes that were issued in the previous months, for $2 million each.

On June 26, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "June 26 Note") to an accredited investor. The Note has a principal amount of $2,400,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on June 26, 2024 (the "June 26 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $6.50 per share (the "Conversion Price"), subject to a beneficial ownership limitation equivalent to 9.99% (the "Beneficial Ownership Limitation").

On July 18, 2023, the Company entered into an Exchange Agreement (the "July 18 Exchange Agreement") with the holder of promissory notes of the Company (the "Holder") pursuant to which the Holder agreed to exchange aggregate principal amount of $6 million of the Company's 25% Senior Secured Convertible Promissory Notes (the "July 18 Exchange Notes") for 6,000 shares of Series C Stock. The $6 million Senior Secured Convertible Promissory Notes is the aggregate of three promissory notes that were issued in the previous months, for $2 million each.

On July 25, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "July 25 Note") to an accredited investor. The Note has a principal amount of $2,000,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on July 25, 2024 (the "July 25 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The July 25 Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $6.50 per share, subject to a beneficial ownership limitation equivalent to 9.99% (the "Beneficial Ownership Limitation").

On August 25, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "August 25 Note") to an accredited investor. The Note has a principal amount of $2,400,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on August 25, 2024 (the "August 25 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The August 25 Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $5.00 per share, subject to a beneficial ownership limitation equivalent to 9.99% (the "Beneficial Ownership Limitation").

On September 27, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "September 27 Note") to an accredited investor. The Note has a principal amount of $2,400,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on September 27, 2024 (the "September 27 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The September 27 Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $5.00 per share, subject to a beneficial ownership limitation equivalent to 9.99% (the "Beneficial Ownership Limitation").

On November 2, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "November 2 Note") to an accredited investor. The Note has a principal amount of $2,400,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on November 2, 2024 (the "November 2 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The November 2 Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $2.50 per share, subject to a beneficial ownership limitation equivalent to 9.99% (the "Beneficial Ownership Limitation").

On December 12, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "December 12 Note") to an accredited investor. The Note has a principal amount of $2,000,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on December 12, 2024 (the "December 12 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The December 12 Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $2.50 per share, subject to a beneficial ownership limitation equivalent to 9.99% (the "Beneficial Ownership Limitation").

The unpaid principal of and interest on the Notes above constitute our unsubordinated obligations and are senior and preferred in right of payment to all our subordinated indebtedness and equity securities outstanding as of the Issuance Date; provided, however, that we may incur or guarantee additional indebtedness after the Issuance Date, whether such indebtedness are senior, pari passu or junior to the obligations under the Note, which are secured by all of our right, title and interest, in and to, (i) all fixtures (as defined in the Uniform Commercial Code, the "UCC") and equipment (as defined in the UCC), and (ii) all of our intellectual property as specified in the Note, subject to certain exclusions as described in the Notes.

NASDAQ Letter

On March 14, 2023, the Company received written notice from The Nasdaq Stock Market LLC ("**Nasdaq**") stating that the Company did not maintain a minimum bid price of at least $1.00 for a minimum of ten (10) consecutive business days before the end of the Nasdaq grace period and, therefore, did not regain compliance with Listing Rule 5550(a)(2) by March 13, 2023, as required.

As a result of the foregoing, the Staff informed the Company that its common stock would be subject to delisting from The Nasdaq Capital Market on March 23, 2023, unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). Accordingly, the Company intends to timely request a hearing before the Panel, which request will stay any delisting action by Nasdaq at least pending the issuance of the Panel's decision following the hearing and the expiration of any additional extension period granted by the Panel following the hearing. At the hearing, the Company will present its plan to evidence compliance with the minimum bid price requirement as well as present its plan to comply with Nasdaq's $2,500,000 minimum stockholders' equity requirement for continued listing as set forth in Listing Rule 5550(b)(1).

On September 12, 2023, the Company received written notice from Nasdaq that it would delist the Company's shares of common stock from the Nasdaq Capital Market upon the opening of trading on September 14, 2023. As of this date, the Company's common stock was delisted from the Nasdaq and began trading on the OTC Pink Sheets. On November 17, 2023, the Company successfully uplisted to and began trading on the OTCQB exchange. The transition of the Company's

stock to the OTCQB exchange has not had any impact on its day-to-day operations, nor does the Company anticipate an impact to its operations. The Company is also pursuing an uplist back to the NASDAQ exchange.

Clinical Update

We submitted the IND application for the Deltacel-01 trial in March 2023. On April 28, 2023, the FDA authorized us to proceed with the study. We began the clinical trial activation process during the second quarter of 2023. On October 23, 2023, we entered into a clinical trial agreement with Beverly Hills Cancer Center (BHCC) to conduct our Deltacel-01 Phase 1 Study in patients with stage 4 Non-Small Cell Lung Cancer (NSCLC). Lung cancer is the leading cause of cancer related deaths worldwide, accounting for the highest mortality rates among both men and women. On December 13, 2023, the first patient in the Deltacel-01 trial received the first dose of Deltacel at BHCC. We report no dose-limiting toxicities to date and a favorable preliminary outcome showing stabilization of disease at the 6-week follow-up, and a reduction of the tumor lesion at the two-month follow-up. As we continue to monitor this patient, we enrolled two additional patients at BHCC. On February 28, 2024, we activated a second clinical trial site with Virginia Oncology Associates, PC. in our Deltacel-01 Phase 1 Study, where patient enrollment is expected to begin in April 2024. Also, we plan to open the study at one additional clinical site by the end of March 2024. If we achieve preliminary proof of efficacy from our patients in the Deltacel-01 phase 1 clinical trial, we plan to apply for a breakthrough designation in the summer of 2024.

We plan to continue the development of Isocel and Procel, and we expect to be able to be beginning the activation process for clinical programs 2 to 5 by the first half of 2025, subject to obtaining sufficient financing to support the progression of the development of these additional clinical trial candidates.

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 U.S. Food and Drug Administration's ("FDA") authorization of our investigational new drug ("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, that the FDA was placing our IND applications that we 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, 2021 FDA Communications"). 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 it 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 Securities and Exchange Commission 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, we voluntarily contacted the SEC to report certain information about the Internal Review. Since that time, we have been voluntarily cooperating with requests for information from the SEC and intend to fully cooperate with any further requests from the SEC.

In November 2022, we received a Grand Jury Subpoena (the "Subpoena") from the U.S. Department of Justice requesting certain information from the company in connection with an ongoing investigation being conducted by the Federal Grand Jury in the Southern District of Texas. The Company is not a target of this investigation at this time.

Remediation Actions resulting from the Internal Review

1. The Board approved the inclusion of certain Risk Factors for inclusion in its periodic reports. See Part II, Item 1A. Risk Factors for further information. Such risk factors have been included in our Form 10-K for the year ended December 31, 2022, and in the Form 10-K for the year ended December 31, 2023.

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, if any; (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 Securities and Exchange Commission 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 Stock Market 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. Mr. Bersani has resigned from all Committees of the Board. Subsequently on May 10, 2022, Mr. Bersani was named Chief Executive Officer.

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 November 16, 2022, Frank Tirelli informed the Board of Directors (the " Board") of Kiromic BioPharma, Inc. (the " Company") that he was resigning his position as a director of the Company, effective immediately. Mr. Tirelli also ceased to be a member of the Audit Committee, and the Nominating and Corporate Governance Committee of the Board, effective immediately. Mr. Tirelli's resignation did not involve a disagreement with the Company on any matter relating to the Company's operations, policies or practices.

8. 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.

9. 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.

10. 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.

11. 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.

12. On December 6, 2022, Dr. Karen Reeves informed the Board of Directors (the "Board") of Kiromic BioPharma, Inc. (the "Registrant") that she was resigning her position as a director of the Registrant, effective immediately. Dr. Reeves also ceased to be a member of the Nominating and Corporate Governance Committee, and the Compensation Committee of the Board. Dr. Reeves' resignation did not involve a disagreement with the Registrant on any matter relating to the Registrant's operations, policies or practices.

