As Confidentially Submitted to the Securities and Exchange Commission on November 15, 2019

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

KIROMIC, INC.
(Exact name of registrant as specified in its charter)

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

7707 Fannin, Suite 140
Houston, TX 77054
(832) 968-4888
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Maurizio Chiriva Internati, DBSc., Ph.Ds.
Chief Executive Officer
7707 Fannin, Suite 140
Houston, TX 77054
(832) 968-4888
(Names, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
Louis A. Bevilacqua, Esq.
Bevilacqua PLLC
1050 Connecticut Avenue, NW, Suite 500
Washington, DC 20036
(202) 869-0888

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

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Aggregate Offering Price Per Unit(2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value $0.0001 per share	[ ]	$[ ]	$[ ]	$[ ]
Common Stock, par value $0.0001 per share, issuable upon the exercise of warrants	29,347,827	$[ ]	$[ ]	$[ ]

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares being registered hereunder include such indeterminate number of shares as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

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

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 15, 2019

Common Stock

Kiromic, Inc. ("we," "us," "our" or "our company") is offering up to [ ] shares of its common stock and the selling stockholders named herein are offering up to 39,130,436 shares of common stock, including 9,782,609 shares issuable upon the conversion of series B preferred stock and 29,347,827 shares issuable upon the exercise of warrants held by the selling stockholders, at a fixed price of $[ ] per share in a direct public offering. The offering is being made on a self-underwritten, "best efforts" basis. The selling stockholders may, or may not, elect to sell their shares of common stock covered by this prospectus, as and to the extent they may determine. Such sales, if any, will be made through brokerage transactions on the Nasdaq Stock Market. See the section titled "Plan of Distribution." This is our initial public offering and no public market currently exists for our shares of common stock.

Our Chief Executive Officer, without commission or other remuneration, will sell the common stock to be sold by us. The offering does not require that we sell a minimum number of shares; therefore, not all of the shares may be sold. The amount raised may be minimal and there is no assurance that we will be able to raise sufficient amount to cover our expenses and may not even cover the costs of the offering. Should we be successful in selling all of the common stock offered, we will receive $[ ] in proceeds before expenses. Any funds received as a part of this offering will be immediately available to us for our use. We have not made any arrangements to place the proceeds from this offering in an escrow, trust or similar account. We will not receive any proceeds from the sale of shares by the selling stockholders.

This offering will terminate on the earlier of (i) the date when the sale of all shares is completed, (ii) when our board of directors decides that it is in the best interest of our company to terminate the offering prior to the completion of the sale of all shares or (iii) March 31, 2020, unless extended for up to an additional three months in the sole discretion of our board of directors.

Prior to this offering, there has been no public market for our common stock. We intend to apply to list our common stock on the Nasdaq Global Select Market under the symbol "KRBP." There can be no assurance that our common stock will be approved for listing on the Nasdaq Global Select Market, or that our common stock will ever be listed or quoted on a stock exchange or a quotation service or that any market for our common stock will develop.

We are an "emerging growth company" as defined in the Jumpstart Our Business Act of 2012, as amended, and, as such, are eligible for reduced public company reporting requirements.

An investment in our securities is highly speculative, involves a high degree of risk and should be considered only by persons who can afford the loss of their entire investment. See "Risk Factors" beginning on page 13 of this prospectus.

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

The date of this prospectus is [ ], 2019

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You should rely only on the information contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We have not authorized anyone to provide you with different information. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus, or any free writing prospectus, as the case may be, or any sale of common stock.

For investors outside the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus outside the United States.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, you are cautioned not to give undue weight to this information.

PROSPECTUS SUMMARY

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

THE COMPANY

Overview

We are a clinical stage immuno-oncology, target discovery and gene editing company developing tumor-specific cancer engineered immunotherapies to face and defeat multiple cancer types. We are focused on extending the benefits of immunotherapy by leveraging our proprietary technologies. Our approach seeks to generate a therapeutic immune response in patients by unleashing the demonstrated natural power of a patient's own immune system to recognize tumor-specific peptide sequences presented on cancer cells, known as tumor specific iso-antigens, capable of generating an immunological response and therefore eradicate cancer cells.

We are developing our brand of chimeric antigen receptor, or CAR, T cell product candidates known as ALEXIS (Autologous/Allogenic Leading Ixogenous Isoform). These are designed to treat cancer in the safest and most effective way by capitalizing on the immune system's ability to destroy cancer cells. These products are in the early stages of the U.S. Food and Drug Administration, or FDA, clinical trial process.

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

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

Engineered T Cell Therapy

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

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

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

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

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

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

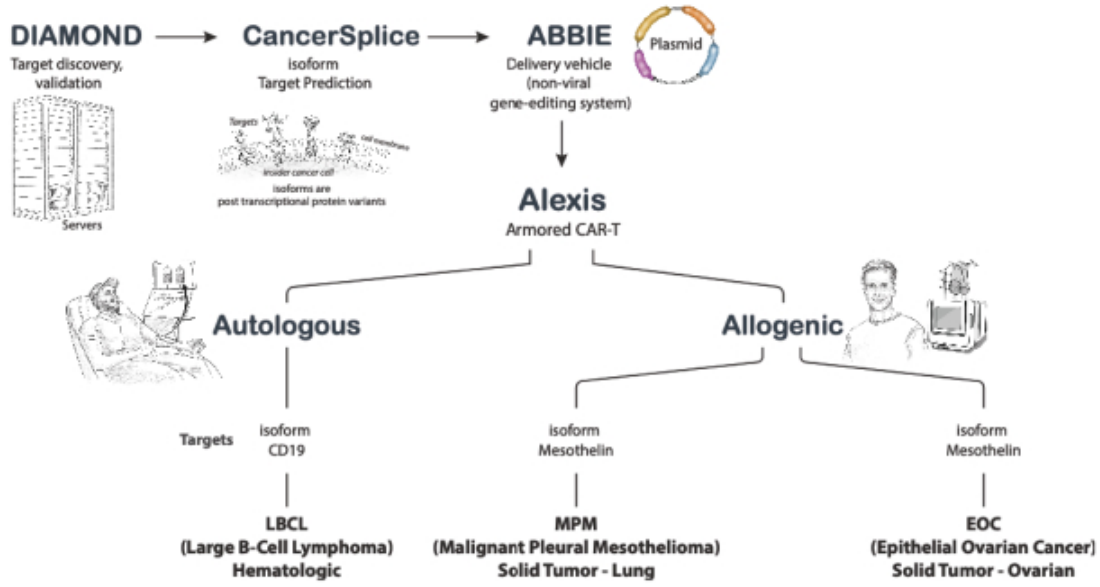
Allogenic engineered T cells are manufactured in a similar manner as autologous, but with two key differences: (1) allogenic T cells are derived from healthy donors, not cancer patients, and (2) allogenic T cells must be genetically engineered to minimize the risk of graft-versus-host disease, a condition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

Our Approach

Our operating motto is Better Target, Better Life ™.

Our goal is to defeat cancer by developing immunotherapies by improving the target discovery and validation. With better targets, we believe our therapies will be more effective than the current crop of immunotherapies using old targets which cannot adapt to rapidly mutating targets.

We plan to use our proprietary technologies, Diamond, CancerSplice and ABBIE, to develop our products. Our development schema below describes our path forward for developing CAR T products for refractory CAR T patients.



Diamond (Screening, Prioritizing, and Harmonizing)

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

Diamond addresses the main challenges in today's clinical pipeline: target identification. Diamond generates a prioritized list of cancer immunological targets for T cells and B cells. These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR T cell therapies and vaccine therapies.

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

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

CancerSplice (Isoform Target Prediction)

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

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

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

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

Finally, CancerSplice also shows a box plot by tissue of expression of the isoform in normal cancer genome atlas tissues and a box plot of the matching isoform in genotype-tissue expression program normal data. The sequence of amino acids that are specific for the selected cancer isoforms are then directly fed to Diamond's artificial neural capsule network for peptide design and prioritization. Therefore, we believe that we have developed unique tools to address the issue with tumor specific iso-antigens through CancerSplice and Diamond.

ABBIE (Delivery Vehicle)

We are currently developing ABBIE (A Binding-Based Integrase Enzyme) for delivery our product candidates. ABBIE is a non-viral gene editing mechanism to insert the target DNA template information into the T cell genome. ABBIE allows the creation of the plasmid ("glue") that goes through the membrane to the nucleus and inserts the genome template into the T cells so that they could express CAR T.

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

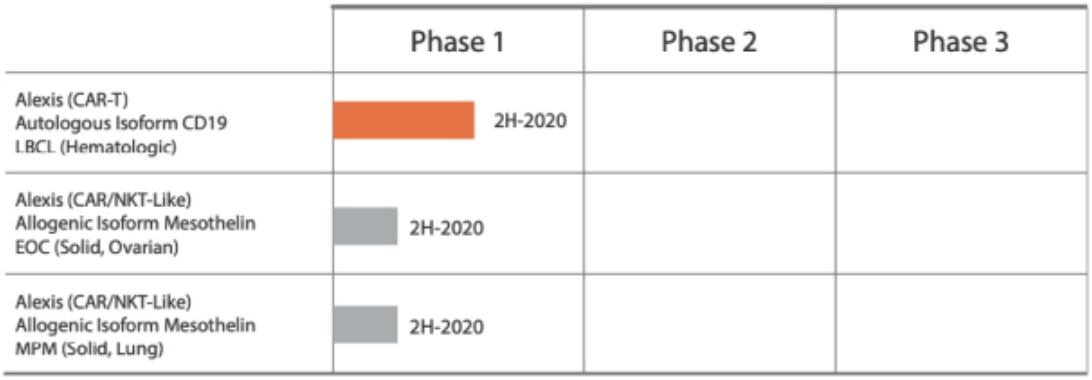
We believe that this gene delivery platform will deliver the DNA template to the T cell genomes at a lower cost and shorter time versus a viral vector. By comparison, a retrovirus vector would have a longer development lead time (12 months) with an increased insertional mutagenesis risk. Insertional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

Our Product Pipeline and Development

Using our proprietary technologies, we are researching and developing multiple product candidates for the treatment of blood cancers and solid tumors. Our product candidates are autologous and allogenic T cells engineered to be used for specific patients or as off-the-shelf treatments for any patient with a particular cancer type. Each product candidate targets a selected antigen expressed on tumor cells and bears specific engineered attributes.

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

Our product pipeline is represented in the diagram below:



ALEXIS ISOFORM CD19

ALEXIS ISOFORM CD19 is our autologous CAR T cell product candidate targeting isoform CD19. This product is currently undergoing preparation for an investigational new drug, or IND, enabling trial. Following the IND enabling trial, we will be applying for a full IND with the FDA.

ALEXIS ISOFORM CD19 targets isoform CD19, an antigen expressed on the surface of B cells, including malignant B cells. In addition to these indications, CD19 targeting CAR T therapies have shown preliminary efficacy in chronic lymphocytic leukemia, mantle cell lymphoma and low-grade non-Hodgkin lymphomas, such as follicular lymphoma or marginal zone lymphoma.

ALEXIS ISOFORM CD19 targets large B cell lymphoma, or LBCL. According to the American Cancer Society, approximately 30,000 individuals are diagnosed with LBCL in the U.S. each year, and 200,000 worldwide. Out of the 30,000 U.S. patients who are initially diagnosed with LBCL each year, we believe that approximately 2,100 (7%) will eventually be eligible for our CAR T cell therapy.

ALEXIS ISOFORM Mesothelin EOC

ALEXIS ISOFORM Mesothelin EOC is our allogenic CAR/NKT-Like cell product candidate targeting isoform mesothelin. We are still planning clinical trials before submitting this product for authorization. ALEXIS ISOFORM Mesothelin EOC represents an innovative approach for stage IV platinum resistant epithelial ovarian cancer and involves the use of cells which are “like” natural killer T cells.

ALEXIS ISOFORM Mesothelin EOC targets epithelial ovarian cancer, or EOC. According to the Foundation for Ovarian Cancer, a chapter of the American Cancer Society, approximately 22,000 individuals are diagnosed with EOC in the U.S. each year, and 300,000 worldwide. Out of the 22,000 U.S. patients who are initially diagnosed with EOC each year, we believe that approximately 15,400 (70%) will eventually be eligible for our CAR/NKT-Like cell therapy.

ALEXIS ISOFORM Mesothelin MPM

ALEXIS ISOFORM Mesothelin MPM is our allogenic CAR/NKT-Like cell product candidate targeting isoform mesothelin. We are still planning clinical trials before submitting this product for authorization. ALEXIS ISOFORM Mesothelin MPM represents an innovative approach for malignant pleural mesothelioma and involves the use of cells which are “like” natural killer T cells.

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

According to the American Cancer Society, approximately 3,000 individuals are diagnosed with MPM in the U.S. each year, and 30,000 worldwide. Out of the 3,000 U.S. patients who are initially diagnosed with MPM each year, we believe that approximately 4,400 (80%) will eventually be eligible for our CAR/NKT-Like cell therapy.

Our Risks and Challenges

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

- We have never been profitable and may never achieve or maintain profitability.
- If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.
- We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.
- Our business is dependent on the successful development, regulatory approval and commercialization of our personalized immunotherapy product candidate, ALEXIS ISOFORM CD19, which is in the early stages of development and has not been tested in humans.
- Our tumor-specific cancer immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.
- We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our immunotherapy candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

- The genome editing field is relatively new and evolving rapidly, and other existing or future technologies may provide significant advantages over our Diamond, CancerSplice and ABBIE technologies, which could materially harm our business.
- The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies.
- If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.
- Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators.
- We have entered into significant arrangements with collaborators and expect to depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.
- We expect to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.
- We may rely on third parties for the manufacturing process of product candidates, and failure by those parties to adequately perform their obligations could harm our business.
- If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.
- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.
- 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.
- The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.
- 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.
- We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- Negative public opinion and increased regulatory scrutiny of genetic research and therapies involving gene editing may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.
- The products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

- Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.
- The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.
- Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantage.
- Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.

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

Our Corporate History

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

We have one wholly-owned subsidiary, GreenPlanet Pharma, Inc., which was incorporated in the State of Delaware on November 26, 2018. GreenPlanet Pharma, Inc., operates an oral healthcare business. It has developed a mouthwash using a high quality, safe, and natural ingredient formulation to provide effective symptomatic relief for a wide range of oral irritations and health concerns. This subsidiary has not generated any revenues.

Corporate Information

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

Implications of Being an Emerging Growth Company

Upon the completion of this offering, we will qualify as an “emerging growth company” under Jumpstart Our Business Act of 2012, as amended, or the JOBS Act. As a result, we will be permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

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

- submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay” and “say-on-frequency;” and
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

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

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

THE OFFERING	
Shares offered	We are offering up to [ ] shares of common stock and the selling stockholders named herein are offering up to 39,130,436 shares of common stock, including 9,782,609 shares issuable upon the conversion of series B preferred stock and 29,347,827 shares issuable upon the exercise of warrants held by the selling stockholders.
Offering price	$[ ] per share.
Shares outstanding before this offering	100,050,000 shares of common stock, 21,822,301 shares of series A-1 preferred stock and 9,782,609 shares of series B preferred stock.
Shares outstanding after this offering	[ ] shares of common stock, 21,822,301 shares of series A-1 preferred stock, and no shares of series B preferred stock (assuming that the maximum number of shares being offered by us are sold and that all shares of series B preferred stock are converted to common stock and then sold in this offering). See “Description of Securities” for information regarding our series A-1 preferred stock and series B preferred stock.
Duration of offering	This offering will terminate on the earlier of (i) the date when the sale of all shares is completed, (ii) when our board of directors decides that it is in the best interest of our company to terminate the offering prior to the completion of the sale of all shares or (iii) March 31, 2020, unless extended for up to an additional three months in the sole discretion of our board of directors.
Use of proceeds	We estimate our net proceeds from this offering will be approximately $[ ] if the maximum number of shares being offered by us are sold, assuming an initial public offering price of $[ ] per share, after deducting estimated offering expenses payable by us. We will not receive any proceeds from the sale of shares by the selling stockholders. We plan to use the net proceeds of this offering primarily for the Phase 1/2 clinical trials for our ALEXIS ISOFORM CD19 product candidate, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and general corporate purposes. The details of our plans are set forth in the “Use of Proceeds” section.
Risk factors	Investing in our common stock involves a high degree of risk and purchasers of our common stock may lose part or all of their investment. See “Risk Factors” for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed trading market and symbol	We intend to apply to list our common stock on the Nasdaq Global Select Market under the symbol “KRBP.”

The number of shares outstanding is based on shares outstanding as of November 13, 2019 and excludes the following:

- 29,347,827 shares of our common stock issuable upon the exercise of outstanding warrants with an exercise price of $0.0001 per share;
- 22,401,071 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of $0.32 per share; and
- up to an additional 7,548,929 shares of our common stock issuable under our 2017 Equity Incentive Plan.

SUMMARY FINANCIAL INFORMATION

The following summary historical financial information should be read in conjunction with our financial statements and related notes included elsewhere in the prospectus and the information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

The following summary financial data as of December 31, 2018 and 2017 and for the years then ended have been derived from our audited consolidated financial statements included elsewhere in this prospectus.

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

	Years Ended December 31,	
	2018	2017
Statements of Operations Data		
Operating expenses:		
Research and development	$ 1,424,900	$ 2,312,400
General and administrative	1,757,700	3,080,200
Total operating expenses	3,182,600	5,392,600
Loss from operations	(3,182,600)	(5,392,600)
Other expense	(633,100)	(420,800)
Net loss	$ (3,815,700)	$ (5,813,400)
Net loss per share—basic and diluted	$ (0.04)	$ (0.06)

	As of December 31,	
	2018	2017
Balance Sheet Data		
Cash and cash equivalents	$ 384,300	$ 1,049,500
Current assets	560,200	1,419,000
Total assets	876,000	1,681,100
Current liabilities	610,700	472,100
Total liabilities	610,700	6,960,500
Stockholders' equity (deficit)	265,300	(5,279,400)
Total liabilities and stockholders' equity (deficit)	$ 876,000	$ 1,681,000

RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Additionally, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other

strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

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

We identified material weaknesses in our internal control over financial reporting at December 31, 2018, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Though we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not effective.

Notwithstanding the foregoing, in connection with the audit of our financial statements for the year ended December 31, 2018, we and our auditors identified certain control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses resulted from (i) our lack of a formalized internal control framework, (ii) our lack of segregation of duties in the financial reporting process, and (iii) our lack of qualified technical accounting

personnel. These remain material weakness as of the date of this prospectus. In order to remediate this material weakness, we have hired and plan to continue to hire additional accounting, finance, system engineers, and data analysts. We have implemented, and plan to continue to implement, new controls, new processes and technologies to implement formalized internal controls framework and procedures. We cannot assure you that the measures that we have taken to remediate, and that will be taken to remediate, these material weaknesses will be sufficient to prevent future material weaknesses from occurring. We also cannot assure you that we have identified all of our existing material weaknesses.

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

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

Risks Related to our Product Candidates

Our business is dependent on the successful development, regulatory approval and commercialization of our personalized immunotherapy product candidate, ALEXIS ISOFORM CD19, which is in the early stages of development and has not been tested in humans.

We have no products approved for sale. We intend to submit an IND for our initial product candidate, ALEXIS ISOFORM CD19 in the near future. As such, we face significant translational risk with ALEXIS ISOFORM CD19 specifically and our tumor-specific immunotherapy approach generally. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of ALEXIS ISOFORM CD19, as well as other product candidates derived from our tumor-specific immunotherapy approach, which may never occur.

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

We have not previously submitted a biologics license application, or BLA, to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, ALEXIS ISOFORM CD19 or any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

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

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

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

- patient demand for our current or future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidate or any future product candidates to continue our business or achieve profitability.

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

We are using our proprietary technologies to develop tumor-specific immunotherapy product candidates to treat cancer. Our foundational science and product development approach are based on our ability to predict the presence of a patient's tumor-specific iso-antigens, or TSIAs, and develop a TSIA-directed therapy that will elicit a meaningful specific immune-system cell response (T or NKT-Like 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 been limited tested in humans 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 NKT-Like cell response to effectively destroy a tumor.

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

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

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

Diamond, CancerSplice and ABBIE are novel technologies, making it difficult to predict the time, cost and potential success of product candidate development. We have not yet been able to assess the safety and efficacy of any product candidates in humans. Our success depends on our ability to develop and commercialize product

candidates using our novel genome editing technology ABBIE. The novel nature of our technology makes it difficult to accurately predict the developmental challenges we may face for product candidates as they proceed through research, preclinical or greenhouse studies and clinical or field trials.

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

Current or future product candidates may not meet safety and efficacy requirements for continued development or ultimate approval in humans and may cause significant adverse events or toxicities. All of our product candidates are designed to act at the level of DNA, and because animal DNA differs from human DNA, it will be difficult for us to test our therapeutic product candidates in animal models for either safety or efficacy, and any testing that we conduct may not translate to their effects in humans. Moreover, animal models may not exist for some of the targets, diseases or indications that we intend to pursue.

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

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

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

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

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

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

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

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

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

Even if we do commence clinical trials of product candidates and continue to identify new product candidates, such product candidates may never be approved. Failure to successfully identify and develop new product candidates and obtain regulatory approvals for our products would have a material adverse effect on our business and financial condition and could cause us to cease operations.

If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.

