UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

Commission File Number 001-38210

Krystal Biotech, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-1080209**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2100 Wharton Street, Suite 701 Pittsburgh, Pennsylvania	**15203**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (412) 586-5830

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	KRYS	NASDAQ

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the Registrant, based on the closing sales price for such stock on June 28, 2019 as reported by The Nasdaq Stock Market, was $454 million. This calculation excludes 5,670,492 shares held by executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the Registrant.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2020 was 17,357,935.

Portions of the Registrant's definitive proxy statement relating to its 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report where indicated. Such proxy statement will be filed with the US Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict", "project," "seek," "should," "target," "will," "would," or similar expressions and the negatives of those terms. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

Forward-looking statements appearing in a number of places throughout this Annual Report on Form 10-K include, but are not limited to, statements about the following, among other things:

- the initiation, timing, progress and results of preclinical and clinical trials for B-VEC (previously "KB103"), KB105 and any other product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or results of regulatory filings and approvals, including timing of final US Food and Drug Administration marketing and other regulatory approval of B-VEC and KB105;
- our ability to achieve certain accelerated or orphan drug designations from the FDA;
- our estimates regarding the potential market opportunity for B-VEC, KB105 and any other product candidates;
- our research and development programs for our product candidates;
- our plans and ability to successfully develop and commercialize our product candidates, including B-VEC, KB105 and our other product candidates;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scalability and commercial viability of our proprietary manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of our product candidates and gene therapy, in general;
- our competitive position;
- our intellectual property position and our ability to protect and enforce our intellectual property;
- our financial performance;
- developments and projections relating to our competitors and our industry;
- our ability to establish and maintain collaborations or obtain additional funding;
- our estimates regarding expenses, future revenue, capital requirements and needs for or ability to obtain additional financing;
- our ability to successfully resolve any intellectual property or other claims that may be brought against us;
- any statements regarding compliance with the listing standards of The NASDAQ Capital Market;
- the impact of laws and regulations; and
- any statements regarding future economic conditions or performance and any statement of assumptions underlying any of the foregoing.

Forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report. You should read this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 1. Business.

Overview

Krystal Biotech, Inc. (the "Company," "Krystal," "we," or "us," or other similar pronouns) is a clinical-stage gene therapy company dedicated to developing and commercializing novel medicines for patients suffering from skin diseases. We have developed a proprietary gene therapy platform to develop off-the-shelf treatments for skin diseases for which we believe there are no known effective treatments. Our platform consists of a patented engineered viral vector based on the herpes simplex virus type 1 ("HSV-1") containing skin-optimized gene transfer technology, which we refer to as the Skin TARgeted Delivery ("STAR-D") platform. We are initially using our STAR-D platform to develop treatments for rare or orphan monogenic dermatological indications caused by the absence of or a mutation in a single gene. We plan to leverage our platform in the future to expand our pipeline to include non-monogenic dermatological indications and skin conditions.

Our Gene Therapy Platform

We believe that certain inherent features of the HSV-1 virus, combined with the modifications we have made to the virus in the form we employ as our gene delivery backbone, provides our proprietary gene therapy platform with specific advantages over other viral vector platforms for use in dermatological applications, including the following:

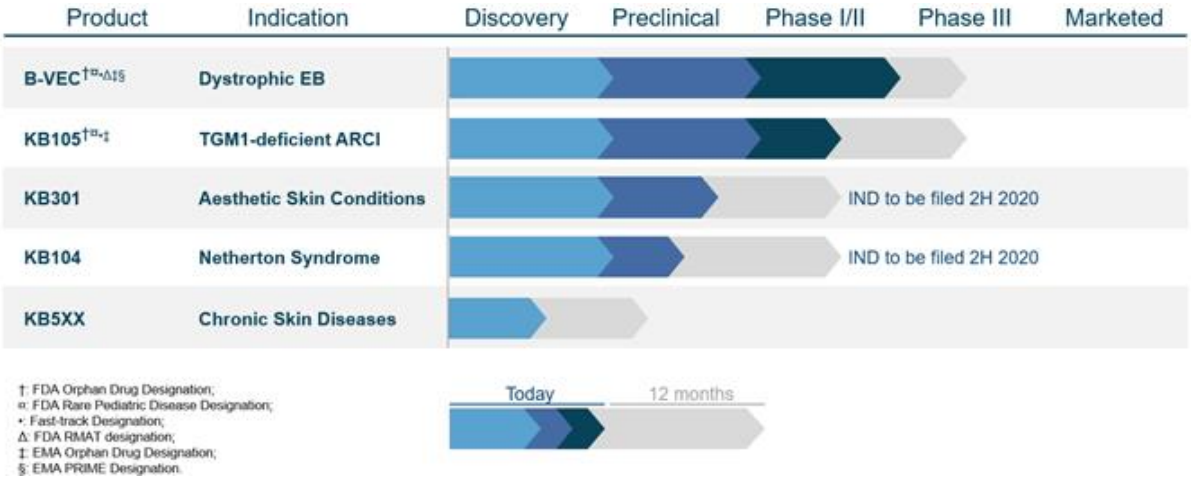
- **Non-Integrating Nature**: Upon entry into cells, the HSV-1 vector persists as an episomal unit in the nucleus, meaning it remains physically separate from the host cell chromosome. Other vectors we are aware of currently being used in the development of gene therapy treatments for dermatological conditions, such as the lentiviral and retroviral vectors, integrate into the host cell DNA to achieve gene expression. Integration into the host cell DNA carries the risk of disrupting host genes and consequently can lead to a risk of causing cancer, or oncogenesis. In contrast, a non-integrating vector such as our HSV-1 vector does not carry the risk of disrupting the expression of host cell genes and the cancer-causing risks such disruptions could create. Also, because the skin cells turnover rapidly, we believe that the risk of disrupting host genes far outweighs any benefits of integration.
- **Payload Capacity**: HSV-1 is a large virus, approximately 150 kilobases, or Kb, of DNA in size. We have made strategic deletions within this genome to remove critical "immediate early", or IE, genes. These IE genes are required for expression of most of the downstream genes that allow the HSV-1 virus to replicate and destroy host cells. Deletion of these IE genes inhibits expression of most of the viral proteins, making the resulting viral vector replication-deficient and non-toxic. These deletions also enable the vector to easily accommodate a payload of 35Kb or greater without any significant impact on yield or titer. In our lead product candidate, beremagene geperpavec ("B-VEC", previously "KB103"), we have successfully inserted two functional copies of the complete ~9Kb human COL7A1 gene. In contrast, packaging capacity for most other viral vectors being used in dermatological indications is under 8Kb, which limits their ability to deliver large skin genes directly to the skin. In addition, we believe the high payload capacity of our viral vector will allow us to insert single and multiple genes and effectors, allowing for the potential treatment of non-monogenic dermatological conditions such as psoriasis, atopic eczema and chronic wounds.

- **High Transduction Efficiency**: Poor infection of skin epithelia has remained a major hurdle for direct delivery of most viral vectors. HSV-1 has a natural affinity, or tropism, for the skin epithelium, consequently our vector penetrates skin cells much more efficiently than other viral vectors, resulting in transduction efficiencies or cell penetration as high as 95% in cell-based studies. This efficient cell infection or penetration ability, along with the high payload capacity of our vector are responsible for the high levels of transgene expression we have observed in animal models. In addition, these factors are critical contributors to our ability to create an off-the-shelf gene therapy treatment where others are taking autologous approaches, such as skin grafts. Because the genes that cause many skin diseases are quite large, many of our competitors can only fit a single gene, or in some cases may need to manipulate the genetic material in order to fit the limited payload capacity of their vectors. Based on published research, we believe that some autologous gene therapy approaches may have transduction efficiencies as low as 10% in skin. To develop an effective treatment in the face of payload capacity and transduction limitations, they may need to introduce the therapeutic gene into a patient's tissues or cells *ex vivo* to create an individual treatment, which is re-administered back to the patient once the gene-modified tissues have achieved a sufficient level of gene expression. The greater payload capacity of our vector and the high transduction efficiencies achieved allow us to deliver a full gene directly to any patient's tissues for *in vivo* gene expression without additional manipulation.
- **Direct Delivery**: Our engineered HSV-1 vector allows for direct topical or intradermal delivery. The advantages of direct delivery are that our products can be administered in an outpatient setting, requiring no hospitalization or expensive, invasive, and time-consuming procedures or sophisticated medical teams. Taking gene therapy to the patient minimizes patient travel and circumvents upfront burdens typical of gene therapies.
- **Repeat Administration**: One of the major challenges with many viral vector platforms is that the host immune system may recognize them as foreign agents and launch a robust immune response, resulting in toxicity and rapid removal of the virus. Wild type HSV-1 is known to persist in the body by becoming latent and hiding from the immune system. We have harnessed the natural ability of HSV-1 to evade host-mediated immunogenicity, while removing specific viral elements that exacerbate the host immunity, thus making our viral vector safer for repeat administration as needed to achieve durability of effect. Because the tendency of our viral vector to invoke an immune response is low, our ability to repeat administration is enhanced.
- **Stability**: HSV-1 is extremely stable and resistant to degradation by physical shearing, solvents, and enzymes, facilitating purification and final formulation of our viral vector product candidates. These characteristics of HSV-1 provide a stability advantage to B-VEC, our lead product candidate. Although frozen for long-term storage, it is also stable under refrigerated conditions for short-term storage and shipment, and stable over several freeze-thaw cycles. This should facilitate our ability to ship our products globally from our manufacturing facilities in Pennsylvania.
- **Reproducible and Scalable Manufacturing**: Successful production of viral vectors involves two steps: (i) the 'upstream' process, which yields a bulk virus harvest; and (ii) the 'downstream' process, which involves purification and concentration of the clinical product. Successful and reproducible execution of both processes is critical for clinical manufacturing and scale-up. Our scientific team collectively has decades of experience and expertise in HSV engineering and purification that has allowed us to successfully optimize our HSV-1 vector production process.
- **Existing Regulatory Precedent**: The first US Food and Drug Agency ("FDA")- and European Medicines Agency ("EMA")-approved oncolytic virus product, Imlygic® by Amgen, for treatment of melanoma, a skin cancer, is based on a genetically engineered HSV-1 virus. Because this product also employs an HSV-1 backbone, it has created a regulatory precedent for approval of an HSV-1-based therapy. In addition, Imlygic® is a chronic therapy, given bi-weekly, which provides support for the use of an HSV-1 backbone in chronic gene therapy of the type we are developing.