13. On July 20, 2023, the Board of Directors of Kiromic BioPharma, Inc. (the "Company") appointed Pam Misajon and Mike Catlin as members of the Board of Directors.

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.
- Changes in laws or the regulatory environment affecting our company.

Emerging Growth Company

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

- Have an auditor report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.
- Comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis).

- Submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency".

- Disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

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

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering, which was October 15, 2020, (b) the date in which our total annual gross revenues exceed $1.07 billion, or (c) the date in which we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (ii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

Components of Results of Operations

Revenue

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

Research and Development Expenses

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

- Salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions.

- Expenses incurred under agreements with third parties, including contract research organizations and other third parties that conduct preclinical research and development activities and clinical trials on our behalf.

- Costs of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and future clinical trials, including the costs of contract manufacturing organizations, that will manufacture our clinical trial material for use in our preclinical studies and potential future clinical trials.

- Costs of outside consultants, including their fees and related travel expenses.

- Costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials.

- License payments made for intellectual property used in research and development activities.

- 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 comprise a larger percentage of our total expenses as we initiate Phase 1 clinical trials for our IND #1, ALEXIS-PRO-1, IND #2, ALEXIS-ISO-1, and IND #3 trial candidates and continue to discover and develop additional candidates. However, management is currently evaluating various cost reduction actions, including suspending research and development expenditures on one or more product candidates, in order to reduce the Company's expenditures and preserve cash. As of the date of this quarterly report, we are not able to predict on what product candidates and how much expenditures we plan to reduce. However, we expect that our research and development and general and administrative costs will increase over the long-term, even if we are able to successfully reduce our costs in the short-term in order to preserve cash in light of the Company's current liquidity situation.

We cannot determine with certainty the duration and costs of future clinical trials of our Deltacel, Procel, and Isocel 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 IND #1, ALEXIS-PRO-1, IND #2, ALEXIS-ISO-1, and IND #3 trial candidates and any other our trial 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 IND #1, ALEXIS-PRO-1, IND #2, ALEXIS-ISO-1, and IND #3 trial 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.

- The expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

- Our ability to effectively address the deficiencies elucidated in the FDA's clinical hold letters for our IND applications related to key chemical manufacturing and control components.

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, development, and manufacturing of product candidates. We also have incurred

and expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table sets forth key components of our results of operations for the years ended December 31, 2023 and 2022.

	Year Ended December 31,		Increase (Decrease)	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 9,624,900	$ 13,920,400	$ (4,295,500)	(31)%
General and administrative	10,314,400	17,193,900	(6,879,500)	(40)%
Total operating expenses	19,939,300	31,114,300	(11,175,000)	(36)%
Loss from operations	(19,939,300)	(31,114,300)	(11,175,000)	(36)%
Other expense:				
Interest expense	(1,852,200)	(166,500)	1,685,700	NM
Litigation settlement	(1,730,000)	(3,463,000)	(1,733,000)	(50)%
Other income	2,572,200	12,800	2,559,400	NM
Total other expense	(1,010,000)	(3,616,700)	(2,606,700)	(72)%
Net loss	$ (20,949,300)	$ (34,731,000)	$ (13,781,700)	(40)%

Research and development expenses.

The following table summarizes our change in research and development expenses by product candidate or development program:

	Year Ended December 31,		Increase (Decrease)	
	2023	2022	$	%
Direct research and development expenses by product candidate:				
AIDT-1 development costs	$ 1,034,100	$ —	$ 1,034,100	NM
ALEXIS-PRO-1	—	1,504,300	(1,504,300)	(100)%
ALEXIS-ISO-1	—	2,367,900	(2,367,900)	(100)%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	3,218,100	4,799,500	(1,581,400)	(33)%
Laboratory supplies and services	821,500	1,226,400	(404,900)	(33)%
Outsourced research and development (net of reimbursements)	1,080,700	490,900	589,800	120 %
Laboratory equipment and maintenance	2,590,800	2,026,000	564,800	28 %
Facility-related costs	707,400	1,206,000	(498,600)	(41)%
Intellectual property	100,500	330,500	(230,000)	(70)%
Other research and development costs	71,800	(31,100)	102,900	NM
Total research and development expenses	$ 9,624,900	$ 13,920,400	$ (4,295,500)	(31)%

NM – Not meaningful

The primary drivers for the reduction in research and development expenses of $4,295,500, or 31%, for the year ended December 31, 2023, compared to December 31, 2022, are as follows:

1- AIDT-1 development cost increased by $1,034,100, related to the prioritization of the Deltacel-01 development.

2- Direct research and development costs for ALEXIS-PRO-1 and ALEXIS-ISO-1 decreased by $1,504,300 and $2,367,900, respectively, related to the prioritization of Deltacel-01 and the temporary suspension of the development of these two product lines.

3- Employee-related costs decreased by $1,581,400, mainly related to a decrease in employee headcount.

4- Laboratory supplies and services decreased by $404,900, primarily due to the temporary suspension of the development of ALEXIS-PRO-1 and ALEXIS-ISO-1.

5- Outsourced research and development increased by $589,800, primarily due to the prioritization of the Deltacel-01 development.

6- Laboratory equipment and maintenance increased by $564,800, primarily due to increased depreciation expense related to purchases of equipment for the development of ALEXIS-PRO that occurred in the third quarter of 2022.

7- Facilities related costs decreased by $498,600, due to the lab expansion attributable to GDT manufacturing during the third quarter of 2022.

8- Intellectual Property expenses decreased by $230,000, related to the Company's alignment towards maintaining our key product candidates (Deltacel, Procel, and Isocel) while certain non-key and legacy technologies had patent applications which either expired or were abandoned.

9- Other research and development costs increased by $102,900 primarily due to employee related expenses incurred in 2023, as well as research and development credits received during the year ended December 31, 2022.

General and administrative expenses. The primary drivers for the reduction in general and administrative expenses of $6,879,500 or 40%, for the year ended December 31, 2023, compared to the year ended December 31, 2022, were primarily due to:

1- A decrease in legal services of $3,279,000 driven by a significant decline in expenses related to the Internal Review and related matters.

2- A decrease in employee-related expenses of $3,472,500 driven by a decline in the average headcount.

Other expenses. The primary drivers for the reduction in other expenses of $2,606,700, for the year ended December 31, 2023, compared to the year ended December 31, 2022, were primarily due to:

1- A decrease in legal settlement fees of $3,463,000 driven by a settlement reached in September 2022 on the Sabby and Empery cases related to the July 2, 2021 public offering, offset by $1,730,000 related to the settlement class action. See Note 7— Commitments and Contingencies for more discussion.

2- An increase in interest expense of $1,685,800 related to the issuance of several convertible promissory notes during the year ended December 31, 2023, compared to the year ended December 31, 2022.

3- An increase in other income of $2,559,400 related to a refund from major vendors for services incurred in clinical trials and legal matters.

Liquidity and Capital Resources

As of December 31, 2023, we had cash and cash equivalents of $3,204,000. 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.

As of February 29, 2024, our cash and cash equivalents balance was $3,896,500. We have 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.

As described above under "Going Concern and Liquidity," in the absence of financing, management anticipates that existing cash resources combined with verbal, non-contractual commitments for additional financing will not be sufficient to meet operating and liquidity needs beyond mid-June 2024. Management may further evaluate various cost reduction actions, including possible reductions in the Company's workforce and suspending research and development expenditures on one or more product candidates, in order to reduce the Company's expenditures and preserve cash. We are limited in our ability to reduce expenditures for known contractual obligations. As a result, we are not able to predict whether any cost reduction actions will be successful or how much longer any such actions will allow the Company to continue to operate without financing.

As previously disclosed, 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 over the long-term, even if we are able to successfully reduce our costs in the short-term in order to preserve cash in light of the Company's current liquidity situation. 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 on our condensed consolidated financial statements. Therefore, these condition raises substantial doubt about our ability to continue as a going concern.