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

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

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

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

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

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

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

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

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

Risks Related to Our Organization, Structure and Operations

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

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing and, if we retain commercialization responsibility for any product candidate we develop alone or with collaborators, sales and marketing personnel, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms or at all given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities

and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

- limited availability of resource allocation and other developmental decisions made by our collaborators about the product candidates or technologies that we seek to develop with them may result in the delay or termination of research programs, studies or trials, repetition of or initiation of new studies or trials or provision of insufficient funding or resources for the completion of studies or trials or the successful marketing and distribution of any product candidates that may receive approval;
- collaborators could independently develop, or develop with third parties, product candidates or technologies that compete directly or indirectly with our product candidates or technologies if the collaborators believe that competitive products or technologies are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization activities or that result in costly litigation or arbitration that diverts management attention and resources.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. If our collaborations do not result in

the successful development and commercialization of product candidates or technologies, or if one of our collaborators terminates its agreement with us, we may not receive any future funding or milestone or royalty payments under the collaboration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may rely on third parties for the manufacturing process of product candidates, and failure by those parties to adequately perform their obligations could harm our business.

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

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

If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market any of our or our collaborators' potential products.

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

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

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

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

Risks Related to Government Regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical

data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product.

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

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

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

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

our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

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

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

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

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

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

trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

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

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our CAR T cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

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

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

If and when our planned Phase 1 clinical trials for ALEXIS ISOFORM CD19 and our other initial product candidates are completed and, assuming positive data, we expect to advance to potential registrational trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. If the results from our clinical trials are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA. For example, the FDA may require that we conduct a comparative trial against an approved therapy including potentially an approved autologous T cell therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will review our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

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

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

We may seek Regenerative Medicine Advanced Therapy, or RMAT, designation for one or more of our product candidates. In 2017, the FDA established the RMAT designation to expedite review of a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. There is no assurance that we will be able to obtain RMAT designation for any of our product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

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

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the

introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. President's administration may impact our business and industry. Namely, the current U.S. President's administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of

marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

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

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

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

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

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

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

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

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

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

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

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

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates, if approved, profitably. In particular, in 2010 the Affordable Care Act was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute. We are still unsure of the full impact that the Affordable Care Act will have on our business.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. On January 22, 2018, the U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain

Affordable Care Act-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. At the federal level, the U.S. President’s administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the current U.S. President’s administration released a “Blueprint”, or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or the HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is

available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the current U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

Risks Related to Intellectual Property

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

The patent positions of biopharmaceutical and biotechnology companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, or 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 circumvented. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter parties review 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 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.

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

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 advantage.

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

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

- we may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we may not be the first to file patent applications covering product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our compositions and methods may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions or methods of use thereof;
- others may design around our patent claims to produce competitive technologies or products that fall outside of the scope of our patents;
- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;

- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- 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; and
- the growing scientific and patent literature relating to engineered endonucleases, including our own patents and publications, may make it increasingly difficult or impossible to patent new engineered nucleases in the future.

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

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

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

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

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.

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

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

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

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

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

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

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

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

For example, we are aware of certain patents held by third parties relating to the modification of T/NKT-Like cells, including the production of CAR-T/NKT-Like cells. Although conducting clinical trials and other development activities with respect to our CAR-T/NKT-Like product candidates is not considered an act of infringement in the United States, if and when any of our CAR-T/NKT-Like product candidates may be approved by the FDA, those third parties may seek to enforce their patents by filing a patent infringement lawsuit against us.

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

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

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

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

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

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

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

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause

product shipment delays or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology.

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

Risks Related to this Offering and the Market for Our Common Stock

Our listing differs significantly from an underwritten initial public offering.

This is not an underwritten initial public offering of our common stock. The proposed listing of our common stock on Nasdaq differs from an underwritten initial public offering in several significant ways, which include, but are not limited to, the following:

- There are no underwriters. Consequently, prior to the opening of trading on Nasdaq, there will be no book building process and no price at which underwriters initially sold shares to the public to help inform efficient and sufficient price discovery with respect to the opening trades on Nasdaq. Therefore, buy and sell orders submitted prior to and at the opening of trading of our common stock on Nasdaq will not have the benefit of being informed by a published price range or a price at which the underwriters initially sold shares to the public, as would be the case in an underwritten initial public offering. Moreover, there will be no underwriters assuming risk in connection with the initial resale of shares of our common stock. Additionally, because there are no underwriters, there is no underwriters' option to purchase additional shares to help stabilize, maintain, or affect the public price of our common stock on Nasdaq immediately after the listing. In an underwritten initial public offering, the underwriters may engage in "covered" short sales in an amount of shares representing the underwriters' option to purchase additional shares. To close a covered short position, the underwriters purchase shares in the open market or exercise the underwriters' option to purchase additional shares. In determining the source of shares to close the covered short position, the underwriters typically consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the underwriters' option to purchase additional shares. Purchases in the open market to cover short positions, as well as other purchases underwriters may undertake for their own accounts, may have the effect of preventing a decline in the market price of shares. Given that there will be no underwriters' option to purchase additional shares and no underwriters engaging in stabilizing transactions, there could be greater volatility in the public price of our common stock during the period immediately following the listing.
- Except for up to [ ] shares that we are offering, there is not a fixed or determined number of shares of common stock available for sale. There can be no assurance that any selling stockholder will sell any of their shares of common stock and there may initially be a lack of supply of, or demand for, shares of common stock on Nasdaq. Alternatively, we may have a large number of selling stockholders who choose to sell their shares of common stock in the near term, resulting in potential oversupply of our common stock, which could adversely impact the public price of our common stock once listed on Nasdaq.
- None of our selling stockholders or other existing stockholders have entered into contractual lock-up agreements or other contractual restrictions on transfer. In an underwritten initial public offering, it is customary for an issuer's officers, directors, and most or all of its other stockholders to enter into a 180-day contractual lock-up arrangement with the underwriters to help promote orderly trading immediately after such initial public offering. Consequently, any of our stockholders, including our directors and officers and other significant stockholders, may sell any or all of their shares of common stock at any time (subject to any restrictions under applicable law), including immediately upon listing. If such sales were to occur in a significant volume in a short period of time following the listing, it may result in an oversupply of our common stock in the market, which could adversely impact the public price of our common stock.

- We will not conduct a traditional "roadshow" with underwriters prior to the opening of trading of our common stock on Nasdaq. Instead, are engaging in certain investor education meetings. There can be no guarantee that these investor education meetings will have the same impact on investor education as a traditional "roadshow" conducted in connection with an underwritten initial public offering. As a result, there may not be efficient or sufficient price discovery with respect to our common stock or sufficient demand among potential investors immediately after our listing, which could result in a more volatile public price of our common stock.
- We have agreed to indemnify the selling stockholders for certain claims arising in connection with sales under this prospectus. Large indemnity payments could adversely affect our business, results of operations, and financial condition.

Such differences from an underwritten initial public offering could result in a volatile market price for our common stock and uncertain trading volume, which may adversely affect your ability to sell any common stock that you may purchase.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. We intend to apply for the listing of our common stock on the Nasdaq Global Select Market under the symbol "KRBP." There is no guarantee that Nasdaq, or any other exchange or quotation system, will permit our common stock to be listed and traded. If we fail to obtain a listing on the Nasdaq Global Select Market, we may seek quotation on the OTCQX Best Market or OTCQB Venture Market operated by OTC Markets Group Inc. These markets are inter-dealer, over-the-counter markets that provide significantly less liquidity than Nasdaq.

Even if our common stock is approved for listing on the Nasdaq Global Select Market, a liquid public market for our common stock may not develop. The initial public offering price for our common stock has been determined by us based upon several factors, including prevailing market conditions, our historical performance, estimates of our business potential and earnings prospects, and the market valuations of similar companies. The price at which the common stock is traded after this offering may decline below the initial public offering price, meaning that you may experience a decrease in the value of your common stock regardless of our operating performance or prospects.

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

After this offering, the market price for our common stock is likely to be volatile, in part because our shares have not been traded publicly. In addition, the market price of our common stock may fluctuate significantly in response to several factors, most of which we cannot control, including:

- quarterly variations in our operating results compared to market expectations;
- adverse publicity about us, the industries we participate in or individual scandals;
- announcements of new offerings or significant price reductions by us or our competitors;
- stock price performance of our competitors;
- fluctuations in stock market prices and volumes;
- changes in senior management or key personnel;
- changes in financial estimates by securities analysts;
- the market's reaction to our reduced disclosure as a result of being an "emerging growth company" under the JOBS Act;

- negative earnings or other announcements by us or our competitors;
- defaults on indebtedness, incurrence of additional indebtedness, or issuances of additional capital stock;
- global economic, legal and regulatory factors unrelated to our performance; and
- the other factors listed in this “Risk Factors” section.

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

None of our stockholders are party to any contractual lock-up agreement or other contractual restrictions on transfer. Following our listing, sales of substantial amounts of our common stock in the public markets or the perception that sales might occur, could cause the market price of our common stock to decline.

In addition to the supply and demand and volatility factors discussed above, sales of a substantial number of shares of our common stock into the public market, particularly sales by our directors, executive officers and principal stockholders, or the perception that these sales might occur in large quantities, could cause the market price of our common stock to decline.

As of November 14, 2019, we have 100,050,000 shares of common stock, 21,822,301 shares of series A-1 preferred stock, 9,782,609 shares of series B preferred stock and warrants for the purchase of 29,347,827 shares of common stock outstanding, all of which are “restricted securities” (as defined in Rule 144 under the Securities Act). Approximately [ ] of these shares may be immediately sold either by the selling stockholders pursuant to this prospectus or by our other existing stockholders under Rule 144 since such shares held by such other stockholders will have been beneficially owned by non-affiliates for at least one year. Moreover, once we have been a reporting company subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act for 90 days and assuming the availability of certain public information about us, (i) non-affiliates who have beneficially owned our common stock for at least six months may rely on Rule 144 to sell their shares of common stock, and (ii) our directors, executive officers, and other affiliates who have beneficially owned our common stock for at least six months, including certain of the shares of common stock covered by this prospectus to the extent not sold hereunder, will be entitled to sell their shares of our common stock subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

Further, as of November 14, 2019, we had 22,401,071 options outstanding that, if fully exercised, would result in the issuance of shares of common stock. All of the shares of common stock issuable upon the exercise of stock options, and an additional 7,548,929 shares reserved for future issuance under our equity incentive plans, will be registered for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance, subject to applicable vesting requirements and compliance by affiliates with Rule 144. A potential oversupply of shares due to sales by these holders could adversely impact the public price of our common stock.

None of our stockholders are subject to any contractual lock-up or other contractual restriction on the transfer or sale of their shares.

We also may issue our capital stock or securities convertible into our capital stock from time to time in connection with a financing, acquisition, investments, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the public price of our common stock to decline.

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

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

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

If you purchase shares in this offering, you will pay more for your shares of common stock than the amount paid by our existing stockholders for their shares on a per share basis. As a result, you will experience immediate and substantial dilution in net tangible book value per share in relation to the price that you paid for your shares. We expect the dilution as a result of the offering to be $[ ] per share to new investors purchasing our shares in this offering if the maximum number of shares being offered are sold, assuming a public offering price of $[ ] per share. In addition, you will experience further dilution to the extent that our shares are issued upon the vesting of restrictive stock or exercise of stock options under any stock incentive plans. All of the shares issuable under our then stock incentive plans will be issued at a purchase price on a per share basis that is less than the assumed public offering price per share in this offering. See “Dilution” for a more complete description of how the value of your investment in our shares will be diluted upon completion of this offering.

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

We intend to the proceeds from this offering primarily for the Phase 1/2 clinical trials for our ALEXIS ISOFORM CD19 product candidate, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and general corporate purposes. However, we have considerable discretion in the application of the proceeds. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of this offering. The net proceeds may be used for corporate or other purposes with which you do not agree or that do not improve our profitability or increase our share price. The net proceeds from this offering may also be placed in investments that do not produce income or that lose value.

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

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

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

In the future, we may attempt to increase our capital resources by entering into additional debt or debt-like financing that is secured by all or up to all of our assets, or issuing debt or equity securities, which could include issuances of commercial paper, medium-term notes, senior notes, subordinated notes or shares. In the event of our liquidation, our lenders and holders of our debt securities would receive a distribution of our available assets before distributions to our stockholders. In addition, any additional preferred stock, if issued by our company, may have a preference with respect to distributions and upon liquidation, which could further limit our ability to make distributions to our stockholders. Because our decision to incur debt and issue securities in our future offerings will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings and debt financing.

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

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

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

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

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

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $[ ] if the maximum number of shares being offered by us are sold, after deducting the estimated offering expenses payable by us. This estimate is based upon an assumed initial public offering price of $[ ] per share. We will not receive any proceeds from the sale of shares by the selling stockholders.

The primary purposes of this offering are to create a public market for our common stock for the benefit of all stockholders, retain talented employees by providing them with equity incentives and obtain additional capital. We plan to use the net proceeds of this offering as follows: approximately 45% for the Phase 1/2 clinical trials for our ALEXIS ISOFORM CD19 product candidate, approximately 25% for intellectual property protection and reinforcement, approximately 15% for IND applications and IND enabling trials and approximately 15% for working capital and general corporate purposes.

We will have broad discretion in the way that we use the net proceeds of this offering. Pending the final application of the net proceeds of this offering, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities. See “Risk Factors—Risks Related to this Offering and the Market for Our Common Stock—We have considerable discretion as to the use of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.”

DIVIDEND POLICY

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

Holders of our series B preferred stock are entitled to dividends at an annual rate of six percent (6%) of the original issue price (currently $0.46 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization). The series B preferred stock dividends accrue from day to day, whether or not declared, and are cumulative; provided however, that such dividends shall be payable only when, as, and if declared by our board of directors. We may not declare, pay or set aside any dividends on shares of any other class or series of capital stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the series B preferred stock then outstanding shall first receive, or simultaneously receive, dividends to which they are entitled. See “Description of Securities” for additional information regarding the series B preferred stock dividends.

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

CAPITALIZATION

The following table sets forth our total capitalization as of December 31, 2018:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of the maximum of $[ ] million of our shares in this offering, after deducting estimated offering expenses payable by us, and after giving effect to the use of proceeds described herein.

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

	December 31, 2018	
	Actual	As Adjusted
Cash and cash equivalents	$ 384,300	$
Long-term debt	—	
Stockholders’ equity:		
Series B Preferred Stock	—	
Series A-1 Preferred Stock	8,727,400	
Common Stock	—	
Additional paid-in capital	10,237,600	
Accumulated deficit	(18,699,700)	
Total stockholders’ equity (deficit)	265,300	
Total capitalization	$ 265,300	$

DILUTION

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

Our net tangible book value was approximately $265,300, or $0.002 per share, as of December 31, 2018. Our net tangible book value represents the amount of our total consolidated tangible assets (which is calculated by subtracting net intangible assets, deferred tax assets, and prepaid offering expenses from our total consolidated assets), less the amount of our total consolidated liabilities. Dilution is determined by subtracting net tangible book value per share, after giving effect to the proceeds we will receive from this offering, at a public offering price of $[ ] per share, and after deducting estimated offering expenses payable by us.

After giving effect to the sale of [ ] shares in this offering by us at an assumed initial public offering price of $[ ] per share, and after deducting estimated offering expenses payable by us, but without adjusting for any other change in our pro forma net tangible book value subsequent to December 31, 2018, our as adjusted net tangible book value would have been $[ ] per share if the maximum amount of shares are sold. This represents an immediate increase in net tangible book value of $[ ] per share to our existing stockholders and immediate dilution of $[ ] per share to new investors purchasing shares in this offering.

The following table illustrates this per share dilution:

Assumed initial public offering price per share	$ [ ]
Net tangible book value per share at December 31, 2018	$ 0.002
As adjusted net tangible book value per share after this offering	$ [ ]
Increase in net tangible book value per share to existing stockholders	$ [ ]
Dilution in net tangible book value per share to new investors	$ [ ]

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

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

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	%	Amount	%	
Common Stock	100,050,000	[ ]%	$6,214,800	[ ]%	$ 0.06
Series A-1 Preferred Stock	21,822,301	[ ]%	9,132,700	[ ]%	0.42
Series B Preferred Stock	9,782,609	[ ]%	4,500,000	[ ]%	0.46
New investors	[ ]	[ ]%	[ ]	[ ]%	[ ]
Total	[ ]	100.00%	$ [ ]	100.00%	$

The number of shares outstanding is based on shares outstanding as of November 13, 2019 and excludes the following:

- 29,347,827 shares of our common stock issuable upon the exercise of outstanding warrants with an exercise price of $0.0001 per share;

- 22,401,071 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of $0.32 per share; and
- up to an additional 7,548,929 shares of our common stock issuable under our 2017 Equity Incentive Plan.

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

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

Overview

We are a clinical stage immuno-oncology, target discovery and gene editing company developing tumor-specific cancer engineered immunotherapies to face and defeat multiple cancer types. We are focused on extending the benefits of immunotherapy by leveraging our proprietary technologies. Our approach seeks to generate a therapeutic immune response in patients by unleashing the demonstrated natural power of a patient's own immune system to recognize tumor-specific peptide sequences presented on cancer cells, known as tumor specific iso-antigens, capable of generating an immunological response and therefore eradicate cancer cells.

We are developing our brand of CAR T cell product candidates known as ALEXIS (Autologous/Allogenic Leading Ixogenous Isoform). These are designed to treat cancer in the safest and most effective way by capitalizing on the immune system's ability to destroy cancer cells. These products are in the early stages of the FDA clinical trial process.

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

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

Principal Factors Affecting Our Financial Performance

Our operating results are primarily affected by the following factors:

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

Emerging Growth Company

Upon the completion of this offering, we will qualify as an "emerging growth company" under the JOBS Act. As a result, we will be permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

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

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

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

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. We will record revenue from collaboration agreements, including amounts related to upfront payments, annual fees for licenses of our intellectual property and research and development funding.

Research and Development Expenses

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

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including CROs and other third parties that conduct preclinical research and development activities and clinical trials on our behalf;

- costs of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and future clinical trials, including the costs of contract manufacturing organizations, or CMOs, that will manufacture our clinical trial material for use in our preclinical studies and potential future clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- license payments made for intellectual property used in research and development activities; and
- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically, identifiable to research activities.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we initiate a Phase 1/2a clinical trial for our ALEXIS ISOFORM CD19 product candidate and continue to discover and develop additional product candidates.

We cannot determine with certainty the duration and costs of future clinical trials of our ALEXIS ISOFORM CD19 product candidate or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our ALEXIS ISOFORM CD19 product candidate and any other our product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our ALEXIS ISOFORM CD19 product candidate, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

General and Administrative Expenses

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

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

Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

The following table sets forth key components of our results of operations for the years ended December 31, 2018 and 2017.

	Years Ended December 31,		Increase (Decrease)	
	2018	2017	$	%
Operating expenses:				
Research and development	$ 1,424,900	$ 2,312,400	$ (887,500)	38.38%
General and administrative	1,757,700	3,080,200	(1,322,500)	42.94%
Total operating expenses	3,182,600	5,392,600	(2,210,000)	40.98%
Loss from operations	(3,182,600)	(5,392,600)	(2,210,000)	40.98%
Other expense				
Interest expense	(633,100)	(420,800)	212,300	50.45%
Total other expense	(633,100)	(420,800)	212,300	50.45%
Net loss	$(3,815,700)	$(5,813,400)	$(1,997,700)	34.36%

Research and development expenses. Our research and development expenses decreased by $887,500, or 38.38%, to $1,424,900 for the year ended December 31, 2018 from $2,312,400 for the prior year. The following table summarizes our research and development expenses by product candidate or development program:

	Years Ended December 31,		Increase (Decrease)	
	2018	2017	$	%
Direct research and development expenses by product candidate:				
Isoform CD19 external development costs	$ 3,900	$ 22,000	$ (18,100)	82.27%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	615,600	505,300	110,300	21.83%
Laboratory supplies and services	85,000	215,600	(130,600)	60.58%
Outsourced research and development	609,200	1,429,200	(820,000)	57.37%
Laboratory equipment and maintenance	6,400	13,900	(7,500)	53.96%
Facility-related costs	103,200	105,500	(2,300)	2.18%
Other research and development costs	1,600	20,900	(19,300)	92.34%
Total research and development expenses	$ 1,424,900	$ 2,312,400	$ (887,500)	38.38%

As illustrated above, the decrease in research and development expenses resulted from (i) a $820,000 decrease in outsourced research and development costs, which primarily included a $514,000 decrease in non-employee stock compensation expenses, a $249,100 decrease in drug manufacturing costs, and a $62,200 decrease in clinical consultant fees, offset by a $5,300 increase in data administration costs; (ii) a $130,600 decrease in laboratory supplies and services costs, primarily driven by a $123,200 decrease in purchases of disposables and consumables and other higher supply purchases in 2017 compared to 2018; (iii) a $19,300 decrease in other

research and development costs, which consisted entirely of decreased intellectual property legal filing costs; (iv) a $18,100 decrease in CD19 external development costs, primarily driven by decreased spending on disposables and consumables attributable to CD19; (vi) a $7,500 decrease in laboratory equipment and maintenance costs; and (vii) a $2,300 decrease in facility-related costs. Those reductions were offset by a $110,300 increase in employee related costs, which was driven by a $300,000 increase in stock compensation expenses for employees, offset by a $170,200 decrease in regular salaries, wages, and bonuses, and a $19,500 decrease in related benefits and payroll taxes.

Management's actions and spending strategies as of December 31, 2018 compared to December 31, 2017 account for the variances discussed above. For example, management identified cash constraints in 2017, and thus created a cost reduction plan. We halted almost all expenses related to drug manufacturing. We also significantly reduced our disposables and consumables spending along with lab supplies to meet our spending targets. Management was able to perform significant research and development to execute our goals in the year ended December 31, 2018 with reduced spending compared to the year ended December 31, 2017.