The above listed benefits of our engineered vector make the STAR-D platform a suitable choice for topical and intra-dermal application and repeat delivery of skin genes in an off-the-shelf and non-invasive manner.

Our Product Candidates

The following table summarizes information regarding our product candidates in various stages of clinical and preclinical development:



Additional detail on our gene therapy platform and clinical development of our product candidates can be found on our website at the following link:

http://ir.krystalbio.com/index.php/static-files/344e2bc7-ba33-44f2-9b07-8798059b2b68

Beremagene Geperpavec ("B-VEC")

Overview

Our lead product candidate, B-VEC seeks to use topical gene therapy to treat dystrophic epidermolysis bullosa, or DEB, a rare and severe monogenic skin disease for which there is currently no approved treatment.

DEB affects the skin and mucosal tissues and is caused by one or more mutations in a gene called COL7A1, which is responsible for the formation of the protein type VII collagen, or COL7, that forms anchoring fibrils that bind the dermis, or inner layer of the skin, to the epidermis, or outer layer of the skin. In DEB patients, the genetic defect in COL7A1 results in loss or malfunctioning of these anchoring fibrils, leading to extremely fragile skin that blisters and tears from minor friction or trauma. Those who are born with DEB are sometimes called "butterfly children," because their skin is likened to be as fragile as the wings of a butterfly. DEB patients may suffer from open wounds, skin infections, fusion of fingers and toes and gastrointestinal tract problems throughout their lifetime, and may eventually develop squamous cell carcinoma, a potentially fatal condition. Based on information from DEBRA International, a worldwide alliance of patient support groups for epidermolysis bullosa, or EB, of which DEB is a subset, we believe there may be as many as 125,000 people who are affected by DEB. We believe that there are, at present, approximately 3,000 diagnosed DEB patients in the United States. There is currently no approved cure for DEB. The current treatment for DEB is limited to palliative care, which is estimated to cost between $200 thousand and $400 thousand annually per patient in the United States.

We believe our approach to treating DEB with B-VEC is novel. The current standard of care for DEB patients is limited to palliative measures that seek to provide relief from some of the symptoms of DEB but do not meaningfully impact disease outcomes. Other known efforts to develop DEB treatments employ autologous approaches to creating therapeutic products. Autologous treatments use a patient's own tissues and cells to manufacture an individualized therapy. Such therapies tend to be expensive, invasive and time consuming to use, and require extensive patient travel, extended hospital stays, highly sophisticated medical teams and procedures. In contrast, B-VEC is designed to be an off-the-shelf treatment for DEB that can be applied topically to a patient's skin. Unlike the current standard of care, B-VEC seeks to treat DEB at the molecular level through gene therapy and is intended to be a non-invasive treatment that can be used without requiring hospitalization or individually customized treatment.

Clinical Development of B-VEC

In October 2019, we announced positive results from our Phase 1/2 clinical trial of B-VEC at Stanford University. Safety data from all patients showed that B-VEC was well tolerated with no serious adverse events (SAEs) reported. The Phase 1 portion of the trial commenced in May 2018 at Stanford University, and we announced positive interim results from this clinical study on two patients in October 2018. The Phase 2 portion of the trial commenced in December 2018 at Stanford University, and we announced positive interim results from this clinical study on two patients in June 2019. We also enrolled two additional patients in the Phase 2 study in June 2019.

In the combined Phase 1 and Phase 2 study, 9 out of 10 wounds treated with B-VEC closed completely (100%). The average time to 100% wound closure on all B-VEC treated wounds in combined Phase 1 and Phase 2 study was 17.4 days (median 14 days). In the combined study, the average duration of wound closure on two patients following 100% wound closure, as of the last follow up, was 113 days (median 110 days).

In the wound that did not close, B-VEC was re-administered resulting in the wound closing completely within 7 days following re-administration. The wound was originally reported to be open for over 4 years. The wound has remained closed for over 100 days (and ongoing).

We anticipate commencing pivotal Phase 3 FDA trials in the first half of 2020.

For more information on the B-VEC Phase 1/2 clinical trial, visit:

http://ir.krystalbio.com/news-releases/news-release-details/krystal-biotech-announces-final-update-phase-12-clinical-trial

KB105

Overview

Our second pipeline candidate, KB105, delivers functional human transglutaminase-1 (“TGM1”) genes using our gene therapy platform to patients with TGM1-deficient autosomal recessive congenital ichthyosis (“ARCI”).

ARCI is a life-long, severe monogenic skin disease. While a number of genetic mutations have been associated with the development of ARCI, the most common cause of ARCI is an inactivating mutation in the TGM1 gene encoding the enzyme transglutaminase-1, a protein that is essential for the proper formation of the skin barrier. Mutations in the TGM1 gene, and the subsequent disruption to the epidermal barrier, leads to pronounced dehydration, trans-epidermal exposure to unwanted toxins and surface microorganisms, and a greatly increased risk of infection. Transglutaminase-1 deficiency is associated with increased mortality in the neonatal period and has a dramatic impact on quality of life.

Patients suffering from ARCI often exhibit life-long pronounced plate-like scaling of the skin, which is often of a dark color and can cover the whole body. Such patients frequently suffer from exposure of the inner eyelid surface due to turning away of the eyelids from the eye (ectropion), the turning outwards of the lips (eclabium), deformities of joint and nasal cartilage (hypoplasia), scarring alopecia (especially at the edge of the scalp) and a thickening of the skin on the palms of the hands and soles of the feet (palmoplantar keratoderma). Additional complications experienced by ARCI patients include episodes of sepsis, fluid and electrolyte imbalances due to impaired skin barrier function, and failure to thrive, especially during the neonatal period and infancy. Severe heat intolerance and nail dystrophy are also frequently observed.

There are approximately 20,000 cases of TGM1-deficient ARCI worldwide and about 400 new cases per year globally. Our approach is to leverage our gene therapy platform using our non-replicating, non-integrating engineered HSV-1 vector to deliver the TGM1 gene to keratinocyte skin cells, potentially allowing them to produce the TGM1 protein that is lacking in this patient population. KB105 is designed to be an off-the-shelf treatment for TGM1-deficient ARCI that can be applied topically and directly to a patient’s skin. The application of KB105 does not require expensive, invasive, time-consuming procedures or sophisticated medical teams. There are currently no treatments targeting molecular correction of this disease.

Clinical Development of KB105

We believe that safety has been established for KB105 based on in vitro and *in vivo* proof-of-concept studies. Biodistribution and toxicity data from animal studies indicate that KB105 can be safely and repeatedly administered to the skin at high doses without systemic vector exposure. Topically applied KB105 has been shown to efficiently transduce permeabilized skin and express human TGM1 in a dose-dependent manner. KB105-expressed TGM1 has colocalized with native TGM1 substrates, indicating delivery to the appropriate epidermal layer. KB105's robust production of TGM1 in vitro and *in vivo* supports its use in ARCI patients.

In September 2019, we initiated a Phase 1/2 clinical trial of KB105. We anticipate interim Phase 1/2 clinical readouts in the first half of 2020.

KB104

Overview

Our third pipeline candidate, KB104, delivers functional Serine Protease Inhibitor Kazal-type 5 ("SPINK5") genes using our gene therapy platform to patients suffering from Netherton Syndrome, which is a debilitating monogenic autosomal recessive skin disorder that causes defective keratinization, severe skin barrier defects, and recurrent infections. Infants with severe Netherton Syndrome symptoms are associated with failure to thrive, hypernatremic dehydration secondary to excess fluid loss, delayed growth, short stature, and recurrent infections. Clinically, Netherton Syndrome is characterized by congenital ichthyosiform erythroderma, hair shaft defects, recurrent infections, and a defective skin barrier. A predisposition to allergies, asthma, and eczema is also characteristic of Netherton Syndrome. Ultimately, those afflicted by Netherton Syndrome often experience chronic skin inflammation, severe dehydration, and stunted growth.

The disease arises due to mutations in the SPINK5 gene, resulting in loss of activity of its encoded serine protease inhibitor protein SPINK5 (also known as Lympho-Epithelial Kazal type-related Inhibitor ("LEKTI")). In healthy individuals, SPINK5 is one of the serine protease inhibitors expressed in the outermost layers of the skin, and it plays a critical role in the regulation of serine proteases which hydrolyze extracellular proteins that hold corneocytes together. In patients suffering from Netherton Syndrome, the suppressive effects of SPINK5 on these serine proteases is abolished due to underlying genetic mutations in the SPINK5 gene. Consequently, hyperactivated serine proteases in the skin cause uncontrolled desquamation, leading to a defective skin barrier.

There are approximately 38,000 cases of patients worldwide and about 700 new cases per year globally. There are no current approved treatments for Netherton Syndrome. Existing approaches are limited to palliative treatments, including topical moisturizers, repair formulas and steroids.

Clinical Development of KB104

A properly localized human SPINK5 gene was detected 48 hours after topical KB104 application in mice without toxicity. KB104-mediated human SPINK5 was expressed in the correct layer of skin at the transcript and protein levels. We anticipate filing an Investigational New Drug, or IND, in the second half of 2020.

KB301

Overview

The skin is largely composed of collagen-rich connective tissue, with dermal collagen, composed primarily of types 1 and 3 collagen fibrils, representing >90% (dry weight) of human skin. The characteristics of skin aging are largely due to aberrant collagen homeostasis, including reduced collagen biosynthesis, increased collagen fibril fragmentation, and progressive loss of dermal collagen culminating in a net collagen deficiency, resulting from both intrinsic (*e.g.*, passage of time, genetics) and extrinsic (*e.g.*, chronic light exposure, pollution) pressures. The goal of skin biorejuvenation is, in part, to enhance the synthesis of human dermal collagens (*i.e.*, neocollagenesis), thereby correcting the molecular defect underlying the aged phenotype. We believe that our approach of directed expression of full-length human type 3 collagen via intradermal application of KB301 provides a unique and straightforward approach to restoring collagen homeostasis, and by extension, reconstructing an optimal physiologic environment in the skin to treat wrinkles.

Facial injectables, including hyaluronic acid, botulinum toxin type A, collagen, polymer fillers, and calcium hydroxyapatite microparticles, are intended to correct perceived facial defects (*e.g.*, fine lines, shallow wrinkles, and deeper furrows), and are administered for both cosmetic and therapeutic indications. In 2017, the global facial injectables market generated more than $7.2 billion in revenue from approximately 8.5 million procedures performed, with a majority (~70%) of revenue being generated in the aesthetic setting. While the United States and Europe represent the largest markets for facial injectables to-date, significant expansion in market share is projected for Asia and Latin America in the coming years. Due to the rising awareness of cosmetic procedures, the growing geriatric population, and a shift from invasive to minimally/non-invasive treatment options, the aesthetics facial injectables market is projected to grow to more than a $12 billion industry by 2025.