Our recent planned underwritten public offering was not successful, and we are currently seeking short-term financing to be able to continue our operations past mid-June 2024. If we are successful in obtaining short-term financing to fund our operations beyond the end of the year, we intend to seek significant additional capital funding to develop our platform, hire scientific professionals and other general and administrative employees, and for 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 any such financings 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 has resulted in litigation which has adversely affected our ability to raise capital. 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 securities litigation, and other risk factors listed in Item 1A. of Part I of our Annual Report on Form 10-K for the year ended December 31, 2023. In consideration of our plans, substantial doubt is not alleviated.

Summary of Cash Flow

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

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (21,225,300)	$ (23,745,900)
Net cash used in investing activities	(206,600)	(4,865,500)
Net cash provided by financing activities	23,990,700	3,902,700
Net increase (decrease) in cash and cash equivalents	2,558,800	(24,708,700)
Cash and cash equivalents at beginning of the period	645,200	25,353,900
Cash and cash equivalents at end of the period	$ 3,204,000	$ 645,200

Cash flows from operating activities

Net cash used in operating activities was $21,225,300 for the year ended December 31, 2023, as compared to $23,745,900 for the year ended December 31, 2022. In the year ended December 31, 2023, the primary cash outflows were from the net loss of $20,949,300 compared to $34,731,000 during the year ended December 31, 2022. Net cash used in operating activities decreased by a total of $2,520,600 year-over-year, mainly due to a decrease in overall expenses. See "Results of Operations" above for further details.

Cash flows from investing activities

Net cash used in investing activities was $206,600 for the year ended December 31, 2023, as compared to $4,865,500 for the year ended December 31, 2022. Our net cash used in investing activities primarily consisted of cash flows for purchases of property and equipment for our cGMP facilities located in our leased facility in Houston, Texas.

Cash flows from financing activities

Net cash provided by financing activities was $23,990,700 during the year ended December 31, 2023, as compared to net cash used of $3,902,700 during the year ended December 31, 2022. The change in cash flows from financing activities for the periods shown are driven by the issuance of approximately $547,900 of equity, and $24,000,000 of convertible notes, offset by $557,200 of repayments of notes payable during the year ended December 31, 2023.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

Fair Value Measurements—The carrying value of our cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, other current liabilities and debt approximate their fair value.

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

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

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

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

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

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2023 or 2022.

Stock-Based Compensation— We record stock compensation expense related to our 2017 Equity Incentive Plan and 2021 Omnibus Equity Incentive Plan in accordance with ASC 718, *Compensation—Stock Compensation*. We measure and recognize stock compensation expense for all stock-based awards, including restricted stock units ("RSUs") and stock options.

Stock compensation expense for RSUs is based on estimated fair values recognized using the straight-line method over the requisite service period, as long as the performance obligations in the RSU agreement are deemed probable by management. 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 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 uses the simplified method to calculate the expected term, which is the average of the contractual term and vesting 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 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. We use our listed OTCQB Market closing price on the grant date to determine common stock valuation.

Recent Accounting Pronouncements

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

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("Topic 842"), which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects

of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On April 8, 2020, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. Accordingly, the Company has adopted Topic 842 effective January 1, 2022 using the modified retrospective approach. 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 $2,232,700, as of January 1, 2022.

In March 2020, the FASB issued ASU 2020-04, "Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting." The ASU, including subsequently issued updates, offers temporary optional expedients and exceptions for applying U.S. GAAP to modifications to agreements such as loans, debt securities, derivatives, and borrowings which reference LIBOR or another reference rate that will partially discontinue after December 31, 2021 and fully cease by June 30, 2023. The expedients and exceptions provided by the standard do not apply to modifications made and hedging relationships entered into or evaluated after that, except for hedging relationships existing as of the phase-out date that an entity has elected certain optional expedients for and are retained through the end of the hedging relationship. The ASU is effective until the replacement for LIBOR is completed. The interest rate on the Company's senior secured convertible promissory note is determined by the investor and does not fluctuate with LIBOR. As such, the Company's adoption of this standard in fiscal year 2023 did not have a significant impact on the consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, "Improvements to Reportable Segment Disclosures (Topic 280)". ASU 2023-07 modifies reportable segment disclosure requirements, primarily through enhanced disclosures about segment expenses categorized as significant or regularly provided to the Chief Operating Decision Maker (CODM). In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. This ASU is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024, with early adoption permitted. The Company currently operates as one reportable segment and does not believe there will be a material impact on the related disclosures in the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures (Topic 740)". ASU 2023-09 requires enhanced disclosures on income taxes paid, adds disaggregation of continuing operations before income taxes between foreign and domestic earnings and defines specific categories for the reconciliation of jurisdictional tax rate to effective tax rate. This ASU is effective for fiscal years beginning after December 15, 2024, and can be applied on a prospective basis. The Company is currently evaluating the impact this new standard will have on the related disclosures in the consolidated financial statements.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision, and with the participation, of our current management, including our CEO and Principal Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2023. Based on this evaluation of our disclosure controls and procedures, our management, including our CEO and Principal Financial Officer, have concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Management's Report on Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Principal Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act and based upon the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO framework").

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the U.S., and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets.
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our directors.
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision, and with the participation, of our current management, including our Chief Executive Officer and Principal Financial Officer, we have conducted an evaluation of the effectiveness of our internal control over financial reporting as defined in Rules 13a-15(f) and 15d–15(f) of the Exchange Act and based on the COSO framework. Based on this evaluation, our management determined that we maintained an effective internal control over financial reporting as of December 31, 2023.

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

Changes in Internal Control over Financial Reporting

The Company is designing and implementing new controls which it believes will improve our internal control over financial reporting as of December 31, 2023.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

PART III

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to our annual meeting of stockholders to be held in 2024 (the "2024 Annual Meeting of Stockholders"), which we intend to file with the SEC within 120 days of the year ended December 31, 2023.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2023.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2023.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2023.

ITEM 14. PRINCIPAL ACCOUNTANT'S FEES AND SERVICES.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2023.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a)(1) Financial Statements:

(a)(2) Financial Statement Schedules:

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

(a)(3) Exhibits:

See item 15(b) below.

(b) Exhibits.

The exhibits listed in the accompanying "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report, as indicated.

ITEM 16. FORM 10-K SUMMARY

None.

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
3.1	Fourth Amended and Restated Certificate of Incorporation of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 21, 2020)
3.2	Second Amended and Restated Bylaws of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
3.3	Certificate of Designation of Preferences, Rights and Limitations of the Series C Convertible Voting Preferred Stock dated March 28, 2023 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 31, 2023)
3.4	Amendment to Bylaws of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on July 18, 2023)
3.5	Amendment to Certificate of Designation of Preferences, Rights and Limitation of the Series C Convertible Voting Preferred Stock dated July 18, 2023 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on July 19, 2023)
4.1	Description of Securities (incorporated by reference to Exhibit 4.1 to the Company's Form 10-K filed on April 8, 2022)
10.1#	License Agreement, dated December 1, 2016, between Mercer University and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.2#	License Agreement, dated September 14, 2018, between CGA 369 Intellectual Holdings, Inc. and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.3#	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 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.4#	Collaboration Agreement, dated February 6, 2020, between University of Texas MD Anderson Cancer Center and Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.5†	Kiromic, Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.6†	Amended and Restated License Agreement by and between the Company and Longwood University, dated as of November 30, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 29, 2021)
10.7	Strategic Alliance Agreement by and between the Company and Leon Office (H.K.) Ltd, effective as of January 28, 2021 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 12, 2021)
10.8	Executive Employment Agreement by and between the Company and Pietro Bersani, effective as of January 27, 2022 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 2, 2022)
10.9	Confidential Information, Inventions, Non-Solicitation and Non-Competition Agreement by and between the Company and Pietro Bersani effective as of January 27, 2022 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on February 2, 2022)

10.10	Indemnification Agreement by and between the Company and Pietro Bersani effective as of January 27, 2022 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on February 2, 2022)
10.11	Standby Equity Purchase Agreement, dated October 13, 2022, by and between Kiromic Biopharma, Inc. and YA II PN, Ltd. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 19, 2022)
10.12	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 27, 2022)
10.13	Form of Note Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 26, 2023)
10.14	Form of Exchange Agreement dated as of March 28, 2023 between the Company and the holder of the Exchange Securities (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 31, 2023)
10.15	Executive Employment Agreement dated as of October 1, 2023 by and between Kiromic Biopharma, Inc. and Brian Hungerford (incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 3, 2023)
21.1*	List of Subsidiaries
23.1*	Consent of Whitley Penn LLP, independent registered public accounting firm
24.1*	Power of Attorney (included on signature page)
31.1*	Certifications of Principal Executive Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certifications of Principal Financial Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of Principal Executive Officer furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certifications of Principal Financial Officer furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within Exhibit 101

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*Filed herewith
† Executive Compensation Plan or Agreement

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

SIGNATURES

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

Date: March 18, 2024

KIROMIC BIOPHARMA, INC.