In addition, total reductions in stock compensation expenses totaled $214,000 in the year ended December 31, 2018 compared to the year ended December 31, 2017. The year ended December 31, 2017 was the first year of the equity incentive plan and the Company incurred $544,000 of stock compensation expense attributable to research and development during that period.

Management granted 14,494,484 options compared to 8,739,000 in the years ended December 31, 2018 and 2017, respectively. The number of options which vested and became exercisable increased by 1,217,667 options and 10,698,817 options in the years ended December 31, 2018 and 2017, respectively. This variance of fully vested options represents the primary driver behind decreased stock compensation expense in the years ended December 31, 2018 and 2017.

General and administrative expenses. Our general and administrative expenses decreased by $1,322,500, or 42.94%, to $1,757,700 for the year ended December 31, 2018 from $3,080,200 for the prior year. The decrease primarily resulted from a decrease in compensation related expenses of $1,062,800, including approximately $842,000 of non-cash stock-based compensation. Other decreases were driven by a $107,500 decrease in legal expenses, a $62,700 decrease in disposal activities, $42,100 decrease in professional services, a $34,200 decrease in allocated depreciation expense, and other expense reductions totaling $13,000 associated with activities such as rent and utilities, supplies, and other costs associated with our business development.

During 2017, an identified cash constraint prompted management to create a cost reduction plan and budget during 2018 focused upon reducing discretionary costs. The reductions in legal expenses and professional services expenses are reflective of those actions.

In addition, key non-cash changes in general and administrative expenses were driven by the reduction in stock-based compensation expenses. Fewer stock-based grants awarded to individuals in 2018 versus 2017. During the year ended December 31, 2017, management granted 14,494,484 options compared to 8,739,000 options in the year ended December 31, 2018. The number of options which vested and became exercisable increased by 1,217,667 options and 10,698,817 options in the years ended December 31, 2018 and 2017, respectively. This variance of fully vested options represents the primary driver behind decreased stock-based compensation expense in the years ended December 31, 2018 and 2017.

Interest expense. Interest expense increased by $212,300, or 50.45%, to $633,100 for the year ended December 31, 2018 from $420,800 for the prior year. Such increase was driven by $725,000 of new issuances of convertible promissory notes in 2018, and a balance of $6,100,400 of accrued principal and interest, all of which accrued interest at a rate of 7% per annum until the December 20, 2018, when they were converted into series A-1 preferred stock. The convertible promissory notes accrued approximately $453,300 of interest expense prior to conversion. In addition, the convertible promissory notes embedded derivative liability increased interest

expenses by approximately $167,000 during 2018 based on increases in the fair value of the liability prior to conversion. The remaining interest expense was driven by accrued interest on proceeds from the series A-1 preferred shares. See "—Liquidity and Capital Resources" below.

Net loss. As a result of the cumulative effect of the factors described above, our net loss decreased significantly to $3,815,700 for year ended December 31, 2018 from $5,813,400 for the prior year.

Liquidity and Capital Resources

As of December 31, 2018, we had cash and cash equivalents of $384,300. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sale of our convertible promissory notes and preferred stock.

We believe that, following our recent offering of series B preferred stock discussed below, our current levels of cash will be sufficient to meet our anticipated cash needs for our operations for at least the next 12 months. However, we have incurred significant operating losses since inception, and we expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase, including in connection with conducting preclinical studies and clinical trials for our product candidates, contracting with CMOs and building out internal capacity to have product manufactured to support preclinical studies and clinical trials, expanding our intellectual property portfolio and providing general and administrative support for our operations.

As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. The sale of additional equity securities could result in dilution to our stockholders. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could limit our ability to expand our business operations and could harm our overall business prospects.

Summary of Cash Flow

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

	Years Ended December 31,	
	2018	2017
Net cash used in operating activities	$ (2,152,900)	$ (3,535,400)
Net cash used in investing activities	(137,300)	(29,700)
Net cash provided by financing activities	1,625,000	4,195,000
Net (decrease) increase in cash and cash equivalents	(665,200)	629,900
Cash and cash equivalents at beginning of the year	1,049,500	419,600
Cash and cash equivalents at end of the year	$ 384,300	$ 1,049,500

Net cash used in operating activities was $2,152,900 for the year ended December 31, 2018, as compared to $3,535,400 for the year ended December 31, 2017. For the year ended December 31, 2018, the net loss of $3,815,700 and interest payable in the amount of $363,400, offset by stock compensation expenses in the amount of $633,000, non-cash interest of $633,100, prepaid expenses and other current assets in the amount of $212,500, convertible promissory notes derivative liability in the amount of $369,000, and accrued expenses and other current liabilities in the amount of $149,400, were the primary drivers of the net cash used in operating activities. For the year ended December 31, 2017, the net loss of $5,813,400 and prepaid expenses and other current assets in the amount of $265,500, offset by stock compensation expenses in the amount of $1,689,000, interest payable

in the amount of $314,800, accounts payable in the amount of $159,100, depreciation in the amount of $115,100, accrued expenses and other current liabilities in the amount of $113,400 and convertible promissory notes derivative liability in the amount of $106,000, were the primary drivers of the net cash used in operating activities.

Net cash used in operating activities increased by a total of $1,382,500 year-over-year. This variance was driven by a reduced net loss amount of $1,997,700. This reduction was driven by management's cost reduction plan for 2018 when a cash constraint was identified in 2017. This plan reduced the overall research and development expense by $887,500 in the year ended December 31, 2018 compared to 2017. Key spending changes in research and development were driven by drug manufacturing cost, disposables and consumables costs, and laboratory supplies spending reductions. See the "—Results of Operations" above for further details. This plan also reduced the overall general and administrative expense by $1,322,500 in the year ended December 31, 2018 compared to 2017. Key spending changes in general and administrative expenses were driven by legal costs and professional services cost reductions. See the "—Results of Operations" above for further details.

Net cash used in investing activities was $137,300 for the year ended December 31, 2018, as compared to $29,700 for the year ended December 31, 2017. Our net cash used in investing activities consisted entirely of purchases of property and equipment.

Net cash provided by financing activities was $1,625,000 for the year ended December 31, 2018, as compared to $4,195,000 for the year ended December 31, 2017. For the year ended December 31, 2018, the net cash provided by financing activities consisted of proceeds from the sale of convertible promissory notes in the amount of $725,000 and proceeds from preferred stock issuance in the amount of $900,000. For the year ended December 31, 2017, the net cash provided by financing activities consisted entirely of proceeds from the sale of convertible promissory notes.

Convertible Promissory Notes

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

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

During 2019, we issued additional convertible promissory notes in the aggregate principal amount of $250,000 to certain investors. The notes accrued interest at a rate of 17% and were to mature on June 1, 2021. These notes were convertible into shares issued in our next financing (as defined in the notes) by dividing the total amount of notes payable, plus accrued interest, by the applicable conversion price (defined generally as 85% of the lowest per share selling price in the next financing). Prior to the issuance of shares of series B preferred stock (as discussed below), each holder agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of series A-1 preferred stock. Therefore, on August 15, 2019, these notes were converted into an aggregate of 632,123 shares of series A-1 preferred stock at a conversion price of $0.43 per share.

In addition, during 2019, we settled an outstanding account payable with a vendor in the amount of $134,600 by issuing to that vendor a convertible promissory note for the amount owed. That convertible promissory note accrued interest at a rate of 6% and was to mature on June 30, 2020. This note was convertible into shares issued in our next financing (as defined in the note) by dividing the total amount of notes payable, plus accrued interest, by the applicable conversion price (defined generally as 90% of the lowest per share selling price in the next financing). Prior to the issuance of shares of series B preferred stock (as discussed below), the holder agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of series A-1 preferred stock. Therefore, on August 15, 2019, this note was converted into 303,396 shares of series A-1 preferred stock at a conversion price of $0.45 per share.

Series A-1 Preferred Stock Financing

Between June 8, 2018 and August 14, 2018, we entered into agreements to issue preferred stock and received advances of $900,000. The advances received under the agreements were recorded as liabilities until the preferred stock was issued and bore interest at a rate of 6.5%. The agreements were amended on September 10, 2018, when, in exchange for additional preferred stock to be issued, the advances no longer bore interest.

On December 20, 2018, 2,032,749 shares of series A-1 preferred stock were issued for $912,800, representing the advances received and accrued interest through September 10, 2018. See “Description of Securities” for more information regarding our series A-1 preferred stock.

Series B Preferred Stock Financing

On September 7, 2019, we entered into a series B preferred stock purchase agreement with certain investors for the sale of shares of our series B preferred stock at a price of $0.46 per share. On September 13, 2019, we sold an aggregate of 7,608,696 shares for total gross proceeds of approximately $3,500,000. On November 13, 2019, we sold an additional 2,173,913 shares for gross proceeds of $1,000,000. We also issued each investor a warrant to purchase three (3) shares of common stock for each series B preferred share purchased, or warrants for an aggregate of 29,347,827 shares of common stock. The warrants have an exercise price of $0.0001 per share and expire ten years after the date of issuance. The warrants are exercisable as follows: (i) 30% of the shares underlying the warrants are exercisable from the date that is six months after the date on which our securities are first listed on a U.S. national securities exchange, (ii) an additional 30% of the shares underlying the warrants are exercisable nine months after such listing date, and (iii) the remaining shares underlying the warrants are exercisable twelve months after such listing date. See “Description of Securities” for more information regarding our series B preferred stock and the warrants issued in this financing.

Investors Rights Agreement

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

securities requested to be included in such registration by any other holders. In addition, if we propose to register any of our securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in certain excluded registrations), we must, at such time, promptly give each holder notice of such registration. Upon the request of each holder given within twenty (20) days after such notice is given by us, we must cause to be registered all of the registrable securities that each such holder has requested to be included in such registration. The registrable securities are being registered in the registration statement of which this prospectus forms a part.

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

The investors' rights agreement also contains a number of additional rights and covenants, including the following:

- *Information and Inspection Rights*. We are required to provide certain financial information to the investors on a monthly, quarterly and annual basis, as well as the budget for each fiscal year. In addition, we are required to provide certain major investors (defined as any investor that, individually or together with its affiliates, holds shares with an aggregate original issue price of at least $500,000) with such other information relating to the financial condition, business, prospects or corporate affairs of our company as any major investor may from time to time reasonably request upon 10 days' notice (subject to certain exceptions). Such major investors are also entitled to visit and inspect our properties, examine our books of account and records and discuss our affairs, finances and accounts with our officers, during normal business hours as may be reasonably requested by the major investor (subject to certain exceptions).
- *Right of First Offer*. If we propose to offer or sell any additional securities, we must first offer such additional securities to each major investor. This right of first offer does not apply to (i) exempted securities (as defined in our certificate of incorporation); (ii) shares of common stock issued in the IPO; and (iii) the issuance of additional shares of series B preferred stock pursuant to the series B preferred stock purchase agreement.
- *Insurance*. We agreed to obtain and maintain from financially sound and reputable insurers directors and officers liability insurance and term "key person" insurance on Maurizio Chiriva Internati in an amount and on terms and conditions satisfactory to the board of directors, until such time as the director elected by the series B preferred stockholders (which we refer to as the preferred stock director) determines that such insurance should be discontinued. In addition, for so long as the preferred stock director is serving on the board of directors, we shall not cease to maintain a directors and officers liability insurance policy, including non-rescindable Side A coverage, in an amount of at least $3,000,000 unless approved by the preferred stock director then in office.
- *Employee Agreements*. We also agreed to cause (i) each person employed by our company or by any subsidiary (or engaged by our company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets, or who develops intellectual property related to our business, to enter into a nondisclosure and proprietary rights assignment agreement; and (ii) certain key employees to enter into a one year noncompetition and nonsolicitation agreement.
- *Employee Stock*. Unless otherwise approved by the board of directors, including the preferred stock director then in office, if any, all future employees and consultants who purchase, receive options to

purchase or receive awards of shares of our capital stock shall be required to execute restricted stock or option agreements, as applicable, providing for (i) vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months; and (ii) a market stand-off provision substantially similar to that contained in the investors' rights agreement. In addition, unless otherwise approved by the board of directors, including the preferred stock director then in office, if any, we shall retain a "right of first refusal" on employee transfers until the IPO and shall have the right to repurchase unvested shares at cost upon termination of employment of a holder of restricted stock.

- *Board Matters*. We also agreed that we will not, without approval of the board of directors, including the affirmative approval of the preferred stock director then in office, if any: (i) make, or permit any subsidiary to make, any loan or advance to, or own any stock or other securities of, any subsidiary or other corporation, partnership or other entity unless it is wholly owned by our company; (ii) make, or permit any subsidiary to make, any loan or advance to any person, including, without limitation, any employee or director of our company or any subsidiary, except advances and similar expenditures in the ordinary course of business or under the terms of an employee stock or option plan approved by the board of directors; (iii) guarantee, directly or indirectly, or permit any subsidiary to guarantee, directly or indirectly, any indebtedness except for trade accounts of our company or any subsidiary arising in the ordinary course of business; (iv) make any investment inconsistent with any investment policy approved by the board of directors; (v) incur any aggregate indebtedness in excess of $100,000 that is not already included in a budget approved by the board of directors, other than trade credit incurred in the ordinary course of business; (vi) enter into or be a party to any transaction with any director, officer or employee or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such person, except for transactions made in the ordinary course of business and pursuant to reasonable requirements of our business and upon fair and reasonable terms that are approved by a majority of the board of directors; (vii) hire, terminate, or change the compensation of the executive officers, including approving any option grants or stock awards to executive officers; (viii) change the principal business of our company, enter new lines of business or exit the current line of business; or (ix) sell, transfer, assign, license, pledge or encumber material technology or intellectual property, other than licenses granted in the ordinary course of business.

The foregoing rights and covenants will terminate (i) immediately before the consummation of the IPO; (ii) upon a deemed liquidation event, as such term is defined in our certificate of incorporation; or (iii) upon the transfer of not less than 50% of the voting securities of our company to one person who is not an existing Series B holder in a single transaction, whichever event occurs first.

Right of First Refusal and Co-Sale Agreement

In connection with the series B preferred stock financing, on September 7, 2019, we entered a right of first refusal and co-sale agreement with the investors and certain stockholders. Pursuant to the right of first refusal and co-sale agreement, certain stockholders provided us with a right of first refusal to purchase any shares of capital stock that such stockholders propose to transfer and also provided the investors with a secondary refusal right to purchase any such shares that we do not elect to purchase. In addition, the right of first refusal and co-sale agreement provides the investors with a right of co-sale, pursuant to which, if the foregoing right of refusals are not exercised, the investors may elect to participate in the proposed sale on a pro rata basis.

Notwithstanding the foregoing, these rights shall not apply (i) in the case of a stockholder that is an entity, upon a transfer by such stockholder to its stockholders, members, partners or other equity holders, (ii) to a repurchase of shares from a stockholder by us at a price no greater than that originally paid by such stockholder for such shares and pursuant to an agreement containing vesting and/or repurchase provisions approved by a majority of the board of directors, (iii) to a pledge of shares that creates a mere security interest in the pledged shares, provided

that the pledgee thereof agrees in writing in advance to be bound by and comply with all applicable provisions of the right of first refusal and co-sale agreement to the same extent as if it were the stockholder making such pledge, or (iv) in the case of a stockholder that is a natural person, upon a transfer of shares by such stockholder made for bona fide estate planning purposes, either during his or her lifetime or on death by will or intestacy to his or her spouse, child (natural or adopted), or any other direct lineal descendant of such stockholder (or his or her spouse), or any other person approved by unanimous consent of the board of directors, or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by such stockholder or any such family members; provided that in the case of clauses (i), (iii), and (iv), the stockholder shall deliver prior written notice to the investors of such pledge, gift or transfer and such shares shall at all times remain subject to the terms and restrictions set forth in the right of first refusal and co-sale agreement and such transferee shall, as a condition to such issuance, deliver a counterpart signature page to the right of first refusal and co-sale agreement as confirmation that such transferee shall be bound by all the terms and conditions of the right of first refusal and co-sale agreement as a stockholder (but only with respect to the securities so transferred to the transferee); and provided further in the case of any transfer pursuant to clause (i) or (iv) above, that such transfer is made pursuant to a transaction in which there is no consideration actually paid for such transfer.

In addition, these rights shall not apply to the sale of any shares to the public in an offering pursuant to an effective registration statement under the Securities Act or pursuant to a deemed liquidation event (as defined in our certificate of incorporation).

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2018 or 2017.

Critical Accounting Policies and Estimates

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

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

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

We account for financial instruments in accordance with ASC 820, *Fair Value Measurements and Disclosures*. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets

or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

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

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

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

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2018 and 2017.

Stock-Based Compensation—We record stock compensation expense related to our 2017 Equity Incentive Plan in accordance with ASC 718, *Compensation—Stock Compensation*. We measure and recognize stock compensation expense for all stock-based awards, including stock options, based on estimated fair values recognized using the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model. The calculation of stock-based compensation expense requires that we make assumptions and judgments about the variables used in the Black-Scholes option-valuation model, including the fair value of our common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

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

Expected Term. The expected term represents the period that our stock options are expected to be outstanding. Due to limitations on the sale or transfer of our common stock as a privately held company, we do not believe our historical exercise pattern is indicative of the pattern we will experience as a future publicly traded company. We have consequently used the SAB No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period. We plan to continue to use the SAB 110 simplified method until we have sufficient trading history as a publicly traded company.

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

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

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

Common Stock Valuations. The fair value of the common stock underlying our stock-based compensation grants has historically been determined by our board of directors, with input from management and third-party valuations. We believe that the board of directors has the relevant experience and expertise to determine the fair value of our common stock. Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-*

Held Company Equity Securities Issued as Compensation, the board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

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

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

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

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

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

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

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

Recent Accounting Pronouncements

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

In February 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-02, *Leases* (Topic 842), which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On October 16, 2019, the FASB changed the effective date of this standard to January 1, 2021. We are currently evaluating the potential impact of this standard on our financial position, results of operations, and cash flows.

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

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On October 16, 2019, the FASB changed the effective date of this standard to January 1, 2023. We are currently evaluating the potential impact of this standard on our financial position, results of operations, and cash flows.

In August 2016, the FASB issued ASU 2016-15 (Topic 230), *Classification of Certain Cash Receipts and Payments*, a new standard providing guidance on statement of cash flow classification on specific issues. The standard is effective for financial statements issued for fiscal periods beginning after December 15, 2018. It is required to be applied on a retrospective approach. We are currently evaluating the potential impact of this standard on our financial position, results of operations, and cash flows.

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

BUSINESS

Overview

We are a clinical stage immuno-oncology, target discovery and gene editing company developing tumor-specific cancer engineered immunotherapies to face and defeat multiple cancer types. We are focused on extending the benefits of immunotherapy by leveraging our proprietary technologies. Our approach seeks to generate a therapeutic immune response in patients by unleashing the demonstrated natural power of a patient's own immune system to recognize tumor-specific peptide sequences presented on cancer cells, known as tumor specific iso-antigens, capable of generating an immunological response and therefore eradicate cancer cells.

We are developing our brand of CAR T cell product candidates known as ALEXIS (Autologous/Allogenic Leading Ixogenous Isoform). These are designed to treat cancer in the safest and most effective way by capitalizing on the immune system's ability to destroy cancer cells. These products are in the early stages of the FDA clinical trial process.

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

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

Our Corporate History

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

We have one wholly-owned subsidiary, GreenPlanet Pharma, Inc., which was incorporated in the State of Delaware on November 26, 2018.

Engineered T Cell Therapy

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

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

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

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

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

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

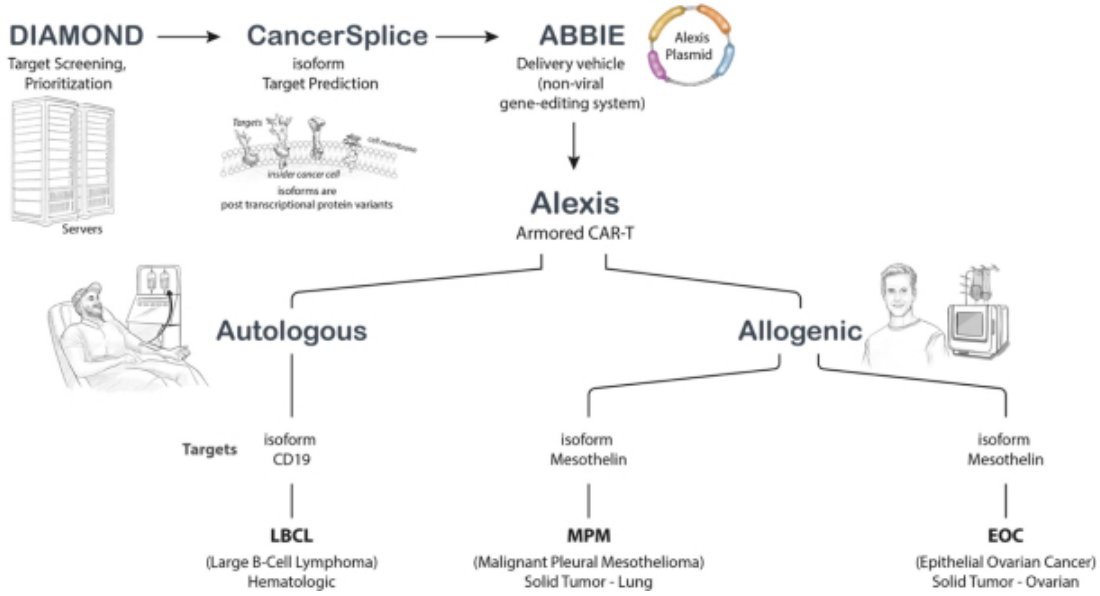
Allogenic engineered T cells are manufactured in a similar manner as autologous, but with two key differences: (1) allogenic T cells are derived from healthy donors, not cancer patients, and (2) allogenic T cells must be genetically engineered to minimize the risk of graft-versus-host disease, a condition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

Our Approach

Our operating motto is Better Target, Better Life ™.