Clinical Development of KB301

Transduction with KB301 induced secretion of mature, full-length type III collagen (COL3) from primary aged human fibroblasts with no observable impact on cell viability, even when the vector was administered at high doses. Properly localized (dermal) human COL3 was detected in a dose-dependent manner within 48 hours of intradermal injection of KB301 in mice without systemic vector exposure or toxicity. Furthermore, KB301 was shown to be similarly effective for human COL3 production after single and repeated intradermal administration to immunocompetent animals, demonstrating safety and efficacy of recurrent dosing. We anticipate filing an Investigational New Drug, or IND, application in the second half of 2020.

Future Opportunities

We are currently focused on skin diseases but have commenced early stage research to apply our gene therapy platform to develop medicines for non-dermatological rare diseases.

We also believe that the large payload capacity of the viral vector in the STAR-D platform will allow us to deliver multiple genes and other effectors using the platform which will afford us the opportunity to treat non-monogenic skin diseases like psoriasis and atopic dermatitis, as well as conditions that are not necessarily the result of an inherited genetic defect, such as chronic wounds and aesthetic skin conditions, such as wrinkles and nasolabial folds. For example, as proof-of concept for STAR-D-mediated delivery of anti-inflammatory antibodies, we have observed positive therapeutic intervention in chronic skin disease progression upon topical application of a vector-encoded antibody in an animal model of atopic dermatitis.

If we are able to successfully develop and commercialize products to treat non-orphan dermatological diseases, we intend to seek collaborative alliances towards commercializing these therapies among the broader population of patients in these indications.

Our vision is to become a fully integrated biotechnology company with in-house facilities compliant with current Good Manufacturing Process (“cGMP”) for to rare diseases and to work with collaborators on broad indications and aesthetic skin conditions. We maintain full royalty-free global rights to all of our product candidates.

Manufacturing

In-House Good Manufacturing Practice (“GMP”) Facilities

On January 24, 2020, we announced the ground breaking of our second commercial gene therapy facility in the Pittsburgh, Pennsylvania area. This cGMP facility, named ASTRA, will have the capacity to produce commercial gene therapy medicines to treat patients suffering from debilitating rare diseases. The ASTRA facility is being designed as a state-of-the-art cGMP manufacturing facility that, beyond expanding Krystal’s current production platform, will allow the in-house incorporation of raw material preparation, excipient manufacturing, testing, packaging, labeling and distribution, fully-integrating all components of the supply chain from starting materials to patient experience. The ASTRA facility will initially be used as a commercial back-up facility for B-VEC. Eventually, the ASTRA facility will expand to produce investigational and commercial material for our pipeline products. We expect the 100,000 square foot facility to be completed and validated with an expected completion date of early 2021.

In January 2019, we completed the construction of our own commercial scale cGMP-compliant manufacturing facility, ANCORIS, to enhance supply chain control, increase supply capacity for clinical trials and ensure commercial demand is met in the event that B-VEC and our other product candidates receive marketing approval. The clinical material for the pivotal trial and initial commercial launch material of B-VEC will be produced at ANCORIS.

We intend to use ASTRA and ANCORIS for clinical and commercial production of our product candidates. Having in-house cGMP facilities will allow us to maintain better quality control, shorter lead times, lower costs and better control over our intellectual property. We intend to continue to devote substantial resources to developing the STAR-D platform which forms the basis of our manufacturing process.

Our Manufacturing Process

Our proprietary manufacturing process for clinical-grade B-VEC was developed and optimized internally based on our STAR-D platform and involves both an upstream production process and downstream purification process. Recombinant viral vectors are made safe by removal of specific viral machinery, including packaging proteins, so that they are rendered incapable of, or attenuated for, replicating in human cells. However, to produce the recombinant virus, these viral proteins have to be re-introduced into the virus production process so that the viral vector can be packaged. In most other viral vector production systems, the missing viral proteins are supplied in one or more individual helper plasmids, along with the base viral vector plasmid. All the plasmids are then co-transfected into a production cell line in the presence of a transfection agent to facilitate viral vector production and packaging. The difficulty of this approach is that it requires c-scale manufacturing and qualification of each of the packaging plasmids and optimization of the transfection method. Even with optimized reagents and methods, significant batch-to-batch variability is seen in viral vector yield and titer that, we believe, drives up the cost of viral vector manufacturing and scale-up and increases the risk of failure during manufacturing.

Our proprietary upstream process for HSV-1 production avoids the aforementioned issues. Our process requires three critical components:

- Production of a master virus seed stock, or MVSS;
- Production of complementing master cell bank, or MCB; and
- Optimized transduction parameters.

For B-VEC, the MVSS is scaled up from a single purified clone of the modified HSV-1 vector expressing the therapeutic COL7A1 gene. The MCB is a complementing cell line that stably expresses the HSV-1 viral proteins that are required for HSV-1 growth but have been deleted from the recombinant HSV-1 backbone. By introducing the deleted proteins into the MCB, as opposed to including them in the viral replication process via co-transfection of individual plasmids, we eliminate the need for multiple qualifications of the plasmids or variability in transfection efficiency from batch to batch, that other production processes face. Infection of the MCB with the MVSS at the optimal concentration results in production of the viral particle. Once the MCB, the MVSS, and the conditions of infection are established, virus production and resultant yield and titer are highly reproducible and scalable over multiple runs, and the risk of failure is minimal.

Optimization of MCB, MVSS and production methods requires extensive knowledge and technical experience with the HSV-1 genome and significant upfront effort to design and select the best virus seed stock and complementing cell line. To date we have screened hundreds of cell line clones to find the best complementing cell lines, and similarly designed and generated the optimal virus seed stocks for our portfolio candidates. The viral seed stock expresses the therapeutic proteins under the control of strong constitutive or tissue-specific promoters and additional non-coding regulatory sequences have been included to optimize gene expression. We also have optimized the transduction conditions to reproducibly obtain high yields of the virus.

Unlike the upstream process, steps used to purify and concentrate the viral vector product are often common across different viral vector platforms and usually involve multiple stages of purification, clarification, concentration, and diafiltration, with the ultimate goal to remove contaminants and concentrate the product. We believe we have successfully developed a robust and reproducible process for purifying our viral vector to required concentrations for clinical use, while successfully removing contaminants to meet FDA guidelines.

We believe that the MVSS and MCB are a vital part of the production of B-VEC, as they will ensure the reproducible production of multiple clinical batches in a short six-week cycle time frame and in a cost-effective manner.

We have made significant investments in developing the most comprehensive and optimized manufacturing process for our vector product candidate including:

- Sufficient scale to support stability of B-VEC with sufficient longevity that a small number of initial batches will likely provide adequate clinical supply up to pivotal Phase 3 trials;
- A proprietary vector manufacturing technique that produces a highly purified B-VEC;
- A critical list of GMP assays to accurately characterize our process and the HSV-1 vectors we produce; and
- A series of high-efficiency purification processes, which can be adapted and customized for our HSV-1 platform products.

We believe these improvements and our continued investment in our STAR-D platform will enable us to develop best in class, next generation gene therapy products for dermatological indications.

Competition

The biotechnology and pharmaceutical industries are highly competitive. In particular, the field of gene therapy is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Some of our competitors have substantially greater financial resources and larger research and development organizations. In addition, our experience in clinical trials, obtaining FDA and other regulatory approvals, and manufacturing and commercialization of products may be more limited.

Epidermolysis Bullosa

A number of companies are developing drug candidates for EB. There is no approved treatment for DEB at this time. We believe our competitors fall into two broad categories:

- **Autologous Approaches:** We are aware of two companies, Abeona and Castle Creek Pharmaceuticals, which are developing autologous or grafting gene therapy approaches to treating DEB.
- **Palliative Treatments:** We are aware of companies such, as Castle Creek Pharmaceuticals, who are developing product candidates taking a palliative approach to treating the disease.

Autosomal Recessive Congenital Ichthyosis (ARCI)

We are aware of companies like Novartis Inc. and Patagonia Pharmaceuticals, LLC who have conducted clinical trials for ARCI in the past. We are unaware of any companies conducting active clinical trials in ARCI presently.

Netherton Syndrome

We are aware that Novartis Inc. has conducted clinical trials for Netherton Syndrome. We are unaware of any companies currently conducting active clinical trials in Netherton Syndrome presently.

Intellectual Property

In January 2020, Krystal diversified its patent estate through the issuance of US Patent and Trademark Office (“USPTO”) patent number 10,525,090 covering our second product candidate, KB105, as well as medical applications of this product for treating ARCI. We believe the speed in which the patent prosecution was successfully concluded for this application is indicative of Krystal’s pioneering work in HSV-based gene therapies in the field of dermatology.

In December 2019, Krystal strengthened its international patent portfolio covering our lead product candidate, B-VEC, when the European Patent Office issued an intent to grant European patent application number 16826873 directed, in part, to pharmaceutical compositions comprising B-VEC, as well as uses thereof.

In October 2019, the USPTO granted the Company US patent number 10,441,614 covering its fully integrated vector platform, STAR-D, for skin-targeted therapeutics, as well as methods of its use for delivering any effector of interest to the skin. This new patent provides further validation of the Company's novel work in the field of skin diseases leveraging its HSV-1-based gene therapy technologies.

In September 2019, the Australian patent office granted the Company its first foreign patent (Application No. 2016401692) in Australia for its lead product candidate B-VEC. This patent covers pharmaceutical compositions comprising B-VEC, as well as medical uses such as the treatment of wounds, disorders, or diseases of the skin, particularly those found in epidermolysis bullosa patients.

On December 18, 2018, the USPTO granted US Patent No. 10,155,016 which covers compositions containing B-VEC, formulated for alternate routes of administration.

On January 16, 2018, we announced that the USPTO had granted US Patent No. 9,877,990, which covers compositions comprising HSV vectors encoding certain effectors and methods of using the same for providing prophylactic, palliative or therapeutic relief of a wound, disorder or disease of the skin. A corresponding international patent application has been filed in accordance with the Paris Cooperation Treaty, which has entered into the national phase in more than ten foreign jurisdictions.