By: /s/ Pietro Bersani
Name: Pietro Bersani
Title: Chief Executive Officer (Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Pietro Bersani, as his true and lawful attorney-in-fact and agent, with the full power of substitution, for him and in his name, place, or stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, 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 his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ PIETRO BERSANI Pietro Bersani	Chief Executive Officer (Principal Executive Officer)	March 18, 2024
/s/ BRIAN HUNGERFORD Brian Hungerford	Chief Financial Officer (Principal Financial Officer)	March 18, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of Kiromic BioPharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kiromic BioPharma, Inc. and subsidiaries (collectively the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, 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, 2023 and 2022, and the results of their operations and their cash flows for the years then ended 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 entity has suffered recurring 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 these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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/ Whitley Penn

We have served as the Company's auditor since 2022.

Houston, Texas

March 18, 2024

KIROMIC BIOPHARMA, INC.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets:		
Current Assets:		
Cash and cash equivalents	$ 3,204,000	$ 645,200
Prepaid expenses and other current assets	1,226,000	1,043,700
Total current assets	4,430,000	1,688,900
Property and equipment, net	6,175,100	8,136,900
Operating lease right-of-use asset, net	1,542,500	2,117,300
Other assets	21,400	24,400
Total Assets	$ 12,169,000	$ 11,967,500
Liabilities and Stockholders' Deficit:		
Current Liabilities:		
Senior secured convertible promissory notes, net	$ 14,000,000	$ 3,809,900
Accounts payable	2,136,000	7,308,100
Accrued expenses and other current liabilities	1,673,400	881,600
Interest payable	1,937,900	142,100
Note payable	—	557,200
Operating lease liability - short term	631,000	584,400
Total current liabilities	20,378,300	13,283,300
Subordinated convertible promissory note	—	2,914,000
Operating lease liability - long term	911,500	1,544,900
Total Liabilities	21,289,800	17,742,200
Commitments and contingencies (Note 8)		
Stockholders' Deficit:		
Preferred Stock, $0.0001 par value: 60,000,000 shares authorized, 14,000 and 0 issued and outstanding, with a liquidation preference of $16,205,500 and $0, as of December 31, 2023 and December 31, 2022, respectively	2	—
Common stock, $0.001 par value: 300,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 1,258,460 and 648,384 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	1,258	648
Additional paid-in capital	113,774,740	96,172,152
Accumulated deficit	(122,896,800)	(101,947,500)
Total Stockholders' Deficit	(9,120,800)	(5,774,700)
Total Liabilities and Stockholders' Deficit	$ 12,169,000	$ 11,967,500

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Operations

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 9,624,900	$ 13,920,400
General and administrative	10,314,400	17,193,900
Total operating expenses	19,939,300	31,114,300
Loss from operations	(19,939,300)	(31,114,300)
Other expense:		
Interest expense	(1,852,200)	(166,500)
Litigation settlement	(1,730,000)	(3,463,000)
Other income	2,572,200	12,800
Total other expense	(1,010,000)	(3,616,700)
Net loss	$ (20,949,300)	$ (34,731,000)
Net loss per preferred share, basic and diluted	$ (1,103.73)	$ —
Net loss per common share, basic and diluted	$ (12.59)	$ (64.42)
Weighted average preferred shares outstanding, basic and diluted	8,773	—
Weighted average common shares outstanding, basic and diluted	1,097,630	544,475

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Stockholders' Deficit

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2021	—	$ —	516,284	$ 516	$ 94,535,784	$ (67,216,500)	$ 27,319,800
Common stock discount amortization	—	—	—	—	344,800	—	344,800
Warrants underlying common stock issuance	—	—	—	—	(344,800)	—	(344,800)
Released restricted stock units	—	—	35,257	35	(35)	—	—
Commitment shares issuance from standby equity purchase agreement	—	—	20,111	20	(20)	—	—
Letter agreement share issuance	—	—	33,333	33	(33)	—	—
Conversion of subordinated convertible notes into shares of common stock	—	—	43,399	44	399,356	—	399,400
Stock compensation expense	—	—	—	—	1,237,100	—	1,237,100
Net loss	—	—	—	—	—	(34,731,000)	(34,731,000)
Balance at December 31, 2022	—	$ —	648,384	$ 648	$ 96,172,152	$ (101,947,500)	$ (5,774,700)
Common stock discount amortization	—	—	—	—	344,700	—	344,700
Warrants underlying common stock issuance	—	—	—	—	(344,700)	—	(344,700)
Conversion of subordinated convertible notes into shares of common stock	—	—	329,086	329	2,913,671	—	2,914,000
Released restricted stock units	—	—	83,973	84	(84)	—	—
Issuance of preferred stock	14,000	2	—	—	13,999,998	—	14,000,000
Commitments shares issuance from standby equity purchase agreement	—	—	197,017	197	658,903	—	659,100
Stock issuance costs	—	—	—	—	(111,200)	—	(111,200)
Stock compensation expense	—	—	—	—	141,300	—	141,300
Net loss	—	—	—	—	—	(20,949,300)	(20,949,300)
Balance at December 31, 2023	14,000	$ 2	1,258,460	$ 1,258	$ 113,774,740	$ (122,896,800)	$ (9,120,800)

See accompanying notes to the consolidated financial statements

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (20,949,300)	$ (34,731,000)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	2,221,100	1,673,400
Operating lease non-cash expense	574,800	394,200
Stock compensation expense	141,300	1,237,100
Litigation settlement loss	—	3,313,400
Gain on sale of equipment	—	(12,800)
Amortization of debt issuance costs	—	9,900
Changes in operating assets and liabilities:		
Accounts receivable	—	16,200
Prepaid expenses and other current assets	(179,300)	662,400
Accounts payable	(5,034,700)	3,790,800
Accrued litigation liability	447,500	—
Accrued expenses and other current liabilities	344,300	140,600
Interest payable	1,795,800	142,100
Operating lease liability	(586,800)	(382,200)
Net cash used for operating activities	(21,225,300)	(23,745,900)
Cash flows from investing activities:		
Capital expenditures	(206,600)	(4,880,500)
Proceeds from sale of equiment	—	15,000
Net cash used for investing activities	(206,600)	(4,865,500)
Cash flows from financing activities:		
Proceeds from senior secured convertible note payable	24,000,000	4,000,000
Proceeds from issuance of common stock	659,100	—
Stock issuance costs	(111,200)	—
Borrowings from note payable	—	610,700
Repayments of note payable	(557,200)	(508,000)
Debt issuance costs	—	(200,000)
Net cash provided by financing activities	23,990,700	3,902,700
Net change in cash and cash equivalents	2,558,800	(24,708,700)
Cash and cash equivalents:		
Beginning of year	645,200	25,353,900
End of period	$ 3,204,000	$ 645,200
Supplemental disclosures of cash flow information:		
Cash paid for interest on note payable	$ 56,400	$ 12,200
Non-cash investing and financing activities:		
Right-of-use asset/liability recognized from ASC 842 implementation	$ —	$ 2,232,700
Exchange of 25% senior convertible promissory notes into preferred stock	$ 14,000,000	$ —
Conversion of subordinated convertible promissory notes into common stock	$ 2,914,000	$ 399,400
Property and equipment in accounts payable	$ 52,700	$ 1,303,000
Right-of-use asset/liability acquired through lease liability	$ —	$ 303,662
Deferred financing costs forgiven	$ 364,700	$ —

See accompanying notes to the 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. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

The Company is an allogeneic Gamma Delta T-cell therapy company featuring unique, proprietary, end-to-end bioinformatic, AI targeting, and manufacturing technologies to address solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and on-site current good manufacturing practices ("cGMP"), which we believe will allow us to leverage a new framework for the next generation of cell therapies.