Our goal is to defeat cancer by developing immunotherapies by improving the target discovery and validation. With better targets, we believe our therapies will be more effective than the current crop of immunotherapies using old targets which cannot adapt to rapidly mutating targets.

We plan to use our proprietary technologies, Diamond, CancerSplice and ABBIE, to develop our products. Our development schema below describes our path forward for developing CAR T products for refractory CAR T patients.



Diamond (Screening, Prioritizing, and Harmonizing)

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

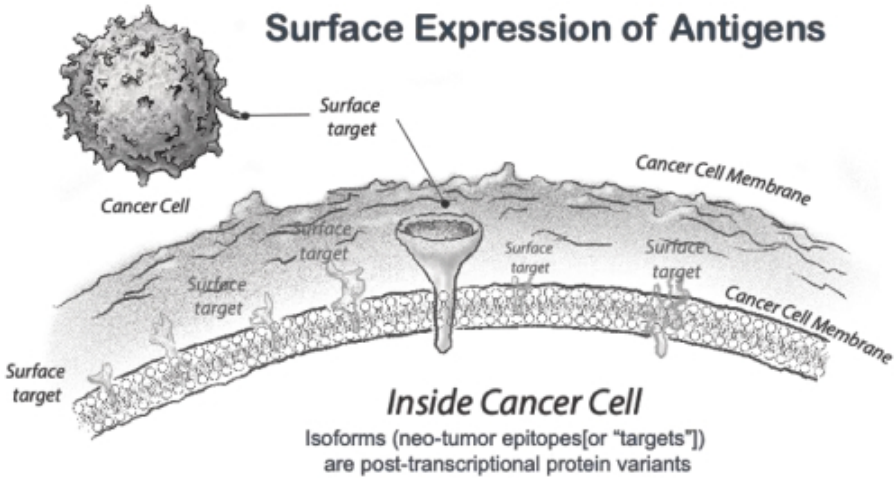
Diamond addresses the main challenges in today's clinical pipeline: target identification. Diamond generates a prioritized list of cancer immunological targets for T cells and B cells. These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR T cell therapies and vaccine therapies.

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

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

CancerSplice (Isoform Target Prediction)

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



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

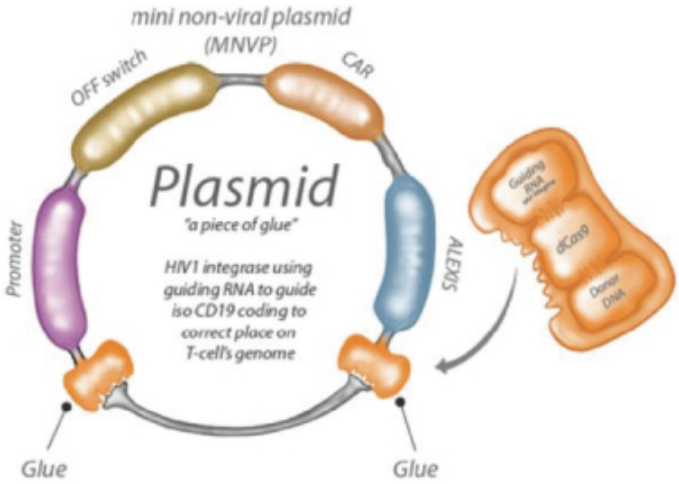
CancerSplice allows for the prediction and prioritization of iso-antigens which could serve as a novel source of tumor targets, highly specific for neoplastic cells but without the drawback of also being highly patient-specific.

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

Finally, CancerSplice also shows a box plot by tissue of expression of the isoform in normal cancer genome atlas tissues and a box plot of the matching isoform in genotype-tissue expression program normal data. The sequence of amino acids that are specific for the selected cancer isoforms are then directly fed to Diamond's artificial neural capsule network for peptide design and prioritization. Therefore, we believe that we have developed unique tools to address the issue with tumor specific iso-antigens through CancerSplice and Diamond.

ABBIE (Delivery Vehicle)

We are currently developing ABBIE (A Binding-Based Integrase Enzyme) for delivery our product candidates. ABBIE is a non-viral gene editing mechanism to insert the target DNA template information into the T cell genome. ABBIE allows the creation of the plasmid ("glue") that goes through the membrane to the nucleus and inserts the genome template into the T cells so that they could express CAR T.



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

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

Manufacturing T Cells

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

Our manufacturing and processing of engineered autologous cell therapy product candidates is based on an improved version of the National Cancer Institute's, or NCI, and Kite Pharma's original manufacturing and processing of engineered T cells. For ALEXIS ISOFORM CD19, we will use the identical anti-CD19 CAR construct and viral vector that is being used in the ongoing NCI clinical trial.

We believe we have streamlined and optimized the NCI's process, such as by removing human serum from the process to minimize risk of viral contamination, moving process steps from an open system to a closed system to minimize the risk of other contamination and standardizing the viral transduction process to help eliminate processing inconsistencies.

Step 1. Collection

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

Step 2. Gene Editing

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

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

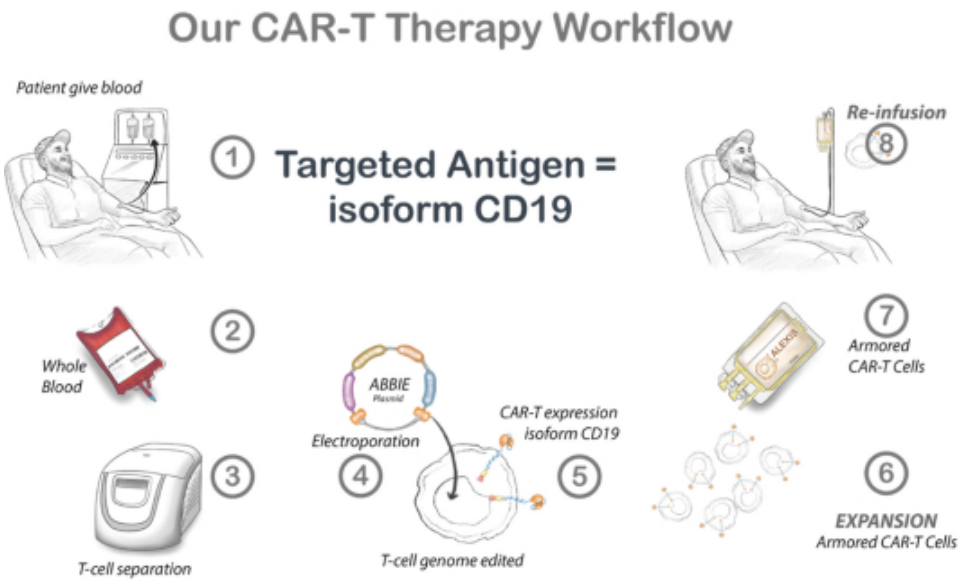
Step 3. Purification, Formulation, and Storage

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

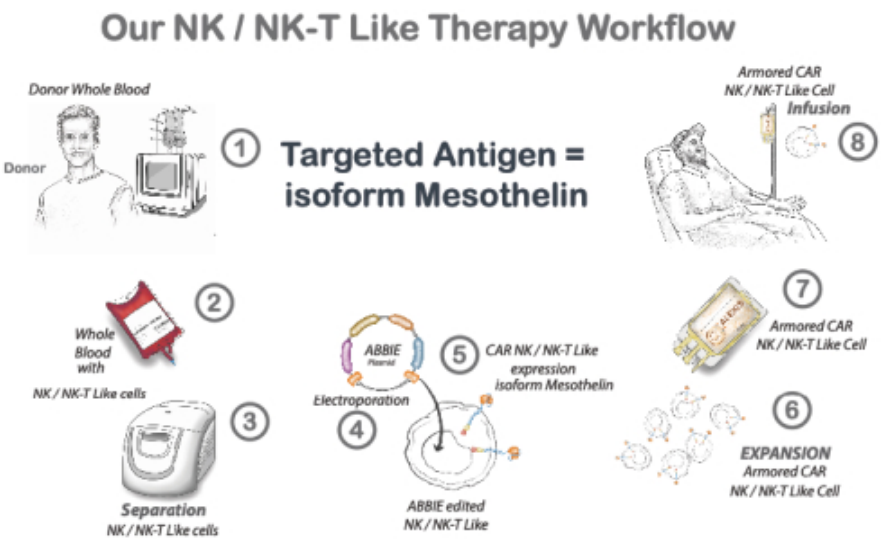
For our autologous products, the engineered T cells are shipped back to the clinical center where they can be administered to the patient. In preparation for administration of the engineered T cells, the patient undergoes a short chemotherapy conditioning regimen, which is intended to improve the survival and proliferative capacity of the newly infused T cells. Because it is important to rapidly treat patients with highly aggressive cancers, we have developed, and are preparing to implement in our Phase 1-2 clinical trial, a T cell engineering process for ALEXIS ISOFORM CD19 that takes approximately two weeks from receipt of the patient's white blood cells to infusion of the engineered T cells back to the patient.

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

The following diagram illustrates our workflow (manufacturing steps) for autologous CAR T cell therapy.



The following diagram illustrates our workflow (manufacturing steps) for allogenic NKT-Like cell therapy.



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

Our Product Pipeline and Development

Using our proprietary technologies, we are researching and developing multiple product candidates for the treatment of blood cancers and solid tumors. Our product candidates are autologous and allogenic T cells engineered to be used for specific patients or as off-the-shelf treatments for any patient with a particular cancer type. Each product candidate targets a selected antigen expressed on tumor cells and bears specific engineered attributes.

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

Our product pipeline is represented in the diagram below:

	Phase 1	Phase 2	Phase 3
Alexis (CAR-T) Autologous Isoform CD19 LBCL (Hematologic)	2H-2020		
Alexis (CAR/NKT-Like) Allogenic Isoform Mesothelin EOC (Solid, Ovarian)	2H-2020		
Alexis (CAR/NKT-Like) Allogenic Isoform Mesothelin MPM (Solid, Lung)	2H-2020		

ALEXIS ISOFORM CD19

ALEXIS ISOFORM CD19 is our autologous CAR T cell product candidate targeting isoform CD19. This product is currently undergoing preparation for an IND enabling trial. Following the IND enabling trial, we will be applying for a full IND with the FDA. The clinical trial for this product candidate is expected to launch during the second half of 2020. We will be the sponsor of the program and lead the clinical development program.

ALEXIS ISOFORM CD19 targets isoform CD19, an antigen expressed on the surface of B cells, including malignant B cells. In addition to these indications, CD19 targeting CAR T therapies have shown preliminary efficacy in chronic lymphocytic leukemia, mantle cell lymphoma and low-grade non-Hodgkin lymphomas, such as follicular lymphoma or marginal zone lymphoma.

The product represents an innovative approach for relapsed B cell acute lymphoblastic leukemia and for refractory large B cell lymphoma and involves the use of adoptive T cells expressing CARs against CD19. We expect our strategy to target B cell malignancies that have become refractory to currently available CAR T cell therapies, and due to the target specificity, are likely to afford a high safety profile.

Target Indications

ALEXIS ISOFORM CD19 targets large B cell lymphoma, or LBCL. According to the American Cancer Society, approximately 30,000 individuals are diagnosed with LBCL in the U.S. each year, and 200,000 worldwide. The growth rate for LBCL is relatively stable.

The standard treatment is R-CHOP chemotherapy, which is a combination treatment consisting of five separate drugs: rituximab (Rituxan), cyclophosphamide, doxorubicin hydrochloride, vincristine (Oncovin, Vincasar PFS), and prednisolone. R-CHOP chemotherapy costs approximately $100,000 per year. Average life expectancy following the failure of R-CHOP chemotherapy is approximately 18 months.

The failure rate for R-CHOP chemotherapy is up to 50%. Up to 60% of failures cannot get stem cell transplants and need CAR T therapy. Standard CAR T therapy costs between approximately $373,000 to $475,000.

Out of the 30,000 U.S. patients who are initially diagnosed with LBCL each year, we believe that approximately 2,100 (7%) will eventually be eligible for our CAR T cell therapy.

Development Plan

ALEXIS ISOFORM CD19 will be studied in a Phase 1 clinical trial for LBCL, including diffuse LBCL, primary mediastinal B cell lymphoma, and transformed follicular lymphoma. We plan to submit an IND and initiate a Phase 1 clinical trial in 2020. We will be the sponsor of the clinical trials, which will be conducted by industry-standard CROs and leading academic institutions in the U.S. and Western Europe.

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

The primary endpoint will be to assess safety and tolerability at increasing dose levels in successive cohorts of patients in order to estimate the maximum tolerated dose and the recommended Phase 2 dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure than the patients are expressing our intended target (isoform CD19).

ALEXIS ISOFORM Mesothelin EOC

ALEXIS ISOFORM Mesothelin EOC is our allogenic CAR/NKT-Like cell product candidate targeting isoform mesothelin. We are still planning clinical trials before submitting this product for authorization.

ALEXIS ISOFORM Mesothelin EOC represents an innovative approach for stage IV platinum resistant epithelial ovarian cancer and involves the use of cells which are “like” natural killer T cells.

Target Indications

ALEXIS ISOFORM Mesothelin EOC targets epithelial ovarian cancer, or EOC. According to the Foundation for Ovarian Cancer, a chapter of the American Cancer Society, approximately 22,000 individuals are diagnosed with EOC in the U.S. each year, and 300,000 worldwide. The growth rate of EOC diagnosis is the U.S. is approximately 1% and it is 2% worldwide.

EOC generally affects elderly women over 60 years old. Genetic mutations and/or a family history of ovarian/breast/colorectal cancer increase the risk of EOC. EOC can metastasize to abdominal peritoneum, which is extremely difficult to treat. The median life expectancy after local recurrence is approximately 24 months.

The standard treatment for EOC involves chemotherapy, which costs approximately $40,000, surgery, which costs approximately $45,000, and radiation, which costs approximately $10,000-$20,000. In total, the standard treatment can cost approximately $100,000. The rate of failure for this treatment is approximately 70%.

Out of the 22,000 U.S. patients who are initially diagnosed with EOC each year, we believe that approximately 15,400 (70%) will eventually be eligible for our CAR/NKT-Like cell therapy.

Development Plan

ALEXIS ISOFORM Mesothelin EOC will be studied in a Phase 1 clinical trial for EOC patients. We plan to submit an IND and initiate a Phase 1 clinical trial in 2020. We will be the sponsor of the clinical trials, which will be conducted by industry-standard CROs and leading academic institutions in the U.S. and Western Europe.

The Phase 1 trial is expected to be an open label, single arm, multi-center, dose escalation, safety, pharmacokinetic and pharmacodynamic clinical trial in adult patients with EOC who have progressed on at least two lines of salvage chemotherapy and/or additional surgical/radiation therapy cell reduction.

The primary goal will be to assess safety and tolerability at increasing dose levels in successive cohorts of patients in order to estimate the maximum tolerated dose and the recommended Phase 2 dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure than the patients are expressing our intended target (isoform Mesothelin).

ALEXIS ISOFORM Mesothelin MPM

ALEXIS ISOFORM Mesothelin MPM is our allogenic CAR/NKT-Like cell product candidate targeting isoform mesothelin. We are still planning clinical trials before submitting this product for authorization.

ALEXIS ISOFORM Mesothelin MPM represents an innovative approach for malignant pleural mesothelioma and involves the use of cells which are “like” natural killer T cells.

Target Indications

ALEXIS ISOFORM Mesothelin MPM targets malignant pleural mesothelioma, or MPM. Mesothelioma is a disease in which malignant (cancer) cells form in the thin layer of tissue that covers organs typically in the chest

or abdomen. Pleura refers to the thin layer of tissue that lines the chest cavity and covers the lungs. The tumors often spread over the surface of organs often without spreading into the organ. They may spread to nearby lymph nodes or in other parts of the body. Malignant mesothelioma may also form in the testicles or heart, but this is rare.

According to the American Cancer Society, approximately 3,000 individuals are diagnosed with MPM in the U.S. each year, and 30,000 worldwide. The growth rate of MPM diagnosis is the U.S. and Western Europe is relatively stable, however, in emerging growth regions where heavy industries are growing, the MPM growth rates are also growing.

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

The standard treatment for MPM involves chemotherapy, which costs approximately $80,000, surgery, which costs approximately $90,000, and radiation, which costs approximately $10,000-$20,000. In total, the standard treatment can cost up to $200,000. Approximately 80% of patients undergoing this treatment will eventually relapse. The average life expectancy after refractory is approximately 7 months.

Out of the 3,000 U.S. patients who are initially diagnosed with MPM each year, we believe that approximately 4,400 (80%) will eventually be eligible for our CAR/NKT-Like cell therapy.

Development Plan

ALEXIS ISOFORM Mesothelin MPM will be studied in a Phase 1 clinical trial for mesothelioma, including pleural and peritoneal mesotheliomas. We plan to submit an IND and initiate a Phase 1 clinical trial in 2020. We will be the sponsor of the clinical trials, which will be conducted by industry-standard CROs and leading academic institutions in the U.S. and Western Europe.

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

The primary goal will be to assess safety and tolerability at increasing dose levels in successive cohorts of patients in order to estimate the maximum tolerated dose and the recommended Phase 2 dose.

Prior to treatment, all patients are expected to undergo selected screening process to assure than the patients are expressing our intended target (isoform Mesothelin).

Our Manufacturing Operations

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

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

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

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

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

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

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

Our Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our most advanced product candidate, ALEXIS ISOFORM CD19, 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.

We are actively building our intellectual property portfolio around our product candidates and our discovery programs, based on our own intellectual property as well as licensed intellectual property. We are the owners of, co-owners of, or the licensee of multiple patents and patent applications in the United States and worldwide. Our

patent portfolio includes protection for our lead product candidates, ALEXIS ISOFORM CD19, ALEXIS ISOFORM Mesothelin EOC and ALEXIS ISOFORM Mesothelin MPM, as well as our other research-stage candidates. Our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward: (1) antigen binding domains directed to the targets of our product candidates; (2) CAR constructs used in our product candidates; (3) methods of treatment for therapeutic indications; (4) manufacturing processes, preconditioning methods, and dosing regimens; and (5) and methods for genetically engineering immune cells suitable for autologous and allogenic use.

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

Our Research and Development Collaborations

We have a collaboration with the University of Texas, MD Anderson Cancer Center. This collaboration is aimed at testing novel immunotherapeutic approaches.

Our Competition

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

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

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

Potential cell therapy competitors include:

- *Autologous T cell therapy competition*: Adaptimmune Therapeutics PLC, Amgen Inc., Autolus Therapeutics plc, bluebird, Gilead (acquired Kite), Novartis International AG, Celgene (acquired Juno), Tmunity Therapeutics, Inc. and Unum Therapeutics Inc.
- *Allogenic T cell therapy competition*: Atara Biotherapeutics, Inc., Celyad S.A., CRISPR Therapeutics AG, Fate Therapeutics Inc., Intellia Therapeutics, Inc., Gilead (acquired Kite), Allogene Therapeutics, Inc., Poseida Therapeutics, Inc., Precision Biosciences, Inc. and Sangamo Therapeutics, Inc.

Competition will also arise from non-cell based immune and other pursued by small-cap biotechnology and large-cap pharmaceutical companies including Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company,

Incyte Corporation, Merck & Co., Inc., and F. Hoffmann-La Roche AG. For instance, we may experience competition from companies, such as Amgen Inc., Regeneron Pharmaceuticals, Inc., Xencor Inc., MacroGenics, Inc., GlaxoSmithKline plc and F. Hoffmann-La Roche AG, that are pursuing bispecific antibodies, which target both the cancer antigen and T cell receptor, thus bringing both cancer cells and T cells in close proximity to maximize the likelihood of an immune response to the cancer cells. Additionally, companies, such as Amgen Inc., GlaxoSmithKline plc and Seattle Genetics, Inc., are pursuing antibody drug conjugates, which utilize the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells.

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

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

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

GreenPlanet Pharma

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

This business is recently formed and the product was recently developed. This business has not generated any revenues.

Regulation

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

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and

scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

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

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

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature

and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Certain clinical trials involving human gene transfer research also must be overseen by an Institutional Biosafety Committee, or IBC, a standing committee to provide peer review of the safety of research plans, procedures, personnel training and environmental risks of work involving recombinant DNA molecules. IBCs are typically assigned certain review responsibilities relating to the use of recombinant DNA molecules, including reviewing potential environmental risks, assessing containment levels, and evaluating the adequacy of facilities, personnel training, and compliance with the National Institutes of Health Guidelines. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in

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

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

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

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or the PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems

incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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

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

product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Orphan Drug Designation

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

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

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

Expedited Development and Review Programs

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

Any product, submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review

and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy, or RMAT, designation was established by FDA in 2017 to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

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

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although a

physician may prescribe a legally available product for an off-label use, if the physicians deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

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

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Marketing Exclusivity

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

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

beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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

Other U.S. Healthcare Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

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

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

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or

fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

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

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

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

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

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

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

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

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

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

Healthcare Reform

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

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

- created an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and added new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded of the list of entities eligible for discounts under the 340B Drug Discount Program;
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expanded healthcare fraud and abuse laws, including the Foreign Corrupt Practices Act, or the FCPA, and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- required reporting of certain financial arrangements with physicians and teaching hospitals;
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to physicians;
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- created a licensure framework for follow on biologic products.

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

On January 22, 2018, the current U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress is continuing to consider legislation that would alter other aspects of the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

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

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level,

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

The Foreign Corrupt Practices Act

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

Additional Regulation

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

Overseas Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

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

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

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

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

European Union General Data Protection Regulation

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

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

California Consumer Privacy Act

California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or the CPPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on

entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Employees

As of the date of this offering circular, we had a total of 8 employees. We also utilize a number of consultants for financial reporting, clinical, regulatory, and SEC compliance.