We believe that the granting of these patents, which are entirely owned by the Company, protects our core STAR-D viral platform and products based thereupon, and affords us freedom to use this platform for the development of novel therapeutics for multiple applications. We continue to advance our IP portfolio actively through the filing of new patent applications, divisionals, and continuations relating to our technologies as we deem appropriate.

In addition to our patents, we rely on trade secrets and know-how to develop and maintain our competitive position. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, through confidentiality agreements and intellectual property assignment agreements with our employees, consultants and commercial partners. We also seek to preserve the integrity and confidentiality of our data, trade secrets, and know-how, including by implementing measures intended to maintain the physical and electronic security of our research and manufacturing facilities, as well as our information technology systems.

Government Regulation and Product Approval

In the United States, the FDA regulates biologic products including gene therapy products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, and regulations and guidance implementing these laws. The FDCA, PHSA and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biologic products. Applications to the FDA are required before conducting human clinical testing of biologic products. Additionally, each clinical trial protocol for a gene therapy product candidate is reviewed by the FDA, and in limited instances the National Institutes of Health, or the NIH, through its Recombinant DNA Advisory Committee, or RAC. FDA approval also must be obtained before marketing of biologic products. 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 and we may not be able to obtain the required regulatory approvals to successfully develop and commercialize our product candidates.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products. Within CBER, the review of gene therapy and related products is in the Office of Cellular, Tissue and Gene Therapies, or the OCTGT, and the FDA has established the Cellular, Tissue and Gene Therapies Advisory Committee, or the CTGTAC, to advise CBER on its reviews. CBER works closely with the NIH and the RAC, which makes recommendations to the NIH on gene therapy issues and engages in a public discussion of scientific, safety, ethical and societal issues related to proposed and ongoing gene therapy protocols. The FDA has provided guidance for the development of gene therapy products generally, including a growing body of guidance documents on chemistry, manufacturing and control, or CMC, clinical investigations and other areas of gene therapy development, all of which are intended to facilitate the industry's development of gene therapy products.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

US Biologic Products Development Process

The FDA must approve a product candidate before it may be legally marketed in the United States. The process required by the FDA before a biologic product candidate may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and *in vivo* studies in accordance with the FDA's current Good Laboratory Practice, or GLP, regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application, which allows human clinical trials to begin unless FDA objects within 30 days;
- approval by each clinical trial site's institutional review board, or IRB and institutional biosafety committee, or IBC before the clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's Good Clinical Practice or GCP regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biologic product candidate for its intended use;
- preparation and submission to the FDA of a biologics license application, or BLA, for marketing approval that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- review of the product by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biologic product candidate is produced to assess compliance with c requirements and to assure that the facilities, methods and controls are adequate to preserve the biologic product candidate's identity, safety, strength, quality, potency and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- payment of user fees and FDA review and approval, or licensure, of the BLA.

Before testing any biologic product candidate in humans, including a gene therapy product candidate, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as *in vivo* studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Concurrent with clinical trials, companies usually must complete some long-term preclinical testing, such as animal studies of reproductive adverse events and carcinogenicity and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted, to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

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 an 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 places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. With gene therapy protocols, if the FDA allows the IND to proceed, but the RAC decides that full public review of the protocol is warranted, the FDA will request at the completion of its IND review that sponsors delay initiation of the protocol until after completion of the RAC review process. The FDA also may impose clinical holds on a biologic 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 for our future product candidates will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Human Clinical Trials Under an IND

Clinical trials involve the administration of the biologic product candidate to healthy volunteers or patients under the supervision of qualified investigators which generally are physicians not employed by or under the control of the trial sponsor. Clinical trials are conducted under written study 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. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising good clinical practices, or GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB and IBC 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 items such 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 their legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed. Clinical trials involving recombinant DNA also must be reviewed by an IBC, a local institutional committee that reviews and oversees basic and clinical research that utilizes recombinant DNA at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

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

- Phase 1. The biologic product candidate initially is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early understanding of its effectiveness. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. Phase 1 clinical trials of gene therapies are typically conducted in patients rather than healthy volunteers.
- Phase 2. The biologic product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Phase 3 clinical trials are commonly referred to as "pivotal" studies, which typically denotes studies that present the data the FDA or other relevant regulatory agencies will use to determine whether or not to approve a biologic product. In Phase 3 studies, the biologic product candidate is administered to an expanded patient population, generally at multiple geographically dispersed clinical trial sites in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the potency and safety of the product for approval. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.
- Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after 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.

Additional Regulation for Gene Therapy Clinical Trials

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors the FDA will consider at each of the above stages of development and relate to, among other things: the proper preclinical assessment of gene therapies; the Chemistry, Manufacturing and Controls, or CMC information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA application; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. Further, the FDA usually recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by 10 years of annual queries, either in person or by questionnaire. The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System, which includes information on gene therapy trials and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these trials.

US Review and Approval Processes

The results of the preclinical tests and clinical trials, together with detailed information relating to the product's CMC and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. For gene therapies, selecting patients with applicable genetic defects is a necessary condition to effective treatment. For the therapy we are currently developing, we believe that diagnoses based on existing genetic tests developed and administered by laboratories certified under the Clinical Laboratory Improvement Amendments, or CLIA, are sufficient to select appropriate patients and will be permitted by the FDA. Under the Prescription Drug User Fee Act, or PDUFA, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual product fee for biologics and an annual establishment license fee on facilities used to manufacture prescription biologics. 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 product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

The FDA reviews a BLA within 60 days of submission to determine if it is substantially complete before it 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 that 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 candidate is safe and potent, or effective, for its intended use, has an acceptable purity profile and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biologic products or biologic 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 product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategies, or REMS, is necessary to assure the safe use of the product candidate.

REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. A REMS could include medication guides, physician communication plans and 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 the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product candidate within required specifications. Additionally, before approving a BLA, the FDA typically will inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

On the basis of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the biologic product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter.

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

The FDA has agreed to specified performance goals in the review of BLAs under the PDUFA. One such goal is to review standard BLAs in 10 months after the FDA accepts the BLA for filing, and priority BLAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Fast Track Designation

The FDA has granted Fast Track designation to B-VEC and KB105. Fast Track designation is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the Fast Track designation provision is to help facilitate development and expedite the review and potential approval of drugs to treat serious and life-threatening conditions. Sponsors of drugs that receive Fast Track designation have the opportunity for more frequent interactions with the FDA review team throughout the development program. These can include meetings to discuss study design, data required to support approval, or other aspects of the clinical program. Additionally, products that have been granted Fast Track designation may be eligible for priority review of a BLA application and the FDA may consider reviewing portions of an NDA before the sponsor submits the complete application, also known as a rolling review.

Orphan Drug Designation

On November 2, 2017, the FDA granted Orphan Drug Designation to the Company's lead product candidate, B-VEC, for the treatment of DEB. On August 7, 2018, the FDA granted orphan drug designation to the Company's second product candidate, KB105 for treatment of patients with TGM1-deficient ARCI.

Under the Orphan Drug Act, the FDA may designate a biologic product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a biologic product available in the United States for treatment of the disease or condition will be recovered from sales of the product

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, meaning that the FDA may not approve any other applications to market the same drug or biologic product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the party holding the exclusivity fails to assure the availability of sufficient quantities of the drug to meet the needs of patients with the disease or condition for which the drug was designated. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Other benefits include reduced regulatory fees, protocol assistance and tax credits for certain clinical research costs.

Orphan medicinal product status in the EU has similar, but not identical benefits. The EMA granted the orphan medicinal product designation, or OMPD, for B-VEC on April 16, 2018, and for KB105 on November 13, 2019.

Regenerative Medicine Advanced Therapy ("RMAT") Designation

The FDA granted RMAT designation to B-VEC for the treatment of DEB in June 2019. Established under the 21st Century Cures Act, RMAT designation is a program designed to expedite the development and approval of regenerative medicine products, including gene therapy products. An investigational therapy is eligible for the RMAT designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates a potential to address unmet medical needs for that disease or condition. The designation includes all the benefits of the FDA's Fast Track and Breakthrough Therapy designations and enables the ability to work more closely and frequently with the FDA to discuss surrogate or intermediate endpoints to support the potential acceleration of approval and satisfy post-approval requirements.

Prime Designation

In March 2019, the EMA granted PRIority MEdicines, or PRIME, eligibility for B-VEC to treat DEB. The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. These medicines are considered priority medicines by the EMA. To be eligible and accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data coupled with non-clinical data. Through PRIME, the EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency. The program is intended to optimize development plans and expedite the review and approval process so that these medicines may reach patients as early as possible.

Rare Pediatric Disease Priority Review Voucher

The FDA also offers a rare pediatric disease drug designation. If a drug receives the designation of a "rare pediatric disease" drug, it is eligible during the FDA marketing process to apply for a Rare Pediatric Disease Priority Review Voucher. According to the FDA website, under the Rare Pediatric Priority Review Voucher Program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. We received the designation of "rare pediatric disease" for B-VEC in December 2016 and for KB105 in August 2018 which makes these two product candidates eligible to apply for a Rare Pediatric Priority Review Voucher.

US patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor's US patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and 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 generally is 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 biologic product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. Moreover, a given patent may only be extended once based on a single product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Post-Approval Requirements

Rigorous and extensive FDA regulation of biologic products continues after approval, particularly with respect to cGMP requirements. Manufacturers are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biologic products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product; recordkeeping requirements; reporting of adverse effects; reporting updated safety and efficacy information; and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA, together with a release protocol, showing a summary of the history of manufacture of the lot and the results of all tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biologic products. A sponsor also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in- patient populations that are not described in the product's approved labeling (known as "off-label use").

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Government Regulation Outside of the United States

In addition to regulations in the United States, sponsors are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of biologic products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not a sponsor obtains FDA approval for a product, a sponsor 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 request for a Clinical Trial Authorization, or CTA, must be submitted to the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trial takes place, much like FDA and the IRB, respectively. Once the CTA request is approved in accordance with the EU and the EU Member State's requirements, clinical trial development may proceed. The requirements and processes governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements of the country or countries in which the clinical trial is performed, as well as the ethical principles that have their origin in the Declaration of Helsinki (whichever provides the greater protection to the clinical trial participants).

Failure to comply with applicable foreign regulatory requirements may result in, among other things, fines; suspension, variation or withdrawal of regulatory approvals; product recalls; seizure of products; operating restrictions; and criminal prosecution.