From a development standpoint, the Company utilizes innovative engineered and non-engineered GDT manufacturing technologies and is developing proprietary, virus-free gene editing tools, to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. The Procel, Isocel, and Deltacel product platform candidates consist 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 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. Procel consists of engineered GDTs targeting PD-L1 positive tumors, while Isocel consists of engineered GDTs targeting solid tumors expressing a tumor-specific variant (Isoform) of Mesothelin ("Iso-Meso").

We currently have three product candidates: 1) Deltacel™, non-engineered GDTs, expanded and activated with proprietary technology; 2) Isocel™, GDTs engineered with an anti-Mesothelin isoform Chimeric Antigen Receptor; and 3) Procel™, GDTs engineered with a PD-1 switch receptor.

The Company is developing a novel and virus-independent engineering method, which will result in the submission of new IND applications for clinical programs. These applications are expected to be ready for submission to the FDA in the first half of 2025, subject to sufficient financing to support the progression of the developments of those additional clinical trial candidates. Depending on evidence from preclinical studies, we may limit the new IND submission to two instead of four: one for Isocel and one for Procel. Refer to Item 1- Business for more information.

Reverse Stock Split — On March 10, 2023, the Company's board of directors approved a one-for-thirty reverse split of the Company's issued and outstanding shares of common stock ("the Reverse Stock Split"). In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of common stock and the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. Any fraction of a share of common stock that would be created as a result of the Reverse Stock Split was rounded up to the next whole share. Unless noted otherwise, all common shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted for the Reverse Stock Split.

Credit Memo — During the year ended December 31, 2023, the Company entered into an engagement letter with a vendor whereby we renegotiated the terms of services to be received and the amounts to be paid for such services. As part of this negotiation, the Company obtained a credit memo (the "Credit Memo") of $1.10 million against the amounts outstanding as of June 30, 2023. This credit memo has been recognized as follows:

- Reduction to accounts payable of $1.10 million
- Reduction of deferred financing costs of $0.36 million
- Increase to other income of $0.74 million

Notice of Delisting — On September 12, 2023, the Company received written notice from the Nasdaq Stock Market, LLC ("Nasdaq") that it would delist the Company's shares of common stock from the Nasdaq Capital Market upon the opening of trading on September 14, 2023. As of this date, the Company's common stock was delisted from the NASDAQ and began trading on the OTC Pink Sheets. On November 17, 2023, the Company successfully uplisted to and began trading on the OTCQB exchange. The transition of the Company's stock to the OTCQB exchange has not had any impact on its day-to-day operations, nor does the Company anticipate an impact to its operations.

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 $21,225,300 for the year ended December 31, 2023, and an accumulated deficit of $122,896,800 as of December 31, 2023. 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. In the event the Company is unable to secure financing sufficient to allow it to meet its obligations as they become due, the Company may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation.

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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). All intercompany balances were eliminated upon consolidation. Operating results for the year ended December 31, 2023, 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 and public offering common stock, and estimating services incurred by third-party service providers used to recognize research and development expense.

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.

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.

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 $91,500 and $107,000 for the years ended December 31, 2023 and 2022, respectively, which are recorded in property and equipment.

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, 2023 and 2022.

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.

Fair Value Measurements— The carrying value of our cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, other current liabilities and debt approximate their fair value.

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

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

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

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

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

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2023 or 2022.

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 Equity Incentive Plan (the "2017 Plan") and the Omnibus 2021 Equity Incentive Plan (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 uses the 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 limited trading history for its common stock price. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of its own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

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

Common Stock Valuations. The closing price listed on the OTCQB Capital Market or previously the NASDAQ Capital Market for the Company's common stock on the date of the grant is used as the common stock valuation.

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. 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 $2,232,700, as of January 1, 2022.

In March 2020, the FASB issued ASU 2020-04, "Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting." The ASU, including subsequently issued updates, offers temporary optional expedients and exceptions for applying U.S. GAAP to modifications to agreements such as loans, debt securities, derivatives, and borrowings which reference LIBOR or another reference rate that will partially discontinue after December 31, 2021 and fully cease by June 30, 2023. The expedients and exceptions provided by the standard do not apply to modifications made and hedging relationships entered into or evaluated after that, except for hedging relationships existing as of the phase-out date that an entity has elected certain optional expedients for and are retained through the end of the hedging relationship. The ASU is effective until the replacement for LIBOR is completed. The interest rate on the Company's senior secured convertible promissory note is determined by the investor and does not fluctuate with LIBOR. As such, the Company's adoption of this standard in fiscal year 2023 did not have a significant impact on the consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, "Improvements to Reportable Segment Disclosures (Topic 280)". ASU 2023-07 modifies reportable segment disclosure requirements, primarily through enhanced disclosures about segment expenses categorized as significant or regularly provided to the Chief Operating Decision Maker (CODM). In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. This ASU is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024, with early adoption permitted. The Company currently operates as one reportable segment and does not believe there will be a material impact on the related disclosures in the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures (Topic 740)". ASU 2023-09 requires enhanced disclosures on income taxes paid, adds disaggregation of continuing operations before income taxes between foreign and domestic earnings and defines specific categories for the reconciliation of jurisdictional tax rate to effective tax rate. This ASU is effective for fiscal years beginning after December 15, 2024, and can be applied on a prospective basis. The Company is currently evaluating the impact this new standard will have on the related disclosures in the consolidated financial statements.

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, RSUs and warrants 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,	
	2023	2022
Net loss	$ (20,949,300)	$ (34,731,000)
Less: Initial Public Offering Common Stock discount amortization	(99,900)	(100,000)
Less: Public Offering Common Stock discount amortization	(244,800)	(244,800)
Less: Undeclared dividends attributable to preferred stock	(2,205,500)	—
Net loss attributable to common shareholders	$ (23,499,500)	$ (35,075,800)

	Year Ended December 31, 2023		Year Ended December 31, 2022	
	Common Stock	Preferred Stock	Common Stock	Preferred Stock
Net loss per share, basic and diluted				
Allocation of undistributed net loss	$ (13,816,900)	$ (9,682,600)	$ (35,075,800)	$ —
Weighted average shares outstanding, basic and diluted	1,097,630	8,773	544,475	—
Basic and diluted net loss per share	$ (12.59)	$ (1,103.73)	$ (64.42)	$ —

For the year ended December 31, 2023, there were 59,632 restricted stock units and 15,416 warrants, that were potentially dilutive securities excluded from the computations of diluted weighted-average shares of common stock.

During the year ended December 31, 2023, the Company entered into an Exchange Agreement whereby outstanding promissory notes totaling $14,000,000 were exchanged for 14,000 shares of Series C Convertible Voting Preferred Stock (the "Series C Stock"). See Note 10 for details about conversion price. The Series C Stock accrues an annual 25% dividend, whether or not declared, which if unpaid is added to the aggregate liquidation preference. During the year ended December 31, 2023, the preferred shareholders earned $2,205,500 of preferred dividends. The dividends were not accrued on the condensed consolidated balance sheet as of December 31, 2023, as these dividends were not declared.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at:

	December 31, 2023	December 31, 2022
Equipment	$ 3,126,300	$ 3,041,900
Leasehold improvements	7,372,100	7,298,500
Office furniture, fixtures, and equipment	137,300	137,300
Software	359,500	359,500
Construction in progress	101,300	—
	11,096,500	10,837,200
Less: Accumulated depreciation	(4,921,400)	(2,700,300)
Total	$ 6,175,100	$ 8,136,900

Depreciation expense was $2,221,100 and $1,673,400 for the years ended December 31, 2023 and 2022, 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, 2023	December 31, 2022
Accrued litigation	$ 447,500	$ —
Accrued compensation	864,900	668,700
Accrued consulting and outside services	361,000	212,900
Total	$ 1,673,400	$ 881,600

6. NOTE PAYABLE

In November 2022, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $610,700 with an annual interest rate of 8.49%, to be paid over a period of eleven months. As of December 31, 2022, this remaining payable balance on the financed amount was $557,200. As of December 31, 2023, this financing arrangement was paid in its entirety.