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

Legal Proceedings

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

MANAGEMENT

Directors and Executive Officers

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

Name	Age	Position
Maurizio Chiriva Internati	51	Chairman, Chief Executive Officer and President
Tony Tontat	54	Chief Financial Officer and Chief Operating Officer
Scott Dahlbeck	58	Chief Medical Officer and Director
Gianluca Rotino	47	Chief Strategy and Innovation Officer and Director
David Spencer	57	Chief Scientific Officer and Director
Angelo Minotti	58	Director

Maurizio Chiriva Internati, DBSc, PhDs. Dr. Chiriva Internati has served as our Chairman and Chief Executive Officer since February 2018 and as our President since October 2019. Prior to that, he served in various other senior positions, including Director of Clinical and Translation Research and Chief Scientific Officer, since he originally joined our company in December 2012. Dr. Chiriva Internati has been an Associate Professor at the MD Anderson Cancer Center in Houston, Texas since August 2019. His research has led to the identification of novel cancer-testis antigens for the development of immunotherapeutic strategies against solid and non-solid tumors. This led to the development of the bioinformatic software Diamond CancerSplice, which is a key core platform of our company, leading to the discovery and prioritization of isoform antigens via insilico system. Dr. Chiriva Internati earned a PhD in Immunology from the University of Nottingham, United Kingdom. He also earned a PhD in Morphological Science from the Università degli Studi di Milano, Italy, and a Doctoral Degree in Biological Sciences from the University of Milan, Italy. Dr. Chiriva-Internati was a Post-Doctoral Fellow in Immunology at the University of Arkansas for Medical Sciences, earned a certificate in Artificial Intelligence from MIT Sloan School of Management and earned a certificate in Financial Technology from Oxford Saïd Business School. Dr. Chiriva Internati was selected to serve on our board of directors due to his tenure with our company and his industry experience.

Tony Tontat. Mr. Tontat has served as our Chief Operating Officer since August 2019 and our Chief Financial Officer since October 2019. Prior to joining us, Mr. Tontat had worked as a business and financial consultant for many private and public companies, helping these companies raise funds at various stages of life cycle. He worked in financial teams to raise funds for public companies like Sorrento Therapeutics, Inc. and NantKwest. He had worked as an investment analyst at healthcare-specialist hedge funds in New York. He had also been an investment banker at HSBC Investment Bank and worked out of their New York and Paris offices. Mr. Tontat earned his BA in Economics from Harvard University.

Scott Dahlbeck, MD, PharmD. Dr. Dahlbeck has served as our Chief Medical Officer since October 2019 and as a member of our board of directors since January 2013. He previously served as our President from January 2013 to October 2019. Dr. Dahlbeck is an expert in prostate cancer research and treatment and has served as a Radiation Oncologist for several cancer centers, including as an Adjunct Assistant Professor in Internal Medicine, Pathology, and Urology at the Texas Tech University Health Sciences Center. Dr. Dahlbeck has also patented, manufactured, and commercialized IP and has more than a decade of experience in medical and oncology commerce. Dr. Dahlbeck earned an MD from the University of Texas Health Science Center at Houston, completed residencies in family practice and radiation oncology, and earned a PharmD degree from the University of Nebraska Medical Center, College of Pharmacy. Dr. Dahlbeck was selected to serve on our board due to his industry experience.

Gianluca Rotino. Mr. Rotino has served as our Chief Strategy and Innovation Officer and as a member of our board of directors since January 2014. Prior to that, he served in various other senior positions, including Chief Business Officer and Executive VP of Corporate Development. Mr. Rotino is a seasoned business executive with

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

David Spencer, PhD. Dr. Spencer has served as our Chief Scientific Officer and as a member of our board of directors since October 2019. Prior to joining us, Dr. Spencer served as the Chief Scientific Officer at Bellicum Pharmaceuticals, Inc., a clinical stage biopharmaceutical company focused on developing novel cellular immunotherapies for various forms of cancer, from July 2014 to March 2019. Prior to that, Dr. Spencer was the Vice Chairman and the Professor of Immunology at Baylor College of Medicine. Dr. Spencer holds a PhD in Molecular Immunology from Massachusetts Institute of Technology, and a Post-Doctoral Fellowship in Immunology from Stanford University School of Medicine where he was a Howard Hughes Medical Institute Fellow. He earned his BA in Chemistry, Magna Cum Laude, from the University of California, San Diego. Dr. Spencer was selected to serve on our board due to his industry experience.

Angelo Minotti. Mr. Minotti has served as a member of our board of directors since October 2019. Mr. Minotti is an entrepreneur with over 35 years of experience in worldwide markets. Mr. Minotti had held the position of CEO in several Italian and European companies as well as serving on the board of Far-East companies. For the past 20 years, he also served on boards of publicly listed companies in East Asia and carries with him significant experience in their capital markets. Mr. Minotti was selected to serve on our board due to his investment and management experience.

Our directors currently have terms which will end at our next annual meeting of the stockholders or until their successors are elected and qualify, subject to their prior death, resignation or removal. Officers serve at the discretion of the board of directors.

Mr. Minotti was designated by certain holders of the series B preferred stock in accordance with the voting agreement described under “Description of Securities—Voting Agreement.” Except for the foregoing, there is no arrangement or understanding between any director or executive officer and any other person pursuant to which he was or is to be selected as a director or executive officer.

Family Relationships

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

Involvement in Certain Legal Proceedings

To the best of our knowledge, except as described below, none of our directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Corporate Governance

Governance Structure

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

The Board's Role in Risk Oversight

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

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

Our board administers its risk oversight function as a whole by making risk oversight a matter of collective consideration. Once the board establishes committees, it is anticipated that much of the work will be delegated to

such committees, which will meet regularly and report back to the full board. It is anticipated that the audit committee will oversee risks related to our financial statements, the financial reporting process, accounting and legal matters, that the compensation committee will evaluate the risks and rewards associated with our compensation philosophy and programs, and that the nominating and corporate governance committee will evaluate risk associated with management decisions and strategic direction.

Independent Directors

The Nasdaq Marketplace Rules generally require that a majority of an issuer's board of directors must consist of independent directors. Our board of directors currently consists of five (5) directors, one of whom is independent. We are in the process of identifying candidates to serve as independent directors. Prior to completion of this offering, we intend to appoint additional independent directors so that a majority of our board of directors will be independent.

Committees of the Board of Directors

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

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

Audit Committee

Our audit committee will consist entirely of directors who satisfy the "independence" requirements of Rule 10A-3 under the Exchange Act and Section 5605 of the Nasdaq Marketplace Rules. At least one of these directors will qualify as an "audit committee financial expert." The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company.

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

Compensation Committee

Our compensation committee will consist entirely of directors who satisfy the "independence" requirements of Rule 10A-3 under the Exchange Act and Section 5605 of the Nasdaq Marketplace Rules. The members of the compensation committee will also be "outside directors" as defined in Section 162(m) of the Internal Revenue Code of 1986, as amended, and "non-employee directors" within the meaning of Section 16 of the Exchange Act. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers.

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

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will consist entirely of directors who satisfy the "independence" requirements of Rule 10A-3 under the Exchange Act and Section 5605 of the Nasdaq Marketplace Rules. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees.

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

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

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

A stockholder may nominate one or more persons for election as a director at an annual meeting of stockholders if the stockholder complies with the notice and information provisions contained in our bylaws. Such notice must be in writing to our company not less than 120 days and not more than 150 days prior to the anniversary date of the preceding year's annual meeting of stockholders or as otherwise required by requirements of the Exchange Act. In addition, stockholders furnishing such notice must be a holder of record on both (i) the date of delivering such notice and (ii) the record date for the determination of stockholders entitled to vote at such meeting.

Code of Ethics

We have adopted a code of ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. Such code of ethics addresses, among other things, honesty and ethical conduct, conflicts of interest, compliance with laws, regulations and policies, including disclosure requirements under the federal securities laws, and reporting of violations of the code.

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

EXECUTIVE COMPENSATION

Summary Compensation Table

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

Name and Principal Position	Year	Salary ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Maurizio Chiriva Internati,	2018	280,000	—	—	280,000
Chief Executive Officer(1)	2017	280,000	—	—	280,000
Tony Tontat,	2018	—	454,064	—	454,064
Chief Operating Officer, and Chief Financial Officer(2)	2017	—	48,170	—	48,170
Scott Dahlbeck,	2018	110,000	—	12,500	122,500
Chief Medical Officer(3)	2017	200,000	—	—	200,000

(1) Of the salaries owed to Dr. Chiriva Internati, only $160,200 and $256,667 was paid in 2018 and 2017, respectively. These differences in 2018 and 2017 were accrued and paid to Dr. Chiriva Internati as a lump sum in September of 2019.

(2) The amount included in option awards represents the aggregate grant date fair value for options granted to Mr. Tontat computed in accordance with FASB ASC Topic 718. There were no other compensation arrangements in 2017 or 2018.

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

Employment and Consulting Agreements

On March 30, 2016, we entered into an employment agreement with Dr. Maurizio Chiriva Internati, our Chief Executive Officer and President, that set forth the terms and conditions his employment with us. The employment agreement establishes an annual base salary of $280,000, which is subject to our discretionary review and adjustment in accordance with our policies, procedures and practices as they may exist from time to time. Dr. Chiriva Internati is also eligible to receive a based bonus in the discretion of our board. Dr. Chiriva Internati is eligible to participate in all medical, personal leave and other employee benefit plans and programs for which he is eligible, subject to the terms and conditions of such plans and programs. Dr. Chiriva Internati's employment is "at will" and may be terminated by us or Dr. Chiriva Internati at any time and for any reason.

On November 10, 2017 and March 13, 2018, the Company granted Tony Tontat 300,000 and 2,000,000 in stock option awards, respectively. The stock options were awarded as part of Mr. Tontat's collaboration with the Company to provide financial advisory, but no formal employment or consulting agreements were in place during the years ended December 31, 2018 and 2017.

On November 2, 2018, we entered into a consulting agreement with Dr. Scott Dahlbeck, our Chief Medical Officer, pursuant to which Dr. Dahlbeck was entitled to a monthly consulting fee of $10,000. In December 2018, we amended this consulting agreement to decrease the monthly consulting fee to $2,500 per month. Thereafter, in August 2019 we further amended the consulting agreement to provide that Dr. Dahlbeck would provide services on an hourly basis at a rate of $400 per hour. Dr. Dahlbeck is not entitled to receive any medical or other benefits from our company. Under the consulting agreement, Dr. Dahlbeck renders the following services to our company: direct the development of clinical strategies and plans to integrate Kiromic compounds into standard medical practice, orchestrate and manage clinical aspects of regulatory strategies and interactions with health authorities, oversee the analysis and interpretation of clinical trial data and the reporting of clinical trial results,

lead interactions with investigators, cooperative groups, and other clinical stakeholders, provide clinical support and work with other members of the management team to develop and communicate the overall corporate strategy, represent the company and its programs to external audiences, including the investment, medical and regulatory communities, as well as pharmaceutical or biotechnology industry collaborators and partners. In addition to leading and supervision the clinical research department as Chief Medical Officer, Dr. Dahlbeck has direct line responsibility for the clinical operations, patient advocacy, medical affairs and reports to our company's Chief Executive Officer.

We have also entered into a consulting agreement with Gianluca Rotino, our Chief Strategy and Innovation Officer. Pursuant to the amended agreement, dated July 20, 2018, Mr. Rotino is entitled to a consulting fee of $400 per hour, provided that he is limited to nineteen (19) hours per month unless he obtains approval from our Chief Executive Officer. The consulting agreement indicates that Mr. Rotino will provide a leadership role for our business development strategies. On November 10, 2017, Mr. Rotino was granted an option for the purchase of 5,164,320 shares of common stock at an exercise price of $0.19 per share, which vested in full on the date of grant.

Outstanding Equity Awards at Fiscal Year-End

The following table includes certain information with respect to the value of all unexercised options and unvested shares of restricted stock previously awarded to the executive officers named above at the fiscal year ended December 31, 2018.

	OPTION AWARDS				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Maurizio Chiriva Internati	—	—	—	—	—
Tony Tontat	300,000	—	—	$ 0.19	11/10/2027
	500,000	—	1,500,000(1)	$ 0.34	03/13/2028
Scott Dahlbeck	—	—	—	—	—

(1) 25% of the options vested on the one year anniversary of the vesting start date (December 15, 2017), with the remaining 1,500,000 shares vesting annually until December 15, 2021 in 500,000 share increments.

Director Compensation

No member of our board of directors received any compensation for his services as a director during the fiscal year ended December 31, 2018.

2017 Equity Incentive Plan

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

Awards that may be granted include incentive stock options as described in section 422(b) of the Internal Revenue Code of 1986, as amended, non-qualified stock options (i.e., options that are not incentive stock

options), stock appreciation rights, or SARs, and awards of restricted stock or restricted stock units, or RSUs. These awards offer our employees, consultants and directors the possibility of future value, depending on the long-term price appreciation of our common stock and the award holder's continuing service with our company or one or more of its subsidiaries.

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

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

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

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

Shares Available Under the Plan: The maximum number of shares of common stock that may be delivered to participants under the Plan is 30,000,000, subject to adjustment for certain corporate changes affecting the shares, such as stock splits. Shares subject to an award under the Plan for which the award is canceled, forfeited or expires again become available for grants under the Plan. Shares subject to an award that is settled in cash will not again be made available for grants under the Plan.

Stock Options:

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

Option Price. The exercise price for stock options will be determined at the time of grant. Normally, the exercise price will not be less than the fair market value on the date of grant, as determined in good faith by the board or committee. As a matter of tax law, the exercise price for any incentive stock option awarded may not be less than the fair market value of the shares on the date of grant. However, incentive stock option grants to any person owning more than 10% of our voting stock must have an exercise price of not less than 110% of the fair market value on the grant date.

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

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

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

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

Other Material Provisions: Awards will be evidenced by a written agreement, in such form as may be approved by the board or committee. In the event of various changes to the capitalization of our company, such as stock splits, stock dividends and similar re-capitalizations, an appropriate adjustment will be made by the board or committee to the number of shares covered by outstanding awards or to the exercise price of such awards. The board or committee is also permitted to include in the written agreement provisions that provide for certain changes in the award in the event of a change of control of our company, including acceleration of vesting. Except as otherwise determined by the board or committee at the date of grant, awards will not be transferable, other than by will or the laws of descent and distribution. Prior to any award distribution, we are permitted to deduct or withhold amounts sufficient to satisfy any employee withholding tax requirements. The board also has the authority, at any time, to discontinue the granting of awards. The board also has the authority to alter or amend the Plan or any outstanding award or may terminate the Plan as to further grants, provided that no amendment will, without the approval of our stockholders, increase the number of shares available under the Plan or change the persons eligible for awards under the Plan. No amendment that would adversely affect any outstanding award made under the Plan can be made without the consent of the holder of such award.

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

PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our voting stock as of November 13, 2019, and as adjusted to reflect the sale of common stock offered by us and the selling stockholders in our initial public offering, for:

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

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

Applicable percentage ownership is based on 100,050,000 shares of common stock, 21,822,301 shares of series A-1 preferred stock and 9,782,609 shares of series B preferred stock outstanding at November 13, 2019. For purposes of computing percentage ownership after this offering, we have also assumed that [ ] shares of common stock will be issued by us and that all shares of series B preferred stock and warrants held by the selling stockholders will be converted to common stock and sold in this offering. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options or other convertible securities held by that person or entity that are currently exercisable or releasable or that will become exercisable or releasable within 60 days of November 13, 2019. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. No holder of our series A-1 preferred stock holds more than 5% of the outstanding shares of our voting stock before or after this offering. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o our company, 7707 Fannin, Suite 140, Houston, TX 77054.

	Shares Beneficially Owned Prior to this Offering				% of Total Voting Power Prior to this Offering(1)	Number of Shares Being Offered	Common Stock Beneficially Owned After this Offering		% of Total Voting Power After this Offering(1)
	Common Stock		Series B Preferred Stock						
	Shares	%	Shares	%			Shares	%	
Named Executive Officers and Directors:									
Maurizio Chiriva Internati	48,051,972	48.03%	0	*	36.50%	0	48,051,972	[ ]%	[ ]
Tony Tontat(2)	1,300,000	1.28%	0	*	*	0	1,300,000	[ ]%	[ ]
Scott Dahlbeck	14,898,796	14.89%	0	*	11.32%	0	14,898,796	[ ]%	[ ]
Gianluca Rotino(2)	5,164,320	4.91%	0	*	3.77%	0	5,164,320	[ ]%	[ ]
David Spencer(2)	200,000	*	0	*	*	0	200,000	[ ]%	[ ]
Angelo Minotti(3)	22,826,088	18.58%	7,608,696	77.78%	19.70%	30,434,784	0	*	*
All executive officers and directors (6 persons named above)	92,441,176	87.89%	7,608,696	77.78%	72.42%	30,434,784	69,615,088	[ ]%	[ ]
Other 5% Stockholders:									
Jose A. Figueroa(4)	16,733,182	16.72%	0	*	12.71%	0	16,733,182	[ ]%	[ ]
Other Selling Stockholders:									
Jui-Lien Chou Ho(5)	6,521,739	6.12%	2,173,913	22.22%	6.29%	8,695,652	0	*	*

* Less than 1%

(1) Percentage of total voting power represents voting power with respect to all shares of our common stock, series A-1 preferred stock and series B preferred stock, as a single class. The holders of our common stock, series A-1 preferred stock and series B preferred stock are entitled to one vote per share. For more information about the voting rights of our common stock, series A-1 preferred stock and series B preferred stock, see "Description of Securities."

(2) Represents an option for the purchase of shares of common stock exercisable within 60 days.

(3) Includes 3,260,870 shares of series B preferred stock and warrants for the purchase of 9,782,610 shares of common stock held directly, 2,173,913 shares of series B preferred stock and warrants for the purchase of 6,521,739 shares of common stock held by Encap (Global) Asset Management Limited and 2,173,913 shares of series B preferred stock and warrants for the purchase of 6,521,739 shares of common stock held by Interactive Engineering EOOD. Mr. Minotti is the Investment Officer of Encap (Global) Asset Management Limited and Interactive Engineering EOOD and has voting and investment control over the shares held by them. Mr. Minotti disclaims beneficial ownership of the shares held by Encap (Global) Asset Management Limited and Interactive Engineering EOOD except to the extent of his pecuniary interest, if

any, in such shares. The address of Encap (Global) Asset Management Limited is 12-S Sebright Plaza, 6-23 Shell Street, North Point, Hong Kong. The address of Interactive Engineering EOOD is 3 Prof. Milko Bichev, Fl 1, District of Oborishet, 1504 Sofia, Region of Sofia, Municipality of Sofia, Bulgaria.

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

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

We do not currently have any arrangements which if consummated may result in a change of control of our company.

TRANSACTIONS WITH RELATED PERSONS

Transactions with Related Persons

There have been no transactions since the beginning of our 2017 fiscal year, or any currently proposed transaction, in which we were or are to be a participant and the amount involved exceeded or exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any related person had or will have a direct or indirect material interest (other than compensation described under “Executive Compensation”).

Promoters and Certain Control Persons

Each of Maurizio Chiriva Internati and Scott Dahlbeck, may be deemed a “promoter” as defined by Rule 405 of the Securities Act. For information regarding compensation, including items of value, that have been provided or that may be provided to these individuals, please refer to “Executive Compensation” above.

DESCRIPTION OF SECURITIES

General

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

We are authorized to issue 300,000,000 shares of common stock, par value $0.0001 per share, and 38,130,435 shares of preferred stock, $0.0001 par value per share, of which 24,000,000 shares have been designated as series A-1 preferred stock and 14,130,435 have been designated as series B preferred stock.

As of the date of this prospectus, there are 100,050,000 shares of common stock, 21,822,301 shares of series A-1 preferred stock and 9,782,609 shares of series B preferred stock issued and outstanding.