Other Healthcare Laws and Regulations

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers on the other. The Patient Protection and Affordable Care Act, or PPACA, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, or the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Certain marketing practices, including off-label promotion, also may implicate the FCA. In addition, the PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or the CMS, information related to payments and other transfers of value to physicians, certain other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which imposes obligations, including mandatory contractual terms, with respect to safeguarding the transmission, security and privacy of protected health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violation of the laws described above or any other governmental laws and regulations may result in penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and imprisonment. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to incurring the costs required to obtain FDA approvals. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all FDA-approved drugs for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The US government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. 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.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. EU member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control company profits. The downward pressure on health care costs has become 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 competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, for example, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected and continues to face major uncertainty due to the status of major legislative initiatives surrounding healthcare reform.

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 Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, 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. Equivalent laws have been adopted in other countries that impose similar obligations.

US Foreign Corrupt Practices Act

The US Foreign Corrupt Practices Act, or FCPA, prohibits US corporations and individuals from engaging in certain activities to obtain or retain business abroad or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Equivalent laws have been adopted in other foreign countries that impose similar obligations.

Employees

As of February 28, 2020, we had 51 full-time and 2 part-time employees, primarily engaged in research and development activities and manufacturing activities. None of our employees are represented by a labor union and we consider our employee relations to be good.

Corporate Information

We commenced operations on April 15, 2016. On March 31, 2017, we converted from a California limited liability company to a Delaware C-corporation, and changed our name from Krystal Biotech, LLC to Krystal Biotech, Inc. Our principal offices are located at 2100 Wharton Street, Suite 701, Pittsburgh, PA 15203, and our telephone number is 412-586-5830. On June 19, 2018, the Company incorporated Krystal Australia Pty Ltd., an Australian proprietary limited company, for the purpose of undertaking preclinical and clinical studies in Australia. On April 24, 2019, the Company incorporated Jeune, Inc. in Delaware, a wholly-owned subsidiary, for the purpose of undertaking preclinical studies for aesthetic skin conditions. Our website address is www.krystalbio.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. You should not rely on any such information in making your decision whether to purchase our common stock. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our investor relations website, http://ir.krystalbio.com/, as soon as reasonably practicable after we electronically file such material with, or furnish it to the Securities and Exchange Commission, or SEC. The SEC also maintains a website that contains reports, proxy and information statements, and other information regarding the Company that we file electronically with the SEC. The address of the website is http://www.sec.gov.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As a smaller reporting company and an emerging growth company, we may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- Reduced obligations with respect to financial data, including presenting only two years of audited financial statements and only two years of selected financial data in this Form 10-K;
- An exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;

- Reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- Exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. For example, we intend to take advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Annual Report on Form 10-K, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced reporting burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to adopt this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 1A. Risk Factors.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred recurring losses and negative cash flows from operations and, at December 31, 2019, we had an accumulated deficit of $39.0 million. Our ability to achieve profitability depends on our ability to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, B-VEC and KB105 and additional product candidates that we may pursue in the future. We do not anticipate generating revenues from product sales for the next year, if ever. We have devoted substantially all our efforts to date to research and development of our gene therapy product candidates, B-VEC and KB105, as well as to building out our infrastructure. We expect that it could be several years, if ever, before we have a commercialized product candidate. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- continue our research and the clinical development of B-VEC and KB105, including our current clinical trials and planned future trials;
- initiate additional clinical trials and preclinical studies for any additional product candidates that we may pursue in the future;
- prepare our Biologics License Application (BLA) , marketing authorization application (MAA) and approvals in certain other countries for B-VEC and KB105;
- ramp-up our in-house commercial-scale current good manufacturing practices or cGMP manufacturing facility;
- manufacture material for clinical trials or potential commercial sales;
- further develop our gene therapy product candidate portfolio;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies; and
- seek marketing approval for B-VEC, KB105 and additional product candidates in the EU and in other key geographies.

To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing the clinical trials for B-VEC and KB105, developing and validating commercial scale manufacturing processes, obtaining marketing approval for this product candidate, manufacturing, marketing and selling any future product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. If we were required to discontinue development of either B-VEC or KB105, if B-VEC or KB105 do not receive regulatory approval, if we do not obtain our targeted indications for B-VEC or KB105, or if B-VEC or KB105 fails to achieve sufficient market acceptance for any indication, we could be delayed by many years in our ability to achieve profitability, if ever, and would materially adversely affect our business prospects and financial condition. Moreover, if we decide to leverage any success with our B-VEC or KB105 product candidates to develop other product opportunities, we may not be successful in such efforts. In any such event, our business will be materially adversely affected.

We currently only have two product candidates, B-VEC and KB105, and are initiating trials for a third candidate KB301 in the near future, and we may never develop, acquire or in-license additional product candidates. We may never succeed in any or all these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of B-VEC and KB105, our expenses could increase and revenue could be further delayed.

We will need to raise additional funding in order to receive approval for B-VEC, KB105 or any other product candidate. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.

To complete the process of obtaining regulatory approval for B-VEC and KB105 and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize B-VEC and KB105, if approved, we will require substantial additional funding. In addition, if we obtain marketing approval for B-VEC or KB105, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur significant costs associated with operating as a public company. We anticipate that we will need additional funding to complete the development of B-VEC, KB105 and any future product candidates and to commercialize any such approved products.

Our future capital requirements will depend on many factors, including:

- the progress, timing, results and costs of our ongoing Phase 1/2 clinical trial for KB105;
- the progress, timing and costs of manufacturing of B-VEC for our planned pivotal Phase 3 clinical trials;
- the continued development and the filing on an investigational new drug, or IND, application for other product candidates;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other product candidates that we may pursue in the future, if any;
- the costs of building and maintaining our own commercial-scale cGMP manufacturing facilities;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with the manufacturing process development and evaluation of third-party manufacturers;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, in the event we receive marketing approval for B-VEC, KB105 or any other product candidates we may develop;
- the extent to which the costs of our product candidates, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors;

- the costs of commercialization activities for B-VEC, KB105 and other product candidates if we receive marketing approval for B-VEC, KB105 or any other product candidates we may develop, including the costs and timing of establishing product sales, medical affairs, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, if any, revenue received from commercial sale of B-VEC, KB105 or any of our other product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements, if any;
- our current license agreements, if any, remaining in effect and our achievement of milestones under those agreements;
- our ability to establish and maintain collaborations and licenses on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, will be derived from or based on sales of product candidates that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all our stockholders. The incurrence of indebtedness 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, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Furthermore, existing stockholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of additional financing may be impacted by, among other things, general market conditions, the market’s perception of our product candidates and growth potential and the market price per share of our common stock

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a development-stage company that commenced operations in 2016. Our efforts to date, with respect to the development of B-VEC and KB105, have been limited to organizing and staffing our company, business planning, raising capital, developing our STAR-D platform and related technologies, identifying B-VEC and KB105 as potential gene therapy product candidates and undertaking preclinical studies and clinical trials of B-VEC and KB105. While we have commenced our first clinical trial of B-VEC and KB105, we have not yet demonstrated the ability to complete clinical trials of B-VEC, KB105 or any other product candidate, obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success, performance or viability may not be as accurate as they could be if we had more experience developing gene therapy products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to transition at some point from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

Risks Related to Our Business

We are early in our development efforts. If we are unable to advance B-VEC and KB105 through clinical trials, obtain regulatory approval and ultimately commercialize B-VEC or KB105, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and B-VEC entered its first clinical trial in May 2018, and KB105 entered its first clinical trial in September 2019. The development and commercialization of B-VEC or KB105 (or any other product candidate we may develop) is subject to many uncertainties, including the following:

- successful enrollment and completion of clinical trials;
- positive results from our current and planned future clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- successful development of our internal manufacturing processes on an ongoing basis and maintenance of our existing arrangements with third-party manufacturers for clinical supply;
- commercial launch of B-VEC and KB105, if and when approved, whether alone or in collaboration with others;
- acceptance of B-VEC and KB105, if and when approved, by patients, the medical community and third-party payors;

If we fail in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize B-VEC and KB105, which would materially harm our business. If we do not receive regulatory approvals for B-VEC and KB105, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Our lead candidate, B-VEC, is in early stage development, and there is no guarantee that the results from preclinical studies will be indicative of our ability to complete or the results to be obtained in the current or future studies and clinical trials.

We initiated our first clinical trial for our lead product candidate B-VEC in May 2018; however, there is no guarantee that results of this or any potential future clinical trials will be positive or that we will be able to complete this or any potential future clinical trials on the anticipated timelines or at all. The positive interim results we have observed for B-VEC in our current clinical trial may not be predictive of the ultimate outcome of that trial or of any future clinical trials, and the current and future clinical trial process may fail to demonstrate that B-VEC is safe for humans and effective for indicated uses, which may cause us to abandon B-VEC. Furthermore, research and discoveries by us or others may identify serious adverse events, undesirable side effects or other unexpected properties of our current and future product candidates, including B-VEC, that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

The regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of B-VEC. Any of the foregoing scenarios could materially harm the commercial prospects for B-VEC and materially and adversely affect our business, financial condition, results of operations and prospects.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize B-VEC and the approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if B-VEC meets its safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of B-VEC. Any of the foregoing scenarios could materially harm the commercial prospects for B-VEC and materially and adversely affect our business, financial condition, results of operations and prospects.

B-VEC is based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

The clinical trial requirements of the FDA, EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the EU or how long it will take to commercialize our product candidates. Approvals by the European Commission may not be indicative of what FDA may require for approval.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review. If we were to engage an NIH-funded institution to conduct a clinical trial, that institution's IBC as well as its IRB, would need to review the proposed clinical trial to assess the safety of the trial. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines.

These regulatory review committees and advisory groups and the new guidelines they promulgate 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 B-VEC or future product candidates or lead to significant post-approval limitations or restrictions. As we advance B-VEC, we will be required to consult with these regulatory and advisory groups and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of B-VEC. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. 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, and our business, financial condition, results of operations and prospects would be materially and adversely affected.

B-VEC may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

There have been several significant adverse side effects in gene therapy trials using other vectors in the past. Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated. If in the future we are unable to demonstrate that such adverse events were caused by the administration process or related procedures, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, B-VEC for any or all targeted indications. Even if we can demonstrate that any serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of B-VEC, the commercial prospects of such product candidate may be harmed and our ability to generate product revenues from this product candidate may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Additionally, if B-VEC receives marketing approval, the FDA could require us to adopt a post-approval safety monitoring program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by B-VEC, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of B-VEC and could significantly harm our business, financial condition, results of operations and prospects.