7. SENIOR SECURED CONVERTIBLE PROMISSORY NOTE

The Company began issuing senior secured convertible promissory notes (each a "CPN" and together the "Notes") payable to a private accredited investor (the "Investor") during 2022. The Company has continued to issue notes to the Investor during 2023.

Through December 31, 2023, the Company has issued to the Investor thirteen notes totaling $28,000,000, of which $24,000,000 were issued during year ended December 31, 2023. The notes are each 25% Senior Secured Convertible Promissory Notes with largely consistent terms including a stated interest rate of 25% per year, a stated conversion price subject to a beneficial ownership limitation and share cap representing a certain percentage of the outstanding shares of Common Stock at the time of conversion, and a one-year maturity. As of December 31, 2023, there were six outstanding notes. Two outstanding notes with a value of $2,400,000, were each issued with a conversion price of $6.50. Two outstanding notes with a value of $2,400,000 were each issued with a conversion price of $5.00. One outstanding note with a value of $2,400,000 was issued with a conversion price of $2.50, and one outstanding note with a value of $2,000,000 was issued with a conversion price of $2.50.

The stated interest rates for these notes increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon the occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the related note on the respective maturity date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency law.

In April 2023 and July 2023, the Company executed an exchange agreement to convert $8,000,000 and $6,000,000 of the senior secured promissory notes principal into shares of preferred stock, respectively. See Note 10 – Stockholder's Deficit for further discussion.

	December 31, 2023	December 31, 2022
Senior secured convertible promissory note, maturing December 12, 2023	$ —	$ 4,000,000
Senior secured convertible promissory note, maturing June 26, 2024	2,400,000	—
Senior secured convertible promissory note, maturing July 25, 2024	2,400,000	—
Senior secured convertible promissory note, maturing August 25, 2024	2,400,000	—
Senior secured convertible promissory note, maturing September 27, 2024	2,400,000	—
Senior secured convertible promissory note, maturing November 2, 2024	2,400,000	—
Senior secured convertible promissory note, maturing December 12, 2024	2,000,000	—
Total convertible promissory note	$ 14,000,000	$ 4,000,000
Less: unamortized debt issuance costs	—	(190,100)
Convertible promissory note, net	$ 14,000,000	$ 3,809,900

As part of the recognition of the Credit Memo, our deferred financing costs related to the convertible debt were derecognized. See Note 1 for more information.

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 December 31, 2023 and 2022, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Legal Proceedings

Jason Terrel Claim

On March 22, 2021, Jason Terrell ("Terrell"), a former consultant 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 16,667 shares of our common stock at a price of $15.00 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 16,667 shares of common stock at a price of $5.10 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 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 on July 21, 2022, the Compensation Committee determined that (i) the Compensation Committee has sole authority under the SOA to resolve the parties' contract interpretation dispute, and (ii) Terrell's most recent options agreement superseded and nullified any option rights Terrell may have had under his prior agreements. On August 2, 2022, the Vice Chancellor issued an order dismissing the Action for lack of subject matter jurisdiction.

On August 23, 2022, Terrell filed a notice of appeal of the Vice Chancellor's order of dismissal to the Delaware Supreme Court.

Oral argument on Terrell's appeal was held before the Delaware Supreme Court on February 8, 2023. On May 4, 2023, the Delaware Supreme Court issued a written opinion (the "Opinion") reversing the Vice Chancellor's order of dismissal and remanding to Chancery Court for further proceedings consistent with the Opinion. In its Opinion, the Delaware Supreme Court affirmed several of the Chancery Court's legal determinations on the motion to dismiss, but concluded that Chancery Court itself should independently review the Compensation Committee's determinations under Delaware law. The Delaware Supreme Court also rejected Terrell's argument that the waiver clause in the third options agreement (which, according to the Company, superseded and extinguished unexercised options under the prior options agreements) was unconscionable.

Pursuant to a stipulated scheduling order, the parties submitted supplemental letter briefs to the Chancery Court in mid-August 2023, addressing the impact of the Opinion on the Company's motion to dismiss. Thereafter, the Chancery Court notified the parties that it had received the supplemental letter briefs and would take the matter under advisement without holding oral argument.

On January 31, 2024, the Chancery Court issued a letter opinion that dismissed Terrell's claims based on the contract-interpretation grounds the Company originally advanced back in 2021, as well as the Delaware Supreme Court's determination that the third options agreement was not unconscionable. The parties are required to submit a stipulated final order to the Chancery Court, reflecting the outcome of the Chancery Court's letter opinion, for approval. Should Terrell appeal the dismissal to the Delaware Supreme Court, the Company intends to vigorously argue that the Chancery Court's dismissal should be affirmed.

Sabby and Empery Claims

On February 2, 2022, 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"). The Company did not disclose the June 16 and 17, 2021 FDA Communications in 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"). The Company then consummated a public offering of $40 million of its common stock pursuant to the Registration Statement on July 2, 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. 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."

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 United States District Court for the Southern District of New York asserting 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. On July 1, 2022, the defendants filed motions to dismiss the complaint. In response, on July 22, 2022, the plaintiffs amended their complaint to, among other things, include the Company's underwriters on the July 2, 2021 public offering, ThinkEquity LLC, as a defendant. 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 two parties reached a settlement agreement in

principle on September 26, 2022, which the Company's board of directors approved on September 27, 2022. The settlement contained a cash component of $75,000 payable to Sabby Entities and $75,000 to Empery Entities.

As part of the settlement, the Company also agreed to issue convertible notes (the "Settlement Notes") in the aggregate principal amount of $1,656,720 to each of the Empery Entities and the Sabby Entities. The Settlement Notes are convertible into shares (the "Conversion Shares") of the Company's common stock at an initial conversion price per share of $9.20 and can be convertible into a maximum of 180,000 shares of the Company's common stock to each of the Empery Entities and Sabby Entities, subject to the adjustment of the conversion price and a beneficial ownership limitation equivalent to 9.99%. The United States District Court for the Southern District of New York granted a motion jointly filed by the plaintiffs and defendants, pursuant to which the Settlement Notes will be unrestricted and exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Conversion Shares, when issued upon conversion of the Settlement Notes in accordance with the terms set forth therein, will also be unrestricted and exempt from the registration requirements of the Securities Act.

This settlement loss resulted in an expense charged as a separate line item within Other expenses on the consolidated statement of operations for $3,463,000 for the year ended December 31, 2022. There was also a related subordinated convertible promissory note totaling $2,914,000 on the balance sheet at December 31, 2022, which Empery held $1,502,700 and Sabby held $1,411,300. During the year ended December 31 ,2023, Empery and Sabby converted the totality of their notes into shares of common stock of 163,268 and 153,333, respectively, at a share price of $9.20.

Karp Class Action

On August 5, 2022, Ronald H. Karp, filed a class action complaint in the United States District Court for the Southern District of New York (the "Karp Class Action") covering the same subject matter as the Sabby Entities' and Empery Entities' claims discussed above and asserting 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 and Section 10(b) of the Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the certain statements and acts made by the defendants between June 25, 2021 and August 13, 2021.

Podmore Class Action

On October 3, 2022, Joseph Podmore filed a class action complaint in the United States District Court for the Southern District of New York (the "Podmore Class Action") covering the same subject matter as the Sabby Entities' and Empery Entities' claim discussed above asserting claims against the Company and certain 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 through the Company's public offering that closed on July 2, 2021 and Section 10(b) of the Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the certain statements and acts made by the defendants between June 25, 2021 and August 13, 2021.

The Karp Class Action and the Podmore Class Action are collectively referred to as the "Class Action". Please refer to the Settlement of the Class Action described more fully below.