Common Stock

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

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

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

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

Preferred Stock

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

Voting Rights. Shares of preferred stock vote together with the holders of common stock on an as-converted basis on all matters for which the holders of common stock vote at any meeting of stockholders or act by written consent, except as required by law. Notwithstanding the foregoing, so long as at least twenty-five percent (25%) of the series B preferred stock collectively remains outstanding, we may not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or our certificate of incorporation) the written consent or affirmative vote of the holders of at least sixty-seven percent (67%) of the then outstanding shares of series B preferred stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a single class on an as-converted basis,

which approval shall not be unreasonably withheld, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(a) the amend, alter or repeal any provision of our certificate of incorporation or bylaws in a manner adverse to the rights of the series B preferred stock;

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

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

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

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

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

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

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

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

(j) enter into or be party to any transaction with any director, officer or employee of our company or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such person other than (i) transactions resulting in payments to or by us in an amount less than $100,000 per year, (ii) transactions made in the ordinary course of business and pursuant to reasonable requirements of our business and on fair and reasonable terms that receive the prior approval of the board or (iii) with the prior approval of the board, including the director that was designated by the holders of the series B preferred stock;

Dividend Rights. Holders of series A-1 preferred stock have no dividend rights. From and after the date of issuance of any shares of series B preferred stock, dividends at an annual rate of six percent (6%) of the original issue price shall accrue on each share of series B preferred stock from the date of issuance of such share. The original issue price for the series B preferred stock is $0.46 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. Series B preferred stock dividends shall accrue from day to day, whether or not declared, and shall be cumulative; provided however, that such dividends shall be payable only when, as, and if declared by the board of directors. We may not declare, pay or set aside any dividends on shares of any other class or series of capital stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the series B preferred stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of series B preferred stock in an amount at least equal to the greater of (a) the amount of the aggregate dividends then accrued on such shares of series B preferred stock and not previously paid, (b) in the case of a dividend on common stock or any class or series that is convertible into common stock, that dividend per share of series B preferred stock as would equal the product of (i) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (ii) the number of shares of common stock issuable upon conversion of a share of series B preferred stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (c) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of series B preferred stock determined by (i) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (ii) multiplying such fraction by an amount equal to the applicable original issue price of the series B preferred stock; provided that, if we declare, pay or set aside, on the same date, a dividend on shares of more than one class or series of capital stock, the dividend payable to the holders of series B preferred stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest preferred stock dividend.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our company or deemed liquidation event, the holders of shares of preferred stock then outstanding shall be entitled to be paid out of the assets of our company available for distribution to its stockholders before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share of preferred stock equal to the applicable original issue price ($0.50 and $0.46 for the series A-1 preferred stock and series B preferred stock, respectively), plus all accrued and unpaid dividends, if applicable, whether or not declared together with any other dividends declared but unpaid thereon. If upon any such liquidation, dissolution or winding up or deemed liquidation event, the assets of our company available for distribution to its stockholders shall be insufficient to pay the holders of shares of preferred stock the full amount to which they shall be entitled, the holders of shares of preferred stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. After the payment of all preferential amounts required to be paid to the holders of shares of preferred stock, the remaining assets available for distribution to stockholders shall be distributed among the holders of the shares of preferred stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock immediately prior to such liquidation, dissolution or winding up or deemed liquidation event. A “deemed liquidation event” means, unless otherwise determined by the holders of at least a sixty-seven percent (67%) of the series B preferred stock then outstanding (voting separately as a class): (a) a merger or consolidation in which our company or a subsidiary is a constituent party and we issue shares pursuant to such merger or consolidation, except any such merger or consolidation in which our shares of capital stock outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (i) the surviving or resulting corporation; or (ii) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such

surviving or resulting corporation; or (b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by our company or any subsidiary of all or substantially all the assets of our company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries if substantially all of the assets of our company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary.

Conversion Rights. Each share of preferred stock is convertible at any time at the option of the holder at the then current conversion rate. In addition, upon the closing of the sale of shares of common stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act resulting in at least $20,000,000 of net proceeds to us, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate. All shares of series A-1 preferred stock or series B preferred stock shall also be automatically converted into shares of common stock at then effective conversion rate upon the vote or written consent of the holders of at least sixty-seven percent (67%) of the then outstanding shares of series A-1 preferred stock or series B preferred stock, as applicable, voting or consenting, as the case may be, as a single class and on an as-converted basis. The conversion rate for the preferred stock is currently one share of common stock for each share of preferred stock, calculated by dividing the original issue price of such share ($0.50 and $0.46 for the series A-1 preferred stock and series B preferred stock, respectively) by the conversion price per share then in effect (currently $0.50 and $0.46 for the series A-1 preferred stock and series B preferred stock, respectively), which is subject to customary adjustments in the event of any stock splits, stock dividends, mergers or reorganizations. Subject to certain exceptions, the conversion price is also subject to adjustment in the event that we issue additional shares of common stock or shares convertible into common stock.

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

Voting Agreement

On September 7, 2019, we entered into a voting agreement with the investors in our series B preferred stock financing and certain other stockholders, pursuant to which such investors and stockholders agreed to vote, or cause to be voted, all shares held by them from time to time to ensure that, at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders, one person designated by a majority of the holders of record as of the date of the voting agreement of shares of series B preferred stock with a purchase price of at least $1,000,000 (which we refer to as the major investors) shall be elected to serve as a director for so long as such major investors continue to beneficially own not less than 25% of the issued and outstanding shares of series B preferred stock. In the absence of any designation from the major investors, the director previously designated by them and then serving shall be reelected if still eligible and willing to serve and otherwise, such board seat shall remain vacant. No director elected by the major investors may be removed from office unless such removal is directed or approved by the affirmative vote of the major investors or the major investors are no longer so entitled to designate or approve such director. Any vacancies created by the resignation, removal or death of such designated director shall be filled in accordance with the foregoing. All parties to the voting agreement agreed to execute any written consents required to perform the foregoing obligations, and we agreed to call a special meeting of stockholders for the purpose of electing directors at the request of any major investor.

Notwithstanding the foregoing, each major investor agreed (i) not to designate or participate in the designation of any director designee to whom, to such major investor’s knowledge, a “bad actor” disqualifying event described in Rule 506(d)(1)(i)-(viii) under the Securities Act is applicable (which we refer to as a disqualified designee), except for a disqualifying event to which Rule 506(d)(2)(ii) or (iii) or (d)(3) is applicable, and (ii) that in the event such major investor becomes aware that any individual previously designated by any such major investor is

or has become a disqualified designee, such major investor shall as promptly as practicable take such actions as are necessary to remove such disqualified designee from the board and designate a replacement designee who is not a disqualified designee.

Each party to the voting agreement also agreed to vote or cause to be voted all shares held by them from time to time and at all times in whatever manner as shall be necessary to increase the number of authorized shares of common stock from time to time to ensure that there will be sufficient shares of common stock available for the exercise of any warrant and/or the conversion of all of the shares of series B preferred stock outstanding at any given time.

Warrants

In connection with our series B financing, we issued warrants for the purchase of 29,347,827 shares of common stock. The warrants have an exercise price of $0.0001 per share and expire ten years after the date of issuance. The warrants are exercisable as follows: (i) 30% of the shares underlying the warrants are exercisable from the date that is six months after the date on which our securities are first listed on a U.S. national securities exchange, (ii) an additional 30% of the shares underlying the warrants are exercisable nine months after such listing date, and (iii) the remaining shares underlying the warrants are exercisable twelve months after such listing date.

Options

As of the date of this prospectus, there are options for the purchase of 22,401,071 shares of common stock outstanding under our 2017 Equity Incentive Plan with a weighted average exercise price of $0.32 per share.

Transfer Agent and Registrar

We are in the process of appointing VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598, telephone 212-828-8436, as the transfer agent for our common stock.

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have [ ] shares of common stock issued and outstanding if the maximum number of shares being offered by us are sold and all shares of series B preferred stock and warrants are converted to common stock and sold in this offering. In addition, the holders of our series A-1 preferred stock may convert their shares into an aggregate of 21,822,301 shares of common stock at any time. All of the shares sold in this offering will be freely transferable without restriction under the Securities Act unless purchased by one of our affiliates as that term is defined in Rule 144 under the Securities Act, which generally includes directors, executive officers and 10% stockholders. Sales of substantial amounts of our shares in the public market could adversely affect prevailing market prices of our shares.

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

Rule 144

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

(i) 1% of the then outstanding common stock, which immediately after this offering will equal approximately [ ] shares if the maximum number of shares being offered by us are sold and all shares of series B preferred stock are converted to common stock; and

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

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

Rule 701

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

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock that is being issued pursuant to this offering. This summary is limited to Non-U.S. Holders (as defined below) that hold our common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This summary does not discuss all of the aspects of U.S. federal income and estate taxation that may be relevant to a Non-U.S. Holder in light of the Non-U.S. Holder's particular investment or other circumstances. Accordingly, all prospective Non-U.S. Holders should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the ownership and disposition of our common stock.

This summary is based on provisions of the Internal Revenue Code of 1986, as amended, or the Code, applicable U.S. Treasury regulations and administrative and judicial interpretations, all as in effect or in existence on the date of this prospectus. Subsequent developments in U.S. federal income or estate tax law, including changes in law or differing interpretations, which may be applied retroactively, could alter the U.S. federal income and estate tax consequences of owning and disposing of our common stock as described in this summary. There can be no assurance that the Internal Revenue Service, or IRS, will not take a contrary position with respect to one or more of the tax consequences described herein and we have not obtained, nor do we intend to obtain, a ruling from the IRS with respect to the U.S. federal income or estate tax consequences of the ownership or disposition of our common stock.

As used in this summary, the term "Non-U.S. Holder" means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an entity or arrangement treated as a partnership;
- an estate whose income is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more "United States persons" (within the meaning of the Code) has the authority to control all of the trust's substantial decisions, or (2) the trust has a valid election in effect under applicable U.S. Treasury regulations to be treated as a United States person.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in such a partnership generally will depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships, and partners in partnerships, that hold our common stock should consult their own tax advisors as to the particular U.S. federal income and estate tax consequences of owning and disposing of our common stock that are applicable to them.

This summary does not consider any specific facts or circumstances that may apply to a Non-U.S. Holder and does not address any special tax rules that may apply to particular Non-U.S. Holders, such as:

- a Non-U.S. Holder that is a financial institution, insurance company, tax-exempt organization, pension plan, broker, dealer or trader in stocks, securities or currencies, U.S. expatriate, controlled foreign corporation or passive foreign investment company;
- a Non-U.S. Holder holding our common stock as part of a conversion, constructive sale, wash sale or other integrated transaction or a hedge, straddle or synthetic security;

- a Non-U.S. Holder that holds or receives our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; or
- a Non-U.S. Holder that at any time owns, directly, indirectly or constructively, 5% or more of our outstanding common stock.

In addition, this summary does not address any U.S. state or local, or non-U.S. or other tax consequences, or any U.S. federal income or estate tax consequences for beneficial owners of a Non-U.S. Holder, including stockholders of a controlled foreign corporation or passive foreign investment company that holds our common stock.

Each Non-U.S. Holder should consult its own tax advisor regarding the U.S. federal, state, local and non-U.S. income and other tax consequences of owning and disposing of our common stock.

Distributions on Our Common Stock

We do not currently expect to pay any cash dividends on our common stock. If we make distributions of cash or property (other than certain pro rata distributions of our common stock) with respect to our common stock, any such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a nontaxable return of capital to the extent of the Non-U.S. Holder's adjusted tax basis in its common stock and will reduce (but not below zero) such Non-U.S. Holder's adjusted tax basis in its common stock. Any remaining excess will be treated as gain from a disposition of our common stock subject to the tax treatment described below in "—Dispositions of Our Common Stock."

Distributions on our common stock that are treated as dividends and that are effectively connected with a Non-U.S. Holder's conduct of a trade or business in the United States will be taxed on a net income basis at the regular graduated rates and in the manner applicable to United States persons. An exception may apply if the Non-U.S. Holder is eligible for, and properly claims, the benefit of an applicable income tax treaty and the dividends are not attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States. In such case, the Non-U.S. Holder may be eligible for a lower rate under an applicable income tax treaty between the United States and its jurisdiction of tax residence. Dividends that are effectively connected with a Non-U.S. Holder's conduct of a trade or business in the United States will not be subject to the U.S. withholding tax if the Non-U.S. Holder provides to the applicable withholding agent a properly executed IRS Form W-8ECI (or other applicable form) in accordance with the applicable certification and disclosure requirements. A Non-U.S. Holder treated as a corporation for U.S. federal income tax purposes may also be subject to a "branch profits tax" at a 30% rate (unless the Non-U.S. Holder is eligible for a lower rate under an applicable income tax treaty) on the Non-U.S. Holder's earnings and profits (attributable to dividends on our common stock or otherwise) that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States. The amount of taxable earnings and profits is generally reduced by amounts reinvested in the operations of the U.S. trade or business and increased by any decline in its equity.

The certifications described above must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. A Non-U.S. Holder may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS. Non-U.S. Holders should consult their own tax advisors regarding their eligibility for benefits under a relevant income tax treaty and the manner of claiming such benefits.

The foregoing discussion is subject to the discussions below under "—Backup Withholding and Information Reporting" and "—FATCA Withholding."

Dispositions of Our Common Stock

A Non-U.S. Holder generally will not be subject to U.S. federal income tax (including U.S. withholding tax) on gain recognized on any sale or other disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States); in such case, the gain will be subject to U.S. federal income tax on a net income basis at the regular graduated rates and in the manner applicable to United States persons (unless an applicable income tax treaty provides otherwise) and, if the Non-U.S. Holder is treated as a corporation for U.S. federal income tax purposes, the "branch profits tax" described above may also apply;
- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of the disposition and meets certain other requirements; in this case, except as otherwise provided by an applicable income tax treaty, the gain, which may be offset by certain U.S. source capital losses, generally will be subject to a flat 30% U.S. federal income tax, even if the Non-U.S. Holder is not treated as a resident of the United States under the Code; or
- we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of (i) the five-year period ending on the date of disposition and (ii) the period that the Non-U.S. Holder held our common stock.

Generally, a corporation is a "United States real property holding corporation" if the fair market value of its "United States real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming in the future, a United States real property holding corporation. However, because the determination of whether we are a United States real property holding corporation is made from time to time and depends on the relative fair market values of our assets, there can be no assurance in this regard. If we were a United States real property holding corporation, the tax relating to disposition of stock in a United States real property holding corporation generally will not apply to a Non-U.S. Holder whose holdings, direct, indirect and constructive, constituted 5% or less of our common stock at all times during the applicable period, provided that our common stock is "regularly traded on an established securities market" (as provided in applicable U.S. Treasury regulations) at any time during the calendar year in which the disposition occurs. However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Non-U.S. Holders should consult their own tax advisors regarding the possible adverse U.S. federal income tax consequences to them if we are, or were to become, a United States real property holding corporation.

The foregoing discussion is subject to the discussions below under "—Backup Withholding and Information Reporting" and "—FATCA Withholding."

Federal Estate Tax

Our common stock that is owned (or treated as owned) by an individual who is not a U.S. citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise and, therefore, may be subject to U.S. federal estate tax.

Backup Withholding and Information Reporting

Backup withholding (currently at a rate of 24%) will not apply to payments of dividends on our common stock to a Non-U.S. Holder if the Non-U.S. Holder provides to the applicable withholding agent a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable form) certifying under penalties of perjury that the Non-U.S.

Holder is not a United States person or is otherwise entitled to an exemption. However, the applicable withholding agent generally will be required to report to the IRS (and to such Non-U.S. Holder) payments of dividends on our common stock and the amount of U.S. federal income tax, if any, withheld from those payments. In accordance with applicable treaties or agreements, the IRS may provide copies of such information returns to the tax authorities in the country in which the Non-U.S. Holder resides.

The gross proceeds from sales or other dispositions of our common stock may be subject, in certain circumstances discussed below, to U.S. backup withholding and information reporting. If a Non-U.S. Holder sells or otherwise disposes of our common stock outside the United States through a non-U.S. office of a non-U.S. broker and the disposition proceeds are paid to the Non-U.S. Holder outside the United States, then the U.S. backup withholding and information reporting requirements generally will not apply to that payment. However, U.S. information reporting, but not U.S. backup withholding, will apply to a payment of disposition proceeds, even if that payment is made outside the United States, if a Non-U.S. Holder sells our common stock through a non-U.S. office of a broker that is a United States person or has certain enumerated connections with the United States, unless the broker has documentary evidence in its files that the Non-U.S. Holder is not a United States person and certain other conditions are met or the Non-U.S. Holder otherwise qualifies for an exemption.

If a Non-U.S. Holder receives payments of the proceeds of a disposition of our common stock to or through a U.S. office of a broker, the payment will be subject to both U.S. backup withholding and information reporting unless the Non-U.S. Holder provides to the broker a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable form) certifying under penalties of perjury that the Non-U.S. Holder is not a United States person, or the Non-U.S. Holder otherwise qualifies for an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be credited against the Non-U.S. Holder’s U.S. federal income tax liability (which may result in the Non-U.S. Holder being entitled to a refund), provided that the required information is timely furnished to the IRS.

FATCA Withholding

The Foreign Account Tax Compliance Act and related Treasury guidance (commonly referred to as FATCA) impose U.S. federal withholding tax at a rate of 30% on payments to certain foreign entities of (i) U.S.-source dividends (including dividends paid on our common stock) and (ii) the gross proceeds from the sale or other disposition after December 31, 2018 of property that produces U.S.-source dividends (including sales or other dispositions of our common stock). This withholding tax applies to a foreign entity, whether acting as a beneficial owner or an intermediary, unless such foreign entity complies with (i) certain information reporting requirements regarding its U.S. account holders and its U.S. owners and (ii) certain withholding obligations regarding certain payments to its account holders and certain other persons. Accordingly, the entity through which a Non-U.S. Holder holds its common stock will affect the determination of whether such withholding is required. Non-U.S. Holders are encouraged to consult their tax advisors regarding FATCA.

PLAN OF DISTRIBUTION

We are offering up to [ ] shares of common stock and the selling stockholders named herein are offering up to 39,130,436 shares of common stock, including 9,782,609 shares issuable upon the conversion of series B preferred stock and 29,347,827 shares issuable upon the exercise of warrants held by the selling stockholders, at a fixed price of $[ ] per share in a direct public offering. The offering is being made on a self-underwritten, “best efforts” basis. The selling stockholders may, or may not, elect to sell their shares of common stock covered by this prospectus, as and to the extent they may determine. Such sales, if any, will be made through brokerage transactions on the Nasdaq Stock Market if we become listed on the Nasdaq Stock Market. This is our initial public offering and no public market currently exists for our shares of common stock.

In connection with our selling efforts in the offering, our Chief Executive Officer, Dr. Maurizio Chiriva Internati, will not register as a broker-dealer pursuant to section 15 of the Exchange Act, but rather will rely upon the “safe harbor” provisions of SEC Rule 3a4-1, promulgated under the Exchange Act.

Generally speaking, Rule 3a4-1 provides an exemption from the broker-dealer registration requirements of the Exchange Act for persons associated with an issuer that participate in an offering of the issuer’s securities. Dr. Chiriva is not subject to any statutory disqualification, as that term is defined in section 3(a)(39) of the Exchange Act. Dr. Chiriva will not be compensated in connection with her participation in the offering by the payment of commissions or other remuneration based either directly or indirectly on transactions in our securities. Dr. Chiriva is not, nor has he been within the past 12 months, a broker or dealer, and he is not, nor has he been within the past 12 months, an associated person of a broker or dealer. At the end of the offering, Dr. Chiriva will continue to primarily perform substantial duties for our company or on its behalf otherwise than in connection with transactions in securities. Dr. Chiriva will not participate in selling an offering of securities for any issuer more than once every 12 months other than in reliance on exchange act Rule 3a4-1(a)(4)(i) or (iii).

We will receive all proceeds from the sale of the [ ] shares being offered on behalf of our company. The proceeds from the 39,130,436 shares held by the selling stockholders, if sold, will not go to the company, but will go to the selling stockholders directly. The price per share is fixed at $[ ] for the duration of this offering. Although our common stock is not listed on a public exchange, we plan to file a listing application with Nasdaq. There can be no assurance that such application will be approved or that our common stock will trade on such market either now or at any time in the future.

Our shares may be sold to purchasers from time to time directly by and subject to the discretion of our company. Further, we will not offer our shares for sale through underwriters, dealers, agents or anyone who may receive compensation in the form of underwriting discounts, concessions or commissions from the company and/or the purchasers of the shares for whom they may act as agents. The shares of common stock sold by us and the selling stockholders may be occasionally sold in one or more transactions; all shares sold under this prospectus will be sold at a fixed price of $[ ] per share.

In order to comply with the applicable securities laws of certain states, the securities will be offered or sold in those states only if they have been registered or qualified for sale; an exemption from such registration or if qualification requirement is available and with which the company has complied.

In addition and without limiting the foregoing, we will be subject to applicable provisions, rules and regulations under the Exchange Act with regard to security transactions during the period of time when this registration statement is effective.

We will pay all expenses incidental to the registration of the shares (including registration pursuant to the securities laws of certain states), which we expect to be no more than $[ ].

Procedures for Subscribing

If you decide to subscribe for any shares in this offering that are offered by us you must (1) execute and deliver a subscription agreement and (2) deliver a check or certified funds to us for acceptance or rejection.

All checks for subscriptions must be made payable to “Kiromic, Inc.” Wire transfer and ACH transfer are also accepted in accordance with instructions provided in the subscription agreement. The company’s transfer agent will register the shares sold in book-entry form and we will promptly provide confirmation of purchase.

Right to Reject Subscriptions

We have the right to accept or reject subscriptions in whole or in part, for any reason or for no reason. All monies from rejected subscriptions will be returned immediately by us to the subscriber, without interest or deductions. Subscriptions for securities will be accepted or rejected with letter by mail within 48 hours after we receive them.

Shares Sold by the Selling Stockholders

If you decide to subscribe for any shares in this offering that are offered by the selling stockholders, the selling stockholders(s) will inform you of their preferred method of payment and the procedures they have for subscribing. Procedures may vary from stockholder to stockholder. It should be noted that we will in no way be involved with any private transactions in which our selling stockholders sell shares of our their own common stock. Selling stockholders may or may not decide to reject subscriptions. This decision is at their own discretion. Selling stockholders will be responsible for following any applicable laws or regulations in regards to the sale(s) of their own shares of common stock.

Listing

We plan to file a listing application for our common stock on the Nasdaq Global Select Market under the symbol “KRBP.” We make no representation that such application will be approved or that the common stock will trade on such market either now or at any time in the future.

No Prior Public Market

Prior to this offering, there has been no public market for our securities and the offering price for our common stock has been determined by us. Among the factors to be considered were the prevailing market conditions, our financial information, market valuations of other companies that we believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the offering price will correspond to the price at which our common stock will trade in the public market subsequent to this offering or that an active trading market for our common stock will develop and continue after this offering.

Offers Outside the United States

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

LEGAL MATTERS

The validity of the shares of common stock covered by this prospectus will be passed upon by Bevilacqua PLLC.