We may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate for its intended indications. Clinical trials are expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or concerns with a class of drug candidates, or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

In addition, if we make manufacturing or formulation changes to B-VEC, we may need to conduct additional studies to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize B-VEC or allow our competitors to bring products to market before we do, which could limit our potential revenue or impair our ability to successfully commercialize B-VEC and may harm our business, financial condition, results of operations and prospects. Any delays, setbacks or failures in our clinical trials could materially and adversely affect our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our drug candidates, we may:

- be delayed in obtaining marketing approval, if at all, or be required to conduct additional confirmatory safety and/or efficacy studies;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution;
- be subject to the addition of labeling statements, such as warnings or contraindications;

- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be negatively impacted, and our ability to generate revenues from our drug candidates may be delayed.

We have a limited number of employees and limited corporate infrastructure and may experience difficulties in managing growth.

We are a small company with a limited number of employees and corporate infrastructure. We have experienced a period of significant expansion in headcount and expect to experience significant expansion of our facilities, infrastructure and overhead as we develop our own manufacturing facility and increase our research and development efforts. Future growth will impose significant added capital requirements, as well as added responsibilities on members of management, including the need to identify, recruit, maintain and integrate new personnel. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for B-VEC, our lead product candidate, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for B-VEC may also be subject to a post-approval safety monitoring program, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. Our current and each of our proposed clinical trials for B-VEC includes a five-year, long-term follow-up phase, limited to confirmed data collection from annual visits with standard care physicians. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of B-VEC or any future product candidate, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize B-VEC and adversely affect our business, financial condition, results of operations and prospects.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of B-VEC. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or 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, which would materially and adversely affect our business, financial condition, results of operations and prospects.

While we have obtained orphan drug designation for B-VEC and KB105, it may not effectively protect us from competition, and we may be unable to obtain orphan drug designation for our future product candidates. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

On November 2, 2017, the FDA granted orphan drug designation to our lead product candidate, B-VEC, for the treatment of DEB and we may seek orphan drug designation from the FDA for our future product candidates. On April 16, 2018, the European Commission granted the Orphan Medicinal Product Designation, or OMPD, for B-VEC. On August 7, 2018, the FDA granted orphan drug designation to our second product candidate, KB105, currently in early clinical development for treatment of patients with transglutaminase 1 (TGM-1) deficient autosomal recessive congenital ichthyosis ("ARCI"), and on October 10, 2019, the European Commission granted the Orphan Medicinal Product Designation for KB105. There are currently no treatments for ARCI, which affects approximately 20,000 patients worldwide. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the European Commission, upon a recommendation from the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU. Additionally, orphan designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biologic product.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States and 10 years in the EU. The exclusivity period in the EU can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even though we have obtained orphan drug exclusivity for B-VEC and KB105, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although like the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply enough quantities of orphan medicinal product.

Breakthrough therapy designation, Regenerative Medicine Advanced Therapy designation, Fast Track designation or Rare Pediatric Disease designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

On May 23, 2018, the FDA granted Fast Track designation in the United States for B-VEC. We have been granted rare pediatric disease designation for B-VEC. On August 23, 2018, the FDA granted rare pediatric disease designation for KB105. In addition, B-VEC was granted Regenerative Medicine Advanced Therapy (RMAT) by FDA in June 2019 and Priority Medicine (PRIME) in March 2019 by EMA. The receipt of any of these designations for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

A RMAT/PRIME therapy product candidate is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease. Drugs designated as RMAT therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process. If a drug, or biologic in our case, is intended for the treatment of a serious or life-threatening condition and the biologic demonstrates the potential to address unmet medical needs for this condition, the biologic sponsor may apply for FDA Fast Track designation. Even after having received Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many biologics that have received Fast Track designation have failed to obtain approval. A sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. We received the designation of “rare pediatric disease” for B-VEC in December 2016 and for KB105 in August 2018 which could qualify us to receive a Rare Pediatric Priority Review Voucher.

There is no assurance we will receive RMAT, PRIME or breakthrough therapy or Fast Track designations for any of our product candidates and the receipt of any of these designations for a product candidate may not result in a faster development process, review or approval and does not assure ultimate approval by the FDA. Further, even though we have received rare pediatric disease designation for B-VEC or KB105, we may not experience a faster review or approval for a subsequent marketing application.

We may expend our limited resources to pursue a product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. 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 royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our efforts focuses on the potential approval of B-VEC and KB105, a key component our strategy is to discover, develop and potentially commercialize a portfolio of product candidates to treat orphan diseases and ultimately, non-orphan diseases. Identifying new product candidates requires substantial technical, financial and human resources, whether any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we may fail to successfully develop and commercialize such product candidates for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our lead product candidate, B-VEC.

We are aware of several companies and institutions that are currently developing alternative autologous or palliative gene therapy approaches for DEB. Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if 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 any product candidate that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier 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. Additionally, technologies developed by our competitors may render B-VEC uneconomical or obsolete, and we may not be successful in marketing B-VEC against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate that we may develop and commercialize.

Risks Related to Manufacturing

Delays in obtaining regulatory approvals of the process and facilities needed to manufacture B-VEC, KB105 or any of our product candidates or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

Before we can begin to commercially manufacture B-VEC, KB 105 or any of our product candidates, whether in a third-party facility or in our own facility, once established, we must pass a pre-approval inspection of our manufacturing facility by the FDA before B-VEC, KB 105 or any of our product candidates can obtain marketing approval. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities. The timeframe required for us to obtain such approvals is uncertain. In order to obtain approval, we will need to ensure that all our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any product candidate that we may develop.

In addition, the manufacturing process used to produce our product candidates is complex, novel and has not been validated for commercial use. In order to produce enough quantities of our product candidates for future clinical trials and initial US commercial demand, we will need to increase the scale of our manufacturing process. The production of our product candidates requires processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the process works and that B-VEC is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

Although we have established our own B-VEC and KB105 manufacturing facility, we may need to utilize third parties to conduct our product manufacturing for the near future. Therefore, we are subject to the risk that these third parties may not perform satisfactorily.

Even if we obtain the validation from the FDA of our cGMP manufacturing facility, we intend to maintain third-party manufacturing capabilities in order to provide multiple sources of supply. In the event that these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture B-VEC in accordance with regulatory requirements or if there are disagreements between us and these third-party manufacturers, we will not be able to complete, or may be delayed in completing, the preclinical studies required to support future IND submissions of other product candidates or the clinical trials required for approval of B-VEC. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense prior to the approval of B-VEC and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our third-party manufacturer fails to comply with applicable cGMP regulations, the FDA and foreign regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition, results of operations and prospects to be materially harmed.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce B-VEC on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of B-VEC could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks related to commercialization of our product candidates

If we are unable to expand our market development capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any product revenue.

We currently have a small market development organization. To successfully commercialize B-VEC and KB105, if approved, we plan to expand our capabilities to promote market access and build awareness. To successfully commercialize any other products that may result from our development programs, we will need to further expand our market development organization, either on our own or with a third party. The development of our own market development team will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaboration agreements regarding any of our product candidates with third parties to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential products. If any of our product candidates is approved but fails to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our gene therapy product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Gene therapy remains a novel technology. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia and death seen in trials using other vectors. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

Our success also will depend upon physicians who specialize in the treatment of DEB prescribing treatments that involve the use of B-VEC and KB105, respectively, in lieu of, or in addition to, other treatments with which they are more familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of B-VEC or demand for any product candidate we may develop. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of B-VEC, stricter labeling requirements for B-VEC if approved and a decrease in demand for B-VEC.

If the market opportunities for B-VEC or our future product candidates are smaller than we believe they are, our product revenues may be adversely impacted, and our business may suffer.

We are currently focusing our research and product development efforts on B-VEC for DEB. Our understanding of both the number of people who have this disease, as well as the subset of people with this disease who have the potential to benefit from treatment with B-VEC, are based on estimates in published literature. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the EU and elsewhere may turn out to be lower than expected or these patients may not be otherwise amenable to treatment with B-VEC or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive B-VEC less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets. Further, the severity of the progression of a disease up to the time of treatment will likely diminish the therapeutic benefit conferred by a gene therapy due to irreversible cell damage. Lastly, certain patients' immune systems might prohibit the successful delivery of certain gene therapy products to the target tissue, thereby limiting the treatment outcomes.

The commercial success of B-VEC, KB105, and any future product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy could result in additional regulations restricting or prohibiting B-VEC and KB105. Even with the requisite approvals from the FDA in the United States, the EMA in the EU and other regulatory authorities internationally, the commercial success of B-VEC and KB105 will depend, in part, on the acceptance of physicians, patients and health care payors of gene therapy products in general, and B-VEC and KB105 in particular, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of gene therapy products and B-VEC and KB105, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of B-VEC and KB105 as demonstrated in clinical trials;
- the efficacy, potential and perceived advantages of B-VEC or KB105 over alternative treatments, if available;
- the cost of B-VEC or KB105 relative to alternative treatments, if any are available;
- the clinical indications for which B-VEC and KB105 are approved by the FDA or the European Commission;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of products and their ability to meet market demand;
- publicity concerning our product candidates or competing products and treatments;
- any restrictions on the use of our products together with other medications; and
- favorable third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for B-VEC or KB105, if approved, or any of our other product candidates that may be approved in the future, which would adversely affect our revenue and results of operations.

We expect that coverage and reimbursement of pharmaceutical may be increasingly restricted both in the US and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Drug pricing by pharmaceutical companies recently has come under increased scrutiny and continues to be subject to intense political and public debate in the US and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the US Specifically, there have been several recent US Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. In some international markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third-party payors, which may render our product candidates, if approved, not commercially viable or may adversely affect our anticipated future revenues and gross margins.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for our future products, which would adversely affect our anticipated revenue and results of operations.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including 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 for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. Currently, no gene therapy product has been approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services, or CMS, the agency responsible for administering the Medicare program. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these types of products. Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European Union Member States. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It also can take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

Ethical, legal and social issues related to genetic testing may reduce demand for our products candidate, if approved.