Settlement in Principle of the Class Action

On August 7, 2023, we entered into a term sheet with the plaintiffs in the Class Action, to settle in principle (and globally resolve) the Class Actions. In the Class Action, the plaintiffs have made allegations and asserted claims against the Company and certain current and former directors and officers, as well as the Company's former underwriter, including for alleged violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 as well as Section 10(b) (and Rule 10b-5 promulgated thereunder) and Section 20(a) of the Securities Exchange Act of 1934 in connection with a public offering by the Company that closed on or about July 2, 2021. We subsequently reached agreement with the plaintiffs in the Class Action on all settlement materials and terms including with respect to payment of up to $2,300,000 and, on September 29, 2023, counsel for plaintiffs submitted the proposed settlement materials to the Court for approval. Of this amount, insurance will cover $570,000, resulting in a net settlement of $1,730,000 owed by the Company. As of December 31, 2023, we have paid $1,282,500 to the plaintiffs, with a remaining balance of $447,500 to be payable according to the term sheet, and recorded in accrued expenses and other current liabilities.

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.

Company 401(k) Plan— During the year ended December 31, 2022, the Company started a defined contribution 401(k) plan covering substantially all full-time employees. Employees are permitted to make voluntary contributions, which the Company matches up to a certain percentage. The plan contribution expense was $220,500 and $291,800 for the years ended December 31, 2023 and December 31, 2022, respectively. These amounts are allocated between research and development and general and administrative expenses in the income statement.

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. 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 December 31, 2023, 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 added 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.

Another amendment to the lease agreement was executed in May 2022 and commenced August 2, 2022. The amendment added approximately 1,458 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on April 30, 2026. In year one, the monthly rent is $2,430 per month, in years two and three monthly rent is $2,490 per month, and in year five monthly rent is $2,552 per month.

There are no variable payments associated with the lease agreements, as the rent payments are predetermined on a fixed schedule and disclosed above.

The following table indicates the balance sheet line items that include the right-of-use assets and lease liabilities for our operating lease:

	December 31, 2023	December 31, 2022
	Operating lease	Operating lease
Right-of-Use Asset		
Operating lease	$ 1,542,500	$ 2,117,300
Total right-of use asset	$ 1,542,500	$ 2,117,300
Lease Liabilities		
Operating lease - short term	$ (631,000)	$ (584,400)
Operating lease - long term	(911,500)	(1,544,900)
Total lease liabilities	$ (1,542,500)	$ (2,129,300)

For the year ended December 31, 2023 and December 31, 2022, the components of lease expense were as follows:

	Years Ended	
	December 31, 2023	December 31, 2022
Operating lease cost allocated to research and development expense	$ 393,900	$ 473,200
Operating lease cost allocated to general and administrative expense	322,200	189,900
Total lease expense	$ 716,100	$ 663,100
Weighted-average remaining lease term	2.34	3.34
Weighted-average discount rate	7.12 %	7.12 %

As of December 31, 2023, the maturities of the Company's operating lease liabilities were as follows:

Maturity of Lease Liabilities	Operating lease
2024	$ 717,600
2025	724,700
2026	242,800
Total lease payments	1,685,100
Less: imputed interest	(142,600)
Present value of lease payments	$ 1,542,500

The Company maintained a month-to-month lease in Arlington, VA, until October 1, 2022, which was 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 recognized the lease payments in profit or loss in the statement of operations on a straight-line basis over the term of the lease. The monthly rent expense prior to termination of the lease was $2,500 per month. For the year ended December 31, 2022, short-term lease expense was $22,500.

The Company entered into a sublease of three suites for the use of certain fixture, fixtures and equipment on June 2, 2023. The lease commenced on June 5, 2023 under an operating lease agreement that is noncancelable until April 29, 2026. The monthly rent is $6,444 and remains flat during the period of the lease. The rent income received for this sublease is recorded in other income.

10. STOCKHOLDERS' DEFICIT

Stock—As of December 31, 2023 and 2022, the Company was authorized to issue 60,000,000 shares of preferred stock (24,000,000 shares designated as Series A-1 Preferred Stock and 16,500,000 shares designated as Series B Preferred stock) and 300,000,000 shares of common stock (1,258,460 and 648,384 shares issued and outstanding, respectively). Additionally, for the year ended December 31, 2023, the Company authorized the issuance of 14,000 shares of Series C Convertible Voting Preferred Stock (the "Series C Stock"). The Company issued 8,000 shares of Series C Stock on April 2, 2023 and 6,000 shares of Series C Stock as part of the two Exchange agreements discussed below, of which 14,000 shares remain outstanding as of December 31, 2023.

The Series C Stock is convertible into shares of the Company's common stock, par value $0.001 per share. The Series C Preferred Stock is voting stock and holders of the Series C Preferred Stock are entitled to vote together with the Common Stock on an as-if-converted-to-Common-Stock basis as determined by dividing the Liquidation Preference with respect to such shares of Series C Preferred Stock by the Conversion Price. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters submitted to a vote of stockholders. Accordingly, holders of Series C Preferred Stock will be entitled to one vote for each whole share of Common Stock into which their Series C Preferred Stock is then-convertible on all matters submitted to a vote of stockholders.

Cumulative Rights of Series C Stock Shareholders— The Series C Stock accumulates undeclared dividends at an annual rate of 25%. Unpaid dividends and undeclared dividends are added to the aggregate Liquidation Preference, which also includes the face value of the Series C Stock outstanding. In the event of any liquidation of the Company, holders of shares of Series C Stock then outstanding shall be entitled to be paid the Liquidation Preference out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of any other shares of capital. As of December 31, 2023 and December 31, 2022, the outstanding Liquidation Preference of the Series C Stock is $16,205,500 and $0, respectively.

Participating Rights of Series C Stock Shareholders— In the event the Company declares a dividend, and all cumulative dividends have been distributed, the Series C stock participates in any remaining declared dividends to be paid equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends paid on shares of common stock.

Exchange Agreements

On April 2, 2023, the Company entered into an Exchange Agreement with the holder of promissory notes to exchange an aggregate principal amount of $8 million of the Company's 25% Senior Secured Convertible Promissory Notes for 8,000 shares of Series C Stock. The $8 million Senior Secured Convertible Promissory Notes is the aggregate of four promissory notes that were issued in the previous months, for $2 million each.

On July 18, 2023, the Company entered into an Exchange Agreement (the "July 18 Exchange Agreement") with the holder of promissory notes of the Company (the "Holder") pursuant to which the Holder agreed to exchange aggregate principal amount of $6 million of the Company's 25% Senior Secured Convertible Promissory Notes (the "July 18 Exchange Notes") for 6,000 shares of Series C Stock. The $6 million Senior Secured Convertible Promissory Notes is the aggregate of three promissory notes that were issued in the previous months, for $2 million each.

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 2,083 shares of common stock at an exercise price of $450.00 per share, which is 125% of the IPO price. The Underwriters' Warrants have a five-year term and were not exercisable prior to April 13, 2021. All of the Underwriters' Warrants were outstanding and exercisable as of December 31, 2023 and 2022.

In connection with the public offering on July 2, 2021, the Company granted the underwriters warrants to purchase an aggregate of 13,333 shares of common stock at an exercise price of $187.50 per share, which is 125% of the IPO price. The Underwriters' Warrants have a five-year term and were not exercisable prior to January 2, 2022. All of the Underwriters' Warrants were outstanding as of December 31, 2023 and 2022. The warrants related to the Public Offering stock discount wll be fully amortized in April 2025.

Standby Equity Purchase Agreement Financing

On October 13, 2022, the Company entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, Ltd. (the "Investor"). Pursuant to the SEPA, the Company has the right to sell to the Investor up to $8,000,000 (the "Commitment Amount") of its shares of common stock, par value $0.001 per share ("Common Stock"), at the Company's request any time during the commitment period commencing on October 13, 2022 and terminating on the earliest of (i) the first day of the month following the 24-month anniversary of the SEPA or (ii) the date on which the Investor has paid for shares of Common Stock equal to the Commitment Amount.