EXPERTS

The consolidated financial statements included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such consolidated financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

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

FINANCIAL STATEMENTS

KIROMIC, INC. AND SUBSIDIARY

AUDITED CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Kiromic, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kiromic, Inc. and subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

Houston, Texas

November 14, 2019

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

Kiromic, Inc. and Subsidiary
Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 384,300	$ 1,049,500
Unbilled receivables from granting agencies	24,300	5,400
Prepaid expenses and other current assets	151,600	364,100
Total current assets	560,200	1,419,000
Property and equipment, net	298,000	247,300
Other assets	17,800	14,800
Total Assets	$ 876,000	$ 1,681,100
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 219,100	$ 223,500
Accrued expenses and other current liabilities	372,600	223,200
Deferred rent, current portion	19,000	25,400
Total current liabilities	610,700	472,100
Interest payable	—	363,400
Deferred rent, net of current portion	—	19,000
Convertible promissory notes	—	5,737,000
Convertible promissory notes derivative liability	—	369,000
Total Liabilities	610,700	6,960,500
Commitments and contingencies (Note 7)		
Stockholders' Equity (Deficit):		
Series A-1 Preferred Stock, $0.0001 par value: 24,000,000 shares authorized as of December 31, 2018; 20,886,782 shares issued and outstanding as of December 31, 2018	8,727,400	—
Common stock: 300,000,000 and 600,000,000 shares authorized as of December 31, 2018 and 2017, respectively; 100,000,000 shares issued and outstanding as of December 31, 2018 and 2017	—	—
Additional paid-in capital	10,237,600	9,604,600
Accumulated deficit	(18,699,700)	(14,884,000)
Total Stockholders' Equity (Deficit)	265,300	(5,279,400)
Total Liabilities and Stockholders' Equity (Deficit)	$ 876,000	$ 1,681,100

See accompanying notes to the consolidated financial statements

Kiromic, Inc. and Subsidiary
Consolidated Statements of Operations

	Years Ended December 31, 2018	2017
Operating expenses:		
Research and development	$ 1,424,900	$ 2,312,400
General and administrative	1,757,700	3,080,200
Total operating expenses	3,182,600	5,392,600
Loss from operations	(3,182,600)	(5,392,600)
Other expense		
Interest expense	(633,100)	(420,800)
Other expense	(633,100)	(420,800)
Loss before income taxes	(3,815,700)	(5,813,400)
Income tax benefits	—	—
Net loss	$ (3,815,700)	$ (5,813,400)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.06)
Weighted average common shares outstanding, basic and diluted	100,000,000	100,000,000
Proforma net loss per common share, basic and diluted (unaudited)	$ (0.03)	
Pro-forma weighted-average common stock outstanding, basic and diluted (unaudited)	120,886,782	

See accompanying notes to the consolidated financial statements

Kiromic, Inc. and Subsidiary
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Series A-1 Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance at January 1, 2017	—	$ —	100,000,000	$ —	$ 7,915,600	$ (9,070,600)	$ (1,155,000)
Stock compensation expense	—	—	—	—	1,689,000	—	1,689,000
Net loss	—	—	—	—	—	(5,813,400)	(5,813,400)
Balance at December 31, 2017			100,000,000		9,604,600	(14,884,000)	(5,279,400)
Issuance of Series A-1 Preferred Stock	2,007,000	900,000	—	—	—	—	900,000
Conversion of convertible promissory notes and accrued interest into Series A-1 Preferred Stock	18,879,782	7,827,400	—	—	—	—	7,827,400
Stock compensation expense	—	—	—	—	633,000	—	633,000
Net loss	—	—	—	—	—	(3,815,700)	(3,815,700)
Balance at December 31, 2018	20,886,782	$ 8,727,400	100,000,000	—	$ 10,237,600	$ (18,699,700)	$ 265,300

See accompanying notes to the consolidated financial statements

Kiromic, Inc. and Subsidiary
Consolidated Statements of Cash Flows

	Years Ended December 31, 2018	2017
Cash flows from operating activities:		
Net loss	$ (3,815,700)	$ (5,813,400)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	80,900	115,100
Stock compensation expense	633,000	1,689,000
Loss on disposal of fixed assets	—	62,700
Non-cash interest	633,100	—
Changes in operating assets and liabilities:		
Unbilled receivables from granting agencies	(18,900)	(5,400)
Inventories	—	14,200
Prepaid expenses and other current assets	212,500	(265,500)
Other assets	(3,000)	—
Accounts payable	(4,400)	159,100
Accrued expenses and other current liabilities	149,400	113,400
Interest payable	(363,400)	314,800
Deferred rent	(25,400)	(25,400)
Convertible promissory notes derivative liability	369,000	106,000
Net cash used for operating activities	(2,152,900)	(3,535,400)
Cash flows from investing activities:		
Purchases of property and equipment	(137,300)	(29,700)
Net cash used for investing activities	(137,300)	(29,700)
Cash flows from financing activities:		
Proceeds from sale of convertible promissory notes	725,000	4,195,000
Proceeds from Series A-1 Preferred Stock issuance	900,000	—
Net cash provided by financing activities	1,625,000	4,195,000
Net change in cash and cash equivalents	(665,200)	629,900
Cash and cash equivalents:		
Beginning of year	1,049,500	419,600
End of year	$ 384,300	$ 1,049,500
Supplemental disclosures of non-cash investing and financing activities:		
Conversion of accounts payable into convertible promissory notes	$ —	$ 130,000
Conversion of convertible promissory notes and accrued interest to Series A-1 Preferred Stock	$ 7,827,400	$ —

See accompanying notes to the consolidated financial statements

Kiromic, Inc. and Subsidiary
Notes to Consolidated Financial Statements
As of and for the Years Ended December 31, 2018 and 2017

1. ORGANIZATION

Nature of Business

Kiromic, Inc. and Subsidiary (the "Company") is a clinical-stage biopharmaceutical company formed under the Texas Business Organizations Code in December 2012. On May 27, 2016, the Company converted from a Texas limited liability company into a Delaware corporation and changed its name from Kiromic LLC to Kiromic Inc. The Company is focused on discovering, developing, and commercializing novel immune-oncology and small molecule therapy applications through its robust product pipeline, which are in the early stages of the US Food and Drug Administration clinical trial process (one Investigational New Drug (IND) application has already been authorized, with two more in pre-IND status). The authorized Phase I/II IND #12612 clinical trial launched in July 2017 in San Antonio and Houston (MD Andersen Cancer Center) and completed in May 2018. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

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

Going Concern—The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability of assets or the reclassification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company has incurred losses, negative cash flows from operations, and has not generated any revenues since its inception. In addition to incurring losses from operations, the Company has primarily financed its operations with the proceeds from equity and debt financing arrangements. The Company's long-term success is dependent upon its ability to successfully develop, commercialize and market its products, earn revenue, obtain additional capital when needed, and, ultimately, to achieve profitable operations. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Thus, conditions and events exist that raised the substantial doubt regarding the Company's ability to continue as a going concern.

In addition, in August 2019, the Company started its planned equity financing with Series B Stock ("Series B Stock") primarily for research and development costs, and general corporate purposes. As of the date these financial statements were available to be issued the Company raised $4,500,000 for 9,782,609 shares of Series B Stock at a price of $0.46 per share.

The holders of the Series B Stock hold a special redemption right. In the event the Company has not filed an initial registration statement with the United States Securities and Exchange Commission and submitted an application to be listed on the Nasdaq Stock Market on or prior to November 15, 2019, subject to Delaware law governing distributions to stockholders and the Company's ability to redeem its shares, all or part of the shares of Series B Stock held by any holder of record as of such date of shares of Series B Stock with an aggregate purchase price of at least $1,000,000 shall thereafter be redeemable at the option of such holders of record commencing any time on or after November 16, 2019 at a price equal to the purchase price paid for such shares plus all unpaid dividends accrued on such shares. Furthermore, in the event that the Company is ultimately approved for listing on a Nasdaq Stock Market tier lower than the Nasdaq Global Select Market, the Special Redemption Right shall remain in effect and may be exercisable on any date thereafter.

Kiromic, Inc. and Subsidiary
Notes to Consolidated Financial Statements
As of and for the Years Ended December 31, 2018 and 2017

Management's plans intended to alleviate substantial doubt are as follows:

- The Company is seeking significant additional capital funding to develop its platform and Pre-IND product lines, additional hiring of scientific professionals and other general and administrative employees, and clinical trials. However, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable.
- If the Company is unable to secure additional funding when desired, management has the ability to eliminate certain forecasted discretionary costs in the event that a cash constraint is identified. Doing so would not impact the intended use of proceeds outlined in the Series B Stock purchase agreements. The use of the proceeds per the agreement are: (i) legal fees, (ii) financial auditing fees, (iii) ordinary operational costs, (iv) contract research organization or clinical site usage costs, (v) hiring employees or consultants, and (vi) costs incurred in connection with the preparation and filing of a registration statement with the United States Securities and Exchange Commission.
- In response to the shares of Series B Stock being redeemable at the option of the holders, the Company has submitted an application to be listed on the Nasdaq Stock Market and intends to file an initial registration statement with the United States Securities and Exchange Commission before November 15, 2019, in which the first two redemption rights become null and void.
- With regards to the ultimate listing on the Nasdaq Global Select Market, the Company has received waivers from all current Series B Stock holders indicating that they will not exercise the associated redemption right and consent to the Company removing such right in a forthcoming amendment to its Second Amended and Restated Certificate of Incorporation.

In response to the Company's expected need for funding to maintain operations for the next twelve months following the date the consolidated financial statements were available to be issued, the Company considered whether sufficient cash balances would sustain non-discretionary research and development costs, clinical trials costs, and general and administrative operating costs per the Series B Preferred Financing agreement signed with the investors. The Company considered projected cash outflows in conjunction with anticipated reimbursed expenses from Phase II of the National Institutes of Health ("NIH") Grant. As of the date these financial statements were available to be issued, the Company has projected to have the necessary funding to meet its working capital needs to continue operations for at least twelve months following the date the consolidated financial statements were available to be issued.

As a result, the Company has concluded that management's plans are probable of being implemented and alleviate substantial doubt about the Company's ability to continue as a going concern.

NIH Grant—In August 2018, NIH, the primary agency of the United States government responsible for biomedical and public health research, awarded a Phase I/II grant to the Company in the amount of $2,235,000 for the development and non-clinical testing of a new anti-arteriosclerosis gene therapy delivered by engineered adeno-associated viral vectors. Phase I of the grant approved amounts of $851,000 and which covers the period September 2018 through August 2019, entitles the Company to reimbursement for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees. Starting in 2020, Phase II of the grant covers reimbursements for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees of $1,384,000.

Kiromic, Inc. and Subsidiary
Notes to Consolidated Financial Statements
As of and for the Years Ended December 31, 2018 and 2017

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). All intercompany balances were eliminated upon consolidation. Operating results for the year ended December 31, 2018 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, the fair value of convertible promissory notes and the related embedded derivative liability, and estimating services expended by third-party service providers used to recognize research and development expense.

Cash and Cash Equivalents—As of December 31, 2018 and 2017, cash and cash equivalents consisted entirely of cash on hand and bank deposits.

Unbilled Receivables from Granting Agencies—Unbilled receivables include certain cost reimbursements owed to the Company resulting from a biomedical research grant from the National Institutes of Health ("NIH"). Direct costs subject to reimbursement are recorded only after actual expenses have been incurred while indirect costs are calculated using the percentage-of-completion accounting method. Unbilled receivables represent qualified cost reimbursements which have not yet been requested from the granting agency due to the timing of the accounting invoicing cycle. The Company estimates the amount of probable credit losses from its existing unbilled receivables in the form of an allowance for doubtful accounts. The Company determines the allowance for doubtful accounts based upon an aging of unbilled receivables, historical experience, and management judgment. Unbilled receivable balances are reviewed individually for collectability. For the years ended December 31, 2018 and 2017, the Company has not experienced any credit-related losses.

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

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

The Company records receivables resulting from activities under its research grant from the NIH. The NIH is an agency of the United States government that is responsible for biomedical and health-related research and

Kiromic, Inc. and Subsidiary
Notes to Consolidated Financial Statements
As of and for the Years Ended December 31, 2018 and 2017

conducts and provides biomedical research funding to non-NIH research facilities through its Extramural Research Program. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the granting agency.

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

Property and Equipment—Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from 2.5 to 8 years. Major replacements and improvements are capitalized as leasehold improvements, while general repairs and maintenance are expensed as incurred. Estimated useful lives of leasehold improvements are the shorter of the remaining lease term or the estimated useful economic life of the specific asset.

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

Asset Description	Estimated Lives
Laboratory Equipment	3 - 8
Leasehold improvements	2.5 - 7
Office Furniture, Fixtures, and Equipment	5
Software	5

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company capitalized software development costs of approximately $121,500 and $0 for the years ended December 31, 2018 and 2017, respectively.

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

Comprehensive Loss—Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) 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 income tax returns, utilizing the accrual basis of accounting. Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due and deferred taxes. Certain transactions of the Company may be subject to accounting methods for income tax purposes, which differ from the accounting methods used in preparing these financial statements in accordance with GAAP. Accordingly, the net income or loss of the Company reported for income tax purposes may differ from the balances reported for those same items in the accompanying financial statements.

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

The Company records uncertain tax positions in accordance with ASC 740 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 statement of operations. No such interest or penalties were recognized during the years ended December 31, 2018 and 2017.

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

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

Proceeds from Grants—During the years ended December 31, 2018 and 2017, the Company recognized $258,000 and $66,000, respectively, as reductions to research and development expense within the statements of operations pursuant to its grant from the NIH.

Convertible Promissory Notes Derivative Liability—The Company has recorded an embedded derivative liability related to the discount on the per share selling price the holders of the convertible promissory notes would receive at the time of conversion in connection with Company's next equity financing ("Next Financing Close"). The embedded derivative liability is initially recorded at fair value, with gains and losses arising from changes in fair value recognized in interest expense in the statements of operations at each period end while such instruments are outstanding. The embedded derivative liability is valued using a probability weighted expected return model. See Note 6.

Upon repurchase of convertible promissory notes, ASC 470-20 requires the Company to allocate total settlement consideration, inclusive of transaction costs, amongst the liability components of the instrument based on the fair value of the liability component immediately prior to repurchase. The difference between the settlement consideration allocated to the liability component and the net carrying value of the liability component would be recognized as gain (loss) on extinguishment of debt in the consolidated statements of operations.

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

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

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

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

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

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

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2018 and 2017.

The following table presents information about the Company's liabilities that are measured at fair value on a non-recurring and recurring basis as of December 31, 2018 and 2017. Per ASC 820, the convertible promissory notes are measured on a non-recurring basis at the relevant measurement date. The convertible promissory notes embedded derivative liability is measured on a recurring basis at the end of each reporting period.

	December 31, 2018			
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Convertible promissory notes	—	—	—	—
Convertible promissory note embedded derivative liability	—	—	—	—

	December 31, 2017			
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Convertible promissory notes	—	—	$5,737,000	$5,737,000
Convertible promissory note embedded derivative liability	—	—	$ 369,000	$ 369,000

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

	2018	2017
Convertible promissory notes		
Beginning balance	$ 5,737,000	$ 1,617,200
Amounts allocated to the embedded derivative liability at inception (at fair value)	(8,000)	(205,200)
Proceeds from issuances of convertible promissory notes	725,000	4,325,000
Conversions into Series A-1 Stock	(6,454,000)	—
Ending balance	$ —	$ 5,737,000

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

	2018	2017
Convertible promissory note embedded derivative liability		
Beginning balance	$ 369,000	$ 57,800
Realized and unrealized gains and losses	167,000	106,000
Fair value of embedded derivative liability at inception	8,000	205,200
Amounts derecognized upon conversion of the related convertible promissory notes	(544,000)	—
Ending balance	$ —	$ 369,000

Nonvested Shares and Nonvested Share Units—Pursuant to the Company's 2017 Stock Incentive Plan (the "Plan"), the Company has the ability to issue a variety of share-based payments and incentives to members, employees, and non-employees through grants of nonvested shares. Nonvested shares confer to the holder the same benefits, rights and privileges of being an actual shareholder in the Company. The vesting conditions include annual, monthly, and fully vested. Annual vesting conditions are for 4 years. Monthly vesting conditions range from 10 to 48 months. Both fully vested and nonvested options are exercisable 10 years from grant date. Cost of nonvested options are determined by the fair market value of the Company's common stock.

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

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

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

Expected Term. The expected term represents the period that the Company's stock options are expected to be outstanding. Due to limitations on the sale or transfer of the Company's common stock as a privately held company, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience as a future publicly traded company. The Company has consequently used the Staff Accounting Bulletin ("SAB") No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period. The Company plans to continue to use the SAB 110 simplified method until it has sufficient trading history as a publicly traded company.

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

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

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

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

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

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- the market performance of comparable publicly traded companies; and
- the U.S. and global capital market conditions.

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

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

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

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

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

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

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

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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 to January 1, 2021. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

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

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On October 16, 2019, the FASB has changed the effective date of this standard to January 1, 2023. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

In August 2016, the FASB issued ASU 2016-15 (Topic 230), *Classification of Certain Cash Receipts and Payments*, a new standard providing guidance on statement of cash flow classification on specific issues. The standard is effective for financial statements issued for fiscal periods beginning after December 15, 2018. It is required to be applied on a retrospective approach. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

On January 1, 2018, the Company adopted ASU 2018-07, *Improvements to Non-employee Share-Based Payment Accounting* (Topic 718). This standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. FASB clarified that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or awards granted in conjunction with

selling goods or services to customers as part of a contract accounted for under ASC 606—Revenue from Contracts with Customers. Since the Company has not generated any revenue to date, this adoption did not result in a material impact on the Company's financial statements and related disclosures.

Correction of an Error—Subsequent to the issuance of the Company's consolidated financial statements as of December 31, 2017, management determined that $1,689,000 was incorrectly recorded to common stock instead of additional paid-in capital on the consolidated balance sheet and the consolidated statement of changes in stockholders' equity (deficit) as of December 31, 2017. As a result, the Company restated the consolidated financial statements as of December 31, 2017 to correct the misstatement. Common stock has been restated from $1,689,000 to $0, and the additional paid-in capital has been restated from $7,915,600 to $9,604,600.

The reclassification error did not impact the consolidated statement of operations or the consolidated statement of cash flows for the year ended December 31, 2017. Management evaluated the materiality of these misstatements from quantitative and qualitative perspectives and concluded it is not material to the prior period.

3. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share is determined by dividing net loss by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the stock options, convertible promissory notes, and convertible preferred stock have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average common shares outstanding used to calculate both basic and diluted loss per common shares are the same.

For the years ended December 31, 2018 and 2017, potentially dilutive securities excluded from the computations of diluted weighted-average common shares outstanding were (in shares):

	2018	2017
Options to purchase	2,043,623	—
Convertible promissory notes	—	2,549,778
Series A-1 Preferred Stock	20,886,782	—
Total	22,930,405	2,549,778

Unaudited Pro Forma Net Loss Per Common Share

Upon the closing of the sale of shares of common stock to the public in an initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $20,000,000 of net proceeds to the Company, all shares of Series A-1 Stock shall automatically be converted into shares of common stock at the then effective conversion rate.

The unaudited pro forma basic and diluted net loss per common share for the year ended December 31, 2018 has been prepared to give effect to adjustments arising upon the completion of such public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per common share does not include any pro forma adjustments to net loss.

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per common share for the year ended December 31, 2018 has been prepared to give effect, upon such a public offering, to the automatic conversion of all outstanding shares of

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Series A-1 Stock into common stock as if the proposed public offering had occurred on the issuance date of the Series A-1 Stock, which was December 20, 2018. Pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31, 2018
Numerator:	
Net loss—basic and diluted	$ (3,815,700)
Pro forma net loss—basic and diluted	$ (3,815,700)
Denominator:	
Weighted-average common stock outstanding—basic and diluted	100,000,000
Pro forma adjustment to reflect automatic conversion of Series A-1 Stock to common stock upon the completion of the proposed initial public offering	20,886,782
Pro forma weighted-average common stock outstanding—basic and diluted	120,886,782
Pro forma net loss per common share—basic and diluted	$ (0.03)

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31:

	2018	2017
Equipment	$ 158,000	$ 158,000
Leasehold improvements	282,600	282,600
Office furniture, fixtures, and equipment	10,100	—
Software	121,500	—
	572,200	440,600
Less: Accumulated depreciation	(274,200)	(193,300)
Total	$ 298,000	$ 247,300

Depreciation expense was $80,900 and $115,100 for the years ended December 31, 2018 and 2017, respectively. Depreciation expense is recorded within general and administrative operating expenses on the consolidated statements of operations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	2018	2017
Accrued consulting and outside services	$221,300	$218,000
Accrued compensation	145,000	—
Accrued other	6,300	5,200
Total	$372,600	$223,200

6. CONVERTIBLE PROMISSORY NOTES

Starting in June 2016, the Company sold convertible promissory notes to certain investors to help finance its operations. The convertible promissory notes were in amounts ranging from $12,500 to $500,000, earning annual interest at 7% and all maturing either on June 1, 2019 or January 2, 2020 (the “Maturity Date”).

The convertible promissory notes were convertible into shares issued in the Company's Next Financing Close by dividing the total amount of convertible promissory notes, plus accrued interest (the "Balance") by the applicable conversion price, as defined in the convertible promissory notes. If the convertible promissory notes have not been converted, the Balance shall be payable in full if the Company consummates a change of control transaction. If there has not been a Next Financing Close or a change in control by the Maturity Date, then at the noteholders' option, the Company shall either repay the Balance then outstanding or convert into the Company's common stock at a set conversion price then in effect, as defined in the convertible promissory notes.