We anticipate that prior to receiving certain gene therapies, patients may be required to undergo genetic testing. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate based on genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities prohibiting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios could decrease demand for our product candidates, if approved.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for them outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of B-VEC or other future product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product candidates, if approved, is also subject to approval. We intend to submit a marketing authorization application to the EMA for approval of B-VEC in the EU but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EU also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. 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 product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of B-VEC or our future product candidates will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our gene therapy platform. Research programs to identify new product candidates require substantial technical, financial and human resources. Although certain of our product candidates are currently in clinical or preclinical development, we may fail to identify other potential product candidates for clinical development for several reasons. For example, our research may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our product candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and product candidates requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain enough numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

Our future success depends on our ability to retain key employees and scientific advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on members of our management team, the loss of whose services may adversely impact the achievement of our objectives. Our employees and scientific advisors are at-will employees and consultants, and the loss of one or more of them might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other qualified employees and scientific advisors for our business, including scientific and technical personnel, also will be critical to our success. There currently is a shortage of skilled individuals with substantial gene therapy experience, which is likely to continue. As a result, competition for skilled personnel, including in gene therapy research and vector manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators and advisors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and advisors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in criminal and civil penalties or sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines, criminal penalties, or other sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future drug candidates.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

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 our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the US pharmaceutical industry. The PPACA, among other things: (i) addresses 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; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Further, on December 14, 2018, US Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA.

While Congress has not passed repeal legislation, the Tax Reform Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biologic products that are demonstrated to be "highly similar" or "biosimilar or interchangeable" with an FDA-approved biologic product. This new pathway could allow competitors to reference data from biologic products already approved after 12 years from the time of approval. This could expose us to potential competition by lower cost biosimilars even if we commercialize a product candidate faster than our competitors. Moreover, the creation of this abbreviated approval pathway does not preclude or delay a third party from pursuing approval of a competitive product candidate via the traditional approval pathway based on their own clinical trial data. Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the time for Medicare contractors to recoup Medicare overpayments to providers from three to five years. Additionally, there have been several recent US Congressional inquiries and proposed bills 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.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The current administration's Blueprint contains certain measures that the US Department of Health and Human Services is already working to implement. Individual states in the United States have also been increasingly 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.

Additional changes may affect our business, including those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse enforcement, and expansion of new programs, such as Medicare payment for performance initiatives.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for B-VEC and KB105 or additional pricing pressures and may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for B-VEC and KB105 and begin commercializing it in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business as well as other jurisdictions. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The PPACA amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity does not have to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The PPACA provides that a claim for items or services resulting from an Anti-Kickback Statute violation is a false claim under the federal False Claims Act. Cases against pharmaceutical manufacturers support the view that certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach
- Notification Rules under HITECH and the Genetic Information Nondiscrimination Act; Other modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;
- federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. 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 our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

We also may incur substantial costs to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, such as the U.S. presidential election and the impact of health and safety concerns, such as the current coronavirus outbreak. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical 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, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store, and transmit, often electronically, confidential data of others. Unauthorized access to our computer systems or stored data could result in the theft or improper disclosure of confidential information, the deletion or modification of records, or could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite implemented security measures, our facilities, systems, and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming and/or human errors, or other similar events which may disrupt our delivery of services or expose the confidential information of our customers and others. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties or government authorities.

Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations or the operations of manufacturing facilities and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as manufacturing facilities, 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. The disaster recovery and business continuity plans that we have in place currently are limited and may not prove adequate in the event of a serious disaster or similar event. Substantially all our current supply of B-VEC and KB105 is located at our manufacturing facility in Pittsburgh, Pennsylvania. We were are in the early stages of constructing an additional manufacturing facility and establishing a relationship with a third-party contract manufacturer as a back-up supplier for the commercial supply of our products, if necessary. 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, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain adequate US and foreign patent protection for our product candidates, including B-VEC and KB105, any future product candidates we may develop, and/or our STAR-D platform, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to successfully commercialize our current product candidates, any future product candidates we may develop, and our platform technologies may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to B-VEC, KB105, additional product candidates in our pipeline, current and future innovations related to our STAR-D platform, and our institutional knowledge. The patent prosecution process is expensive, time-consuming and complex; we may not be able to file, prosecute, maintain, and/or enforce all necessary or desirable patent applications and issued patents at a reasonable cost or in a timely manner. We currently have four issued patents in the United States: (1) US patent No. 9,877,990, covering, in part, pharmaceutical formulations comprising our lead clinical product B-VEC, as well as methods of its use for treating wounds, disorders, and diseases of the skin, which we refer to as the ’990 patent; US patent No. 10,155,016 which covers pharmaceutical compositions containing B-VEC formulated for myriad routes of administration; (3) US patent No. 10,441,614 covering aspects of our STAR-D platform technology, and its uses in

delivering any gene of interest to the skin; and (4) US patent No. 10,525,090, covering pharmaceutical compositions comprising our second clinical product candidate, KB105, and methods of its use for treating TGM1-deficient autosomal recessive congenital ichthyosis. Furthermore, we have seven international patent applications filed in accordance with the Paris Cooperation treaty directed to multiple discovery, preclinical, and clinical programs, including both B-VEC and KB105, as well as multiple patent applications filed in foreign jurisdictions stemming from these international applications. B-VEC is also the subject of patents granted in both Australia and Europe.

Even if we are granted the patents we are currently pursuing, they may not issue in a form that will provide us with the full scope of protection we desire, they may not prevent competitors or other third parties from competing with us, and/or they may not otherwise provide us with a competitive advantage. Our competitors, or other third parties, may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, there is no assurance that the ’990 patent, or any other patent we are granted, will prevent third parties from developing competing technologies. Moreover, our patent estate, including the ’990 patent, does not preclude third parties from having intellectual property rights that could interfere with our freedom to use our platform for dermatological indications. Even assuming patents issue from our pending and future patent applications, changes in either the patent laws or interpretation of the patent laws in the United States and foreign jurisdictions may diminish the value of our patents or narrow their scope of protection.

We also may not be aware of all third-party intellectual property rights potentially relating to technologies similar to our own. Publications of discoveries in the scientific literature often lag their actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, it is impossible to be certain that we were the first to develop the specific technologies as claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

Filing, prosecuting and defending patents on each and every one of our product candidates, current and future innovations related to our STAR-D platform, and our institutional knowledge in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States may differ in scope from those eventually granted in the United States. Thus, in some cases, we will not have the opportunity to obtain patent protection for certain technologies in some jurisdictions outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability (and the ability of any potential future collaborators) to develop, manufacture, market and sell our product candidates, and to freely use our proprietary technologies (*e.g.*, without infringing the rights and intellectual property of others). Many companies and institutions have filed, and continue to file, patent applications related to various aspects of gene therapy. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing, and can be revised before issuance, there may be applications now pending which may later result in issued patents that a third party asserts are infringed by the manufacture, use, sale, or importation of

our products. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to B-VEC, KB105, or related technologies, including, for example, interference proceedings, post grant review challenges, and *inter partes* review before the USPTO. For example, a third party may bring an *inter partes* review challenging our patents and any future patent that may be granted to us. Our competitors or other third parties may assert infringement claims against us, alleging that our therapeutics, manufacturing methods, formulations or administration methods are covered by their patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue, and against whom our patent portfolio may therefore have no deterrent effect.

There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patents or other intellectual property rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize our products, including B-VEC. In order to successfully challenge the validity of any such US patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such US patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such US patent. In such a hypothetical situation, there is no assurance that a court of competent jurisdiction would find that B-VEC, KB105, or our other product candidates or technologies do not infringe a third-party patent.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcomes are uncertain. If we are found, or believe there is a risk that we may be found, to infringe a third party's valid and enforceable intellectual property rights, we could be required (or may choose) to obtain a license from such a third party to continue developing, manufacturing and marketing our technologies. However, we may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and further, it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies, including B-VEC. We also could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our technologies, including B-VEC, or force us to cease some or all our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming. Competitors may infringe our current or future patents, should such patents issue, or we may be required to defend against claims of infringement or other unauthorized use of intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our scientific and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims asserting that we, our employees or our advisors have wrongfully used or disclosed alleged trade secrets of other parties, including current or former employers, or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including potential competitors, and we have and may in the future enter into agreements providing us with rights to intellectual property of third parties for limited purposes. Although we try to observe the terms of agreements under which we obtain access to third party intellectual property and to ensure that our employees and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties or the current or former employers of employees or advisors. For instance, a third party has asserted that we referred to an HSV-1 vector it provided to us in one of our patent applications in breach of agreements between us and such third party. We believe this assertion is without merit, but litigation may be necessary to defend against this claim, or claims from others that may be asserted in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may be subject to an injunction and may lose valuable intellectual property rights or personnel. Moreover, any such litigation, or the threat thereof, may adversely affect our ability to hire new employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, which would have an adverse effect on our business, results of operations, and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

While it is our policy to require our employees and contractors who may be involved in the conception of intellectual property to execute agreements assigning such intellectual property rights to us, unforeseen complications may arise when fully and adequately executing such an agreement with each party who, in fact, conceives of intellectual property that we regard as our own. Examples of such complications may include, for example, when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. Such complications may lead to us being forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Moreover, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be insufficient in fully perfecting ownership of inventions developed by that individual. Disputes about the ownership of intellectual property that we may own may have a material adverse effect on our business.

Changes in US patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included several significant changes to US patent law, including provisions that affected the way patent applications are prosecuted, and altered strategies regarding patent litigation. These provisions also switched the United States from a “first-to-invent” system to a “first-to-file” system, allowed third-party submissions of prior art to the USPTO during patent prosecution, and set forth additional procedures to attack the validity of a patent through various post grant proceedings administered by the USPTO. As patent reform legislation can inject serious uncertainty into the patent prosecution and litigation processes, it is not clear what impact future patent reform legislation will have on the operation of our business. However, such future legislation, and its implementation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain given the ever evolving and constantly shifting nature of precedential patent cases decided by both the US Court of Appeals for the Federal Circuit and the US Supreme Court. We cannot assure you that our efforts to seek patent protection for our technology and product candidates will not be negatively impacted by the future court decisions or changes in guidance or procedures issued by the USPTO. These decisions, and any guidance issued by the USPTO (or changes thereto), could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property rights in the future.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently have not registered our trademarks and trade names. Once trademarks or trade names have been registered, they may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which are important for building name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. There also could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to patents, trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to our product candidates but that are not covered by the claims of our current patents, or of patents that we may own or license in the future;
- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain aspects of the concerned technologies;
- others may independently develop similar or alternative technologies, or duplicate any of our technologies, potentially without falling within the scope of our current or future issued claims, thus not infringing our intellectual property rights;
- it is possible that our filed or future patent applications will not lead to issued patents;
- issued patents to which we currently hold rights or to which we may hold rights in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to any future intellectual property rights licensed to us on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we do not have or pursue patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent application covering certain of our trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to this Offering and Ownership of our Common Stock

Our Chief Executive Officer and Chairman of the Board of Directors and our founder, Chief Operating Officer and director will maintain the ability to substantially influence all matters submitted to stockholders for approval.