The shares would be purchased at 95.0% of the Market Price (as defined in the agreement) and would be subject to certain limitations, including that the Investor could not purchase any shares that would result in it owning more than 9.99% of the outstanding Common Stock after such purchase (the "Ownership Limitation") or an aggregate of 19.9% of the outstanding Common Stock as of the date of the SEPA (the "Exchange Cap"). The Exchange Cap will not apply under certain circumstances, including to any sales of Common Stock under the SEPA that equal or exceed $9.33, representing the lower of (i) the closing price of the Common Stock as reflected on Nasdaq.com immediately preceding the date of the SEPA, or (ii) the average closing price of the Common Stock for the five trading days immediately preceding the date of the SEPA.

Pursuant to the SEPA, the Company also paid a subsidiary of the Investor, a structuring fee in the amount of $10,000 and issued to the Investor 20,111 shares of Common Stock as a commitment fee on October 13, 2022 (the "Commitment Shares"). The Company incurred a stock-based compensation expense of $193,665 related to this issuance. In the event of the Commitment Increase, the Company will issue to the Investor an additional number of shares of Common Stock determined by dividing $120,000 by the average of the daily VWAPs for the five trading days prior to the date of delivery by the Company of written notice of the Commitment Increase.

In connection with the SEPA agreement, on October 31, 2022, the Company entered into a letter agreement with an accredited investor (the "Investor"), pursuant to which the Company agreed to issue to the Investor 33,333 shares (the "Shares") of the Company's common stock in consideration of the Investor's services to the Company in identifying investors. The Company issued the Shares to the Investor on October 31, 2022 and incurred a stock-based compensation expense of $298,000 related to this issuance. The Shares were issued in reliance upon the exemption from the registration requirements of the Securities Act, provided by Section 4(a)(2) of the Securities Act as sales by an issuer not involving any public offering.

Total compensation recognized in general and administrative expenses for the issuance of the Commitment Shares and the shares issued to the Investor totaled $491,665 during the year ended December 31, 2022.

On May 24, 2023, we exercised the Commitment increase under the SEPA and issued to YA II PN, Ltd. 97,000 shares of common stock at a purchase price of $3.89, for an advance amount of $377,000.

On June 2, 2023, we exercised an additional Commitment increase under the SEPA and issued to YA II PN, Ltd. 100,000 shares of common stock at a purchase price of $2.82, for an advance amount of $282,100.

11. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan— Restricted Stock Units

The following table summarizes the activity for all RSUs outstanding under the 2017 Plan at:

	2023		2022	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of period	650	$ 259.50	17,028	$ 374.40
Granted	—	—	—	—
Vested	(273)	255.85	(433)	297.00
Cancelled and forfeited	(57)	260.10	(15,945)	382.50
Nonvested RSUs at December 31	320	$ 285.36	650	$ 259.50

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, 2023 and 2022, as follows:

	December 31,	
	2023	2022
Research and development	$ 26,400	$ 38,900
General and administrative	32,100	22,200
Total	$ 58,500	$ 61,100

As of December 31, 2023, there was $255,800 unrecognized stock compensation expense related to unvested restricted stock units.

2017 Stock Incentive Plan— Stock Options

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

	2023		2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	11,286	$ 254.40	12,697	$ 257.10
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled and forfeited	(5,433)	215.35	(1,411)	277.50
Balance at December 31	5,853	$ 285.36	11,286	$ 254.40
Options exercisable at December 31:	5,853	$ 285.36	11,218	$ 256.20

In addition, the weighted average remaining contractual life for the options is 3.93 years and 4.93 years as of December 31, 2023 and December 31, 2022, respectively. The options have no intrinsic value as of December 31, 2023 or December 31, 2022.

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, 2023 and 2022, as follows:

	December 31,	
	2023	2022
Research and development	$ —	$ 65,000
General and administrative	—	30,000
Total	$ —	$ 95,000

As of December 31, 2023, there was no unrecognized stock compensation expense related to unvested stock options.

As of December 31, 2022, total unrecognized stock compensation expense is $4,700, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 0.29 years.

2021 Stock Incentive Plan—Restricted Stock Units

The following table summarizes the activity for all RSUs outstanding under the 2021 Plan at:

	2023		2022	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of period	684	$ 133.20	2,068	$ 165.60
Granted	138,343	1.45	24,610	12.30
Vested	(83,700)	0.23	(25,241)	33.00
Cancelled and forfeited	(621)	126.60	(753)	206.40
Nonvested RSUs at December 31	54,706	$ 1.56	684	$ 133.20

Total stock compensation expense recognized from stock-based compensation awards classified as RSUs were recognized in the consolidated statements of operations for years ended December 31, 2023 and 2022, as follows:

	December 31,	
	2023	2022
Research and development	$ 37,700	$ 56,300
General and administrative	44,900	302,200
Total	$ 82,600	$ 358,500

The vested outstanding restricted stock units that have not been released to grantees as of December 31, 2023, were included in calculation of weighted average common shares outstanding, basic and diluted (See Note 3, Net Loss Per Common Share). The Company plans to release these shares to the grantees in the near future. Since there is a possibility that any portion of those shares could be sold as part of the release, the shares will be released in compliance with the Company's insider trading policy when there is an open trading window and grantees are not in possession of any material non-public information.

2021 Stock Incentive Plan — Stock Options

The following table summarizes the activity for all stock options outstanding at December 31, 2023 under the 2022 Plan:

	2023		2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	21,420	$ 12.90	—	$ —
Granted	—	—	24,480	12.90
Exercised	—	—	—	—
Cancelled and forfeited	(9,180)	12.90	(3,060)	—
Balance at December 31	12,240	$ 12.90	21,420	$ 12.90
Options exercisable at December 31:	12,240	$ 12.90	21,420	$ 12.90
Weighted average grant date fair value for options granted during the year:		$ —		$ 10.80

In addition, the stock options had weighted average remaining contractual life of 3.93 years. There was no stock compensation expense during the year ended December 31, 2023 or December 31, 2022.

12. INCOME TAXES

For the years ended December 31, 2023 and 2022, 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, 2023 and 2022.

	2023	2022
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, 2023 or 2022 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:

	2023	2022
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 16,178,000	$ 12,668,900
Stock compensation expense	470,700	3,371,900
Research and development tax credit	2,156,300	874,400
Sec. 174 Research and experimentation expense	3,206,600	2,293,000
Property and equipment	260,200	105,800
Intangible assets	81,600	88,500
Lease liability	323,900	428,400
Accrued expenses	139,700	158,500
Total gross deferred tax assets	22,817,000	19,989,400
Valuation allowance	(22,493,100)	(19,563,500)
Right-of-use assets	(323,900)	(425,900)
Net deferred tax assets (liabilities)	—	—

As of December 31, 2023 and 2022, the Company has U.S. net operating loss ("NOL") carryforwards of $77,037,900 and $60,328,200, respectively. NOL carryforwards of $6,126,173 are subject to expiration beginning in 2036. The remaining approximately $70,911,727 of NOL carryforwards may be carried forward indefinitely until it is fully utilized.

The NOL carryforwards may be subject to annual limitations due to "change in ownership" provisions of Internal Revenue Code Section 382 ("Section 382") that can be triggered due to future ownership changes. Additionally, the NOL loss carryforwards are subject to examination and adjustments by the Internal Revenue Service until the statute of limitations closes on the year in which the NOL is utilized.

As of December 31, 2023 and 2022, 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, 2023, the Company is not currently under audit by any income tax authority.

13. SUBSEQUENT EVENTS

Issuance of Senior Secured Convertible Promissory Note

On January 8, 2024, February 12, 2024 and March 7, 2024, the Company issued a 25% Senior Secured Convertible Promissory Note to an investor (each a "Subsequent Note" and together the "Subsequent Notes"). Each Subsequent Note has a principal amount of $2,000,000, bears interest at a rate of 25% per annum and matures 365 days from the date of issuance, on which the principal balance and accrued but unpaid interest under each Subsequent Note is due and payable. The interest rate for each Subsequent Note will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

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 U.S. will transfer to us. Molipharma agreed 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.

On February 28, 2024, we notified Molipharma of the Company's intent not to renew, allowing the Joint Venture to expire on April 2, 2025.