The estimated fair value of the conversion discount related embedded derivative was determined using a probability-weighted expected return model. The probability of a Next Financing Close occurring prior to the Maturity Date was determined to be 55% during 2017. The net present value of the conversion discount related embedded derivative was measured using a discount rate of 50% as of December 31, 2018 and 2017. Below is a table that outlines the initial value of issuances and the bifurcated embedded derivative liability during the years ended December 31, 2018 and 2017:

	2018	2017
Convertible promissory notes- issuances	$ 725,000	$ 4,325,000
Embedded derivative liability		
Initial fair value upon issuance of convertible promissory notes	271,000	263,000
Change in fair value	273,000	106,000
Converted embedded derivative liability into Series A-1 Stock	(544,000)	—
Embedded derivative liability balance at December 31	$ —	$ 369,000

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

7. COMMITMENTS AND CONTINGENCIES

Facility Lease Agreements—The Company leases its premises in Houston, Texas under a noncancelable operating lease expiring in May 2019. The Company may extend this lease for up to two years. The Company formerly had offices in Lubbock, TX which was closed down when its lease expired in July 2017. In October and November of 2018, the Company renewed the office space lease in Houston, Texas until May 1, 2021. The total lease payments per month will be $14,807 beginning April 1, 2019. The Company records rent expense on a straight-line basis over the term of the respective leases.

As of December 31, 2018, future minimum commitments under facility lease agreements were as follows:

	Amount
2019	$ 178,000
2020	178,000
2021	59,000
Total	$ 415,000

Annual rent expense for the facility lease agreements was $156,700 and $189,900 for the years ended December 31, 2018 and 2017, respectively, and is included as an allocation between research and development and general and administrative expense in the statements of operations.

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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, 2018 and 2017, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Legal Proceedings—In the normal course of business, the Company may have various claims in process and other contingencies. The Company regularly assesses all contingencies and believes, based on information presently known, the Company is not involved in any matters that would have a material effect on the Company's financial position.

8. STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock—From inception in December 2012 through May 2016, the Company raised proceeds from capital contributions for common stock at a $0.001 par value, net of redemptions, totaling $6,214,800. When the Company converted from Kiromic, LLC to Kiromic, Inc., the shares converted from two classes to a single class of common stock. At the time of conversion, the par value on the two classes of common stock eliminated, and the par value of common stock transferred entirely into additional paid-in capital. There were no additional raises from common stock that occurred in the years ended December 31, 2018 or 2017.

The Company authorized shares of 300,000,000 and 600,000,000 as of December 31, 2018 and 2017, respectively. The certificate of incorporation authorizing 600,000,000 shares was dated May 27, 2016. The Company amended its certificate of incorporation on December 20, 2018 to reduce the number of authorized shares. As of December 31, 2018, and 2017, the Company issued 100,000,000 shares of common stock.

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

The Company has never paid dividends and has no plans to pay dividends on common stock. As of December 31, 2017, the Company adopted a stock option plan. It has 20,000,000 shares authorized for grants and there are 1,813,516 shares and 7,701,891 shares available for issuance as of December 31, 2018 and 2017, respectively (see Note 9).

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

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

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

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

Each share of Series A-1 Stock is convertible at any time at the option of the holder at the then current conversion rate. In addition, upon the closing of the sale of shares of common stock to the public in an initial public offering pursuant to an effective registration statement under the Securities Act resulting in at least $20,000,000 of net proceeds to the Company, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate.

Conversion of Convertible Promissory Notes —On December 20, 2018, the Company's certificate of incorporation was amended to authorize 24,000,000 shares Series A-1 Stock. This amendment qualified as the Next Financing Close with respect to the convertible promissory notes. Therefore, the outstanding principal and accrued interest was converted into Series A-1 Stock. At the time of conversion, outstanding principal and accrued interest of the convertible promissory notes totaled $7,541,600. Per the convertible promissory notes, the conversion price was $0.40. Accordingly, 18,854,033 shares were issued to convert the outstanding principal and accrued interest into Series A-1 Stock.

9. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan

In January 2017, the Company's board of directors approved the adoption of the Plan. The Plan permits the Company to grant up to 20,000,000 shares of the Company's common stock awards, including incentive stock options; nonstatutory stock options; and conditional share awards to employees, directors, and consultants of the Company. All granted shares that are canceled, forfeited, or expired are returned to the Plan and are available for grant in conjunction with the issuance of new common stock awards. Stock options granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over an agreed service period.

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

	2018	2017
Risk-free interest rate	2.24% - 2.92%	2.06% - 2.15%
Expected volatility	74.54% - 78.16%	74.69% - 77.65%
Expected life (years)	4.93 - 6.01	5.00 - 5.87
Expected dividend yield	0%	0%

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

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

	2018		2017	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	12,298,109	$ 0.19	—	$ —
Granted	8,739,000	0.33	14,494,484	0.19
Cancelled and forfeited	(2,850,625)	0.24	(2,196,375)	0.19
Balance at December 31	18,186,484	$ 0.25	12,298,109	$ 0.19
Options exercisable at December 31:	11,916,484	$ 0.21	10,698,817	$ 0.19
Weighted average grant date fair value for options granted during the year:		$ 0.18		$ 0.15

The following table summarizes additional information about stock options outstanding and exercisable at December 31, 2018 and 2017 under the Plan:

	Options Outstanding				Options Exercisable		
Year Ended December 31,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2017	12,298,109	9.86	$ 0.19	$ —	10,698,817	$ 0.19	$ —
2018	18,186,484	9.16	$ 0.25	$ 1,687,000	11,916,484	$ 0.21	$ 1,589,500

Total stock compensation expense recognized for all stock-based compensation awards recognized in the statements of operations for the years ended December 31, 2018 and 2017, is as follows:

	2018	2017
Research and development	$ 303,000	$ 544,000
General and administrative	330,000	1,145,000
Total	$ 633,000	$ 1,689,000

As of December 31, 2018, total unrecognized stock compensation expense is $1,338,800, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 3.3 years.

10. INCOME TAXES

For the years ended December 31, 2018 and 2017, the Company recognized no provision or benefit from income taxes.

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The following is a reconciliation of the effective income tax rate to the statutory federal income tax rate for the years ended December 31, 2018 and 2017.

	2018	2017
Federal income tax at statutory rates	21.00%	34.00%
Federal income tax rate reduction	— %	(18.00)%
Change in valuation allowance	(21.00)%	(16.00)%
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. In accordance with ASC 740, *Income Taxes*, the Company recorded a valuation allowance to fully offset the net deferred tax asset, because it is not more likely than not that the Company will not realize future benefits associated with these deferred tax assets as of December 31, 2018 and 2017 due to the significant uncertainty about the realization of the deferred tax asset until the Company can operate profitably.

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

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

	2018	2017
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 1,941,000	$ 1,286,500
Stock compensation expense	487,600	354,700
Property and equipment	—	8,800
Intangible assets	36,100	11,300
Total gross deferred tax assets	2,464,700	1,661,300
Valuation allowance	(2,455,100)	(1,661,300)
Property and equipment	(9,600)	—
Net deferred tax assets (liabilities)	$ —	$ —

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Subsequent to the issuance of the Company's financial statements as of December 31, 2017, management determined that the deferred tax assets related to net operating loss carryforwards and stock compensation expense as of December 31, 2017 were incorrectly recorded as they did not include the cumulative effects of the net operating loss carryforwards and did not present the stock compensation expense deferred tax asset. As a result, the Company's disclosure above has been restated from the amounts previously reported. There were no changes made to the net deferred tax assets (liabilities) balance as of December 31, 2017. Management evaluated the materiality of these misstatements from quantitative and qualitative perspectives and concluded it is not material to the prior period. The restatement is presented below:

	As Previously Reported	Adjustment	As Restated
Deferred tax assets (liabilities)			
Net operating loss carryforwards	$ 919,773	$ 366,727	$ 1,286,500
Stock compensation expense	—	354,700	354,700
Total gross deferred tax assets	939,927	721,373	1,661,300
Valuation allowance	$(939,927)	$(721,373)	$(1,661,300)

As of December 31, 2018 and 2017, the Company has a U.S. net operating loss ("NOL") carryforward of $9,242,900 and $6,126,200, respectively. The NOL carryforwards may be subject to annual limitations due to the "change in ownership" provisions of Internal Revenue Code Section 382 ("Section 382"). Additionally, the NOL loss carryforwards are subject 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, 2018 and 2017, 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, 2018, the Company is not currently under audit by any income tax authority.

11. RELATED PARTY TRANSACTIONS

Through December 31, 2018, the Company maintained two separate consulting agreements with the Company's Chief Strategy Officer (the "CSO") and the Chief Medical Officer (the "CMO")

Beginning in the year ended December 31, 2014, the Company entered into its first consulting agreement with the CSO. Pursuant to the amended agreement dated July 20, 2018, the CSO is entitled to a consulting fee of $400 per hour, provided that he is limited to nineteen (19) hours per month unless he obtains approval from the Company's Chief Executive Officer. The consulting agreement indicates that the CSO will provide a leadership role for the Company's business development strategies. Total consulting fees paid to the CSO totaled $119,100 and $145,500 in the years ended December 31, 2018 and 2017, respectively.

Beginning in the year ended December 31, 2018, the Company entered into its first consulting agreement with the CMO. Pursuant to the amended agreement on December 1, 2018, the CMO is entitled to a monthly consulting fee of $2,500 per month. The consulting agreement indicates that the CMO will direct the development of clinical strategies and plans to integrate the Company's compounds into standard medical practice. Total consulting fees paid to the CMO in the year ended December 31, 2018 was $12,500.

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12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the consolidated balance sheet date through November 14, 2019, the date at which the consolidated financial statements were available to be issued and determined that other than the events mentioned below, no events or transactions occurred that are required to be disclosed.

2019 Convertible Promissory Notes

The Company issued additional convertible promissory notes in 2019 (the "2019 Notes") for an aggregate principal amount of $250,000 with a coupon rate of 17%, and maturing on June 1, 2021.

The Company also settled an accounts payable with a vendor in the amount of $134,600 by issuing it a 2019 Note for the amount owed accruing interest at a rate of 6% per annum, and maturing on June 30, 2020.

The 2019 Notes were convertible into shares issued in the Company's Next Financing Closing by dividing the total amount of principal and interest outstanding under each of the 2019 Notes by the respective conversion price set forth in each 2019 Note. Prior to the Company's issuance of shares of Series B Stock (as discussed below), each holder of 2019 Notes agreed to voluntarily convert the amounts of principal and interest then outstanding under its 2019 Note into shares of Series A-1 Stock. The amounts outstanding under the 2019 Notes with a maturity date of June 1, 2021 were converted at a conversion price of 85% of the Series A-1 Stock price per share, or $0.43. The amounts outstanding under the 2019 Notes with a maturity date of June 30, 2020 were converted at a conversion price of 90% of the Series A-1 Stock price per share, or $0.45. The aggregate amounts of principal and interest outstanding under the 2019 Notes were converted into a total of 935,519 shares of Series A-1 Stock.

Preferred Share Issuance

On September 13, 2019, the Company amended and restated its certificate of incorporation to authorize the issuance of up to 14,130,435 shares of Series B Stock. On September 13, 2019, the Company issued 7,608,696 shares of Series B Stock for $3,500,000. On November 13, 2019, the Company issued an additional 2,173,913 shares of Series B Stock for $1,000,000. From the dates of issuance on the Series B Stock, shares have accrued unpaid dividends at an annual rate of 6% per share. The Company has not declared any dividends.

In connection with the sale of the Series B Stock, each investor was issued warrants to purchase three shares of Common Stock for each share of Series B Stock purchased at a price of $0.0001 per share of Common Stock ("Warrants"). The Warrants become exercisable in accordance with the schedule set forth below following completion by the Company of an initial public offering and thereafter may be exercised at any time prior to expiration ten years from the date of issuance.

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

The Series B conversion price shall initially be equal to the Series B Original Issue Price of $0.46 per share divided by the rate at which shares of Series B Stock may be converted into shares of common stock.
The holders of the Series B Stock hold a special redemption right. In the event the Company has not filed an initial registration statement with the United States Securities and Exchange Commission and submitted an

application to be listed on the Nasdaq Stock market on or prior to November 15, 2019, subject to Delaware law governing distributions to stockholders and the Company's ability to redeem its shares, all or part of the shares of Series B Stock held by any holder of record as of such date of shares of Series B Stock with an aggregate purchase price of at least $1,000,000 shall thereafter be redeemable at the option of such holders of record commencing any time on or after November 16, 2019 at a price equal to the purchase price paid for such shares plus all unpaid dividends accrued on such shares. Also, in the event that the Company is ultimately approved for listing on a Nasdaq Stock Market tier lower than the Nasdaq Global Select Market, the special redemption right shall remain in effect and may be exercisable on any date thereafter. If the Company is unable to execute a redemption upon request of a holder, interest shall accrue on the shares at rate of 14.6%, or warrants underlying the shares may be exercisable and the fair market value of the shares of common stock received in connection therewith shall be treated as payment in exchange for the shares of Series B Stock submitted for redemption by such holder.

2017 Equity Incentive Plan Share Increase

On September 25, 2019, the board of directors approved an additional 10,000,000 shares to be reserved and authorized under the Plan. This approval increased the total number of authorized shares from 20,000,000 to 30,000,000.

Common Stock

PROSPECTUS

[ ], 2019

Through and including [ ], 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to each dealer's obligation to deliver a prospectus when acting as underwriter, and with respect to its unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of common shares being registered. All amounts, other than the SEC registration fee, Nasdaq listing fee and FINRA filing fee, are estimates. We will pay all these expenses.

	Amount
SEC registration fee	$
Nasdaq listing fee	
Accounting fees and expenses	
Legal fees and expenses	
Transfer agent fees and expenses	
Printing and related fees	
Miscellaneous	
Total	$

Item 14. Indemnification of Directors and Officers

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement in connection with specified actions, suits and proceedings whether civil, criminal, administrative, or investigative, other than a derivative action by or in the right of the corporation, if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification extends only to expenses, including attorneys' fees, incurred in connection with the defense or settlement of such action and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation, bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our certificate of incorporation and bylaws provide for indemnification of directors and officers to the fullest extent permitted by law, including payment of expenses in advance of resolution of any such matter.

We intend to enter into separate indemnification agreements with our directors and officers. Each indemnification agreement will provide, among other things, for indemnification to the fullest extent permitted by law and our certificate of incorporation and bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements will provide for the advancement or payment of all expenses to the indemnitee and for reimbursement to us if it is found that such indemnitee is not entitled to such indemnification under applicable law and our certificate of incorporation and bylaws.

We maintain standard policies of insurance under which coverage is provided (a) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act, and (b) to us with respect to payments which we may make to such officers and directors pursuant to the above indemnification provision or otherwise as a matter of law.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities

During the past three years, we issued the following securities, which were not registered under the Securities Act.

Starting in June 2016, we sold convertible promissory notes to certain investors to help finance our operations. The notes were in amounts ranging from $12,500 to $500,000, earning annual interest at 7% and all maturing on June 1, 2019. As of December 31, 2017, the outstanding balance on these notes was $6,106,000. The notes were convertible into shares issued in our next financing (as defined in the notes) by dividing the total amount of convertible promissory notes, plus accrued interest, by the applicable conversion price (defined generally as 80% of the lowest per share selling price in the next financing).

On December 20, 2018, following the issuance of shares of series A-1 preferred stock described below, the outstanding principal and accrued interest was converted into shares of series A-1 preferred stock. At the time of conversion, the outstanding principal and accrued interest of the notes totaled approximately $7,541,600. Accordingly, the notes were converted into an aggregate of 18,854,033 shares of series A-1 preferred stock at a conversion price of $0.40 per share.

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

During 2019, we issued additional convertible promissory notes in the aggregate principal amount of $250,000 to certain investors. The notes accrued interest at a rate of 17% and were to mature on June 1, 2021. These notes were convertible into shares issued in our next financing (as defined in the notes) by dividing the total amount of notes, plus accrued interest, by the applicable conversion price (defined generally as 85% of the lowest per share selling price in the next financing). Prior to the issuance of shares of series B preferred stock (as discussed below), each holder agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of series A-1 preferred stock. Therefore, on August 15, 2019, these notes were converted into an aggregate of 632,123 shares of series A-1 preferred stock at a conversion price of $0.43 per share.

In addition, during 2019, we settled an outstanding account payable with a vendor in the amount of $134,600 by issuing to that vendor a convertible promissory note for the amount owed. That convertible promissory note accrued interest at a rate of 6% and was to mature on June 30, 2020. This note was convertible into shares issued in our next financing (as defined in the note) by dividing the total amount of the convertible promissory note, plus accrued interest, by the applicable conversion price (defined generally as 90% of the lowest per share selling price in the next financing). Prior to the issuance of shares of series B preferred stock (as discussed below), the holder agreed to voluntarily convert the amounts of principal and interest then outstanding into shares of series A-1 preferred stock. Therefore, on August 15, 2019, this note was converted into 303,396 shares of series A-1 preferred stock at a conversion price of $0.45 per share.

On September 7, 2019, we entered into a series B preferred stock purchase agreement with certain investors for the sale of shares of our series B preferred stock at a price of $0.46 per share. On September 13, 2019, we sold an aggregate of 7,608,696 shares for total gross proceeds of approximately $3,500,000. On November 13, 2019, we sold an additional 2,173,913 shares for gross proceeds of $1,000,000. We also issued each investor a warrant to purchase three (3) shares of common stock for each series B preferred share purchased, or warrants for an aggregate of 29,347,827 shares of common stock. The warrants have an exercise price of $0.0001 per share and expire ten years after the date of issuance. The warrants are exercisable as follows: (i) 30% of the shares underlying the warrants are exercisable from the date that is six months after the date on which our securities are

first listed on a U.S. national securities exchange, (ii) an additional 30% of the shares underlying the warrants are exercisable nine months after such listing date, and (iii) the remaining shares underlying the warrants are exercisable twelve months after such listing date.

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

Item 16. Exhibits.

(a) Exhibits

Exhibit No.	Description
3.1*	Third Amended and Restated Certificate of Incorporation
3.2*	Amended and Restated Bylaws
4.1*	Form of Warrant to Purchase Common Stock
5.1*	Opinion of Bevilacqua PLLC
10.1*	Form of Subscription Agreement
10.2*	Series B Preferred Stock Purchase Agreement, dated September 7, 2019, among Kiromic, Inc. and certain investors
10.3*	Investors' Rights Agreement, dated September 7, 2019, among Kiromic, Inc. and certain investors
10.4*	Right of First Refusal and Co-Sale Agreement, dated September 7, 2019, among Kiromic, Inc., certain investors and certain stockholders
10.5*	Voting Agreement, dated September 7, 2019, among Kiromic, Inc., certain investors and certain stockholders
10.6*	Form of Securities Purchase Agreement for Series A-1 Preferred Stock
10.7*	Convertible Promissory Note issued by Kiromic, Inc. to Prevail Partners on May 30, 2019
10.8*	Form of 17% Convertible Promissory Note
10.9*	Form of 7% Convertible Promissory Note
10.10*	Stockholders' Agreement, dated May 27, 2016, among Kiromic, Inc. and certain stockholders
10.11*	Lease Agreement, dated October 9, 2015, between Timothy L. Sharma d/b/a Cambridge Properties and Kiromic, Inc.
10.12*	Second Amendment to Lease Agreement, dated May 6, 2016, between Cambridge Properties and Kiromic, Inc.
10.13*	Third Amendment to Lease Agreement, dated November 7, 2018, between Cambridge Properties and Kiromic, Inc.
10.14*	Fourth Amendment to Lease Agreement, dated October 8, 2019, between Cambridge Properties and Kiromic, Inc.
10.15†*	Employment Agreement, dated March 20, 2016, between Kiromic, Inc. and Maurizio Chiriva Internati
10.16†*	Consulting Agreement, dated November 2, 2018, between Kiromic, Inc. and Scott Dahlbeck
10.17†*	Consulting Agreement, dated July 20, 2018, between Kiromic, Inc. and Gianluca Rotino
10.18†*	Kiromic, Inc. 2017 Equity Incentive Plan

Exhibit No.	Description
10.19*	Form of Independent Director Agreement
10.20*	Form of Indemnification Agreement
14.1*	Code of Ethics
23.1*	Consent of Deloitte & Touche LLP
23.2*	Consent of Bevilacqua PLLC (included in Exhibit 5.1)
24.1*	Power of Attorney (included in the signature page)

* To be filed by amendment
† Executive Compensation Plan or Agreement

(b) Financial Statement Schedules

All financial statement schedules are omitted because the information called for is not required or is shown either in the consolidated financial statements or in the notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sells are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement.

(iii) To include material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 and Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) For determining liability of the undersigned Registrant under the Securities Act to any purchaser in the initial distribution of the securities, that in a primary offering of securities of the undersigned Registrant pursuant to this

registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(a) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(b) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;

(c) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and

(d) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That, insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Houston, State of Texas, on [ ], 2019.

KIROMIC, INC.

By: /s/ Maurizio Chiriva Internati
Maurizio Chiriva Internati
Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Maurizio Chiriva Internati and Tony Tontat as his or her true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement and to file a new registration statement under Rule 461, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Maurizio Chiriva Internati Maurizio Chiriva Internati	Chairman and Chief Executive Officer (principal executive officer)	[ ], 2019
/s/ Tony Tontat Tony Tontat	Chief Financial Officer (principal financial and accounting officer)	[ ], 2019
/s/ Scott Dahlbeck Scott Dahlbeck	Director	[ ], 2019
/s/ Gianluca Rotino Gianluca Rotino	Director	[ ], 2019
/s/ David Spencer David Spencer	Director	[ ], 2019
/s/ Angelo Minotti Angelo Minotti	Director	[ ], 2019