As of December 31, 2019, Krish S. Krishnan and Suma M. Krishnan, our Chief Executive Officer and Chairman of the Board and our founder, Chief Operating Officer and director, respectively, in the aggregate, beneficially owned shares representing approximately 24% of our capital stock. As a result, they will be able to substantially influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons would substantially influence the election of directors and approval of any merger, consolidation or sale of all or substantially all our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company that our public stockholders disagree with.

If securities analysts publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If securities analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies specifically has experienced extreme volatility that has often been unrelated to the operating performance of such companies. As a result of this volatility, you may not be able to sell your common stock at or above the price that you paid for it. The market price of our common stock may be influenced by many factors, including:

- our ability to successfully proceed to and conduct clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not “emerging growth companies.” In particular, while we are an “emerging growth company: (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act; (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements; (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. Investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will continue to incur costs as a result of becoming a public company, and such costs may increase if and when we cease to be an "emerging growth company."

As a public company, we expect to continue to incur significant legal, accounting, insurance and other expenses, including costs associated with public company reporting requirements. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect compliance with these public reporting requirements and associated rules and regulations to increase expenses, particularly after we are no longer an emerging growth company, although we are currently unable to estimate these costs with any degree of certainty. We could be an emerging growth company until the end of 2022, after which, we will incur additional costs applicable to public companies that are not emerging growth companies.

If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. After we are no longer an emerging growth company under the JOBS Act, beginning no later than our year ending December 31, 2023, Section 404 of the Sarbanes-Oxley Act requires our auditors to deliver an attestation report on the effectiveness of our internal control over financial reporting in conjunction with their opinion on our audited financial statements. Substantial work on our part is required to implement appropriate processes, document the system of internal control over key processes, assess their design, remediate any deficiencies identified and test their operation. This process is expected to be both costly and challenging. We cannot give any assurances that material weaknesses will not be identified in the future in connection with our compliance with the provisions of Section 404 of the Sarbanes-Oxley Act. The existence of any material weakness would preclude a conclusion by management and our independent auditors that we maintained effective internal control over financial reporting. Our management may be required to devote significant time and expense to remediate any material weaknesses that may be discovered and may not be able to remediate any material weakness in a timely manner. The existence of any material weakness in our internal control over financial reporting could also result in errors in our financial statements that could require us to restate our financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, all of which could lead to a decline in the per-share trading price of our common stock

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 80% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We have broad discretion in the use of our cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and marketable securities and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Third-party expectations relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. Some investors may use these factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased in number, resulting in varied and in some cases inconsistent standards. In addition, the criteria by which companies’ corporate responsibility practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy such new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies. Furthermore, if our competitors’ corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other stakeholders or our initiatives are not executed as planned, our reputation and financial results could be adversely affected

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store, and transmit, often electronically, confidential data of others. Unauthorized access to our computer systems or stored data could result in the theft or improper disclosure of confidential information, the deletion or modification of records, or could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite implemented security measures, our facilities, systems, and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming and/or human errors, or other similar events which may disrupt our delivery of services or expose the confidential information of our customers and others. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties or government authorities.

Any of these developments could have a material adverse effect on our business, financial condition, and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Below is a summary of our leased properties as of December 31, 2019:

We lease approximately 25,000 square feet of combined laboratory and office space in Pittsburgh, Pennsylvania that we use for our research, development and manufacturing efforts. This lease expires in February 2027.

On December 26, 2019, we entered into a lease agreement for our second commercial gene therapy facility in the Pittsburgh, Pennsylvania area. The 100,000 square foot facility is under construction and is expected to be completed by early 2021. The lease will commence when the space is available for access, which is anticipated to be in the second half of 2020, and has an initial term that lasts until October 31, 2035.

Item 3. Legal Proceedings.

We are not a party to any litigation that is expected to result in a material loss.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Capital Market under the symbol "KRYS" since September 20, 2017. Prior to that time, there was no public market for our common stock.

On February 28, 2020, there were five stockholders of record of our common stock. We are unable to estimate the total number of stockholders represented by these record holders, as many of our shares are held by brokers and other institutions on behalf of our stockholders. The closing price of our common stock was $53.45 per share as of February 28, 2020 as reported on the Nasdaq Capital Market.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any further determination to pay dividends on our capital stock will be at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2019.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans are hereby incorporated by reference to our Definitive Proxy Statement.

Sales of Unregistered Securities

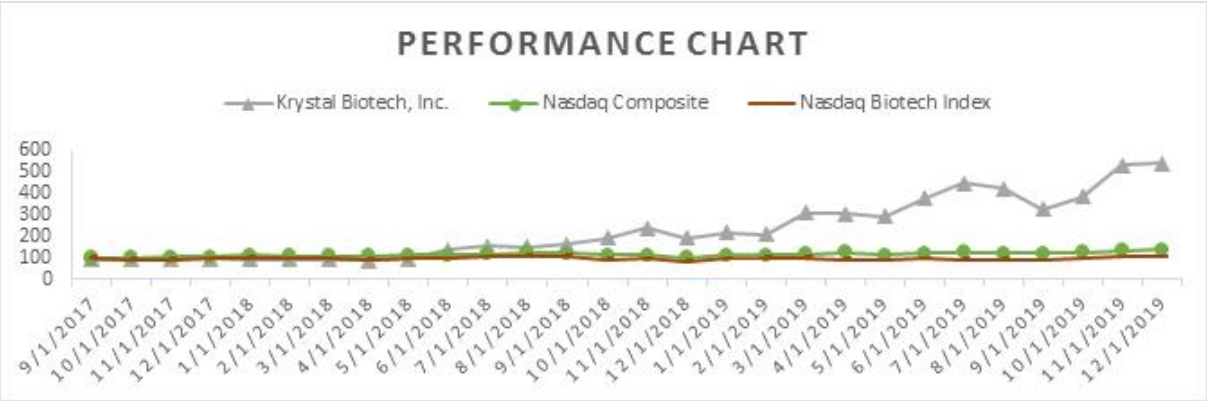
There were no sales of unregistered securities by us during the fourth quarter of 2019. Prior to the fourth quarter of 2019, sales of unregistered securities, if any, were previously reported in our quarterly reports on Form 10-Q and current reports on Form 8-K filed with the SEC during 2019.

Stock Performance Graph

Set forth below is a graph comparing the cumulative total return on an indexed basis of a $100 investment in the Company's common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index commencing on September 20, 2017 (the date our common stock began trading on The Nasdaq Stock Market) and continuing through December 31, 2019. The graph assumes our closing sale price on September 20, 2017 of $10.64 per share as the initial value of our common stock for indexing purposes. Points on the graph represent the performance as of the last business day of each of the months indicated.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

This performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Exchange Act or incorporated by reference into any filing of Krystal Biotech, Inc. under the Securities Act or the Exchange Act, except to the extent we specifically incorporate it by reference into such filing. The past performance of our common stock is no indication of future performance.



Trade Date	Krystal Biotech, Inc.	Nasdaq Composite	Nasdaq Biotech Index
9/20/2017	100.00	100.00	100.00
9/29/2017	93.70	100.62	100.28
10/31/2017	93.05	104.21	94.45
11/30/2017	98.68	106.47	94.96
12/29/2017	98.87	106.93	96.36
1/31/2018	93.80	114.80	103.07
2/28/2018	94.74	112.65	97.55
3/29/2018	94.83	109.41	96.30
4/30/2018	90.32	109.45	93.44
5/31/2018	96.71	115.27	97.82
6/29/2018	139.76	116.33	99.14
7/31/2018	154.61	118.83	105.26
8/31/2018	154.51	125.61	110.32
9/28/2018	165.23	124.63	110.11
10/31/2018	193.70	113.16	94.04
11/30/2018	238.53	113.55	98.45
12/31/2018	195.30	102.78	87.38
1/31/2019	217.29	112.79	99.08
2/28/2019	210.15	116.67	101.73
3/29/2019	309.21	119.72	100.83
4/30/2019	307.80	125.39	95.97
5/31/2019	295.30	115.44	90.12
6/28/2019	378.48	124.01	98.41
7/31/2019	451.22	126.63	95.38
8/30/2019	422.93	123.34	92.86
9/30/2019	326.36	123.90	89.79
10/31/2019	386.00	128.44	96.74
11/29/2019	531.11	134.22	107.80
12/30/2019	541.64	138.57	108.32

Item 6. Selected Financial Data.

The following selected financial data of the Company for each of the periods indicated are derived from the Company's audited consolidated financial statements. The financial statements of the Company as of December 31, 2019 and 2018 and for the years ended December 31, 2019 and 2018, and the related reports of the independent registered public accounting firm are included elsewhere in this Annual Report on Form 10-K. The data presented below should be read in conjunction with the Company's financial statements, the notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

	Years Ended December 31,			
(In thousands, except shares and per share data)	**2019**	**2018**	**2017**	**2016**
Expenses				
Research and development	$ 15,616	$ 7,761	$ 3,208	$ 741
General and administrative	6,465	4,155	1,564	402
Total operating expenses	22,081	11,916	4,772	1,143
Loss from operations	(22,081)	(11,916)	(4,772)	(1,143)
Other Expense				
Interest and other income, net	2,993	1,027	(3,148)	(7)
Total interest and other income	2,993	1,027	(3,148)	(7)
Net loss	(19,088)	(10,889)	(7,920)	(1,150)
Net loss applicable to stockholders	$ (19,088)	$ (10,889)	$ (7,920)	$ (1,150)
Net loss attributable to common stockholders per share: Basic and diluted	$ (1.20)	$ (0.97)	$ (1.48)	$ (1.31)
Weighted-average common shares outstanding: Basic and diluted	15,901,083	11,203,081	5,360,536	877,490

(In thousands)	**December 31, 2019**	**December 31, 2018**	**December 31, 2017**	**December 31, 2016**
Balance sheet data:				
Cash and cash equivalents	$ 187,514	$ 103,670	$ 49,591	$ 1,923
Working capital	192,553	110,054	49,274	2,126
Total assets	209,023	116,116	50,114	2,182
Accrued expenses and other current liabilities	2,123	1,708	447	1
Related party promissory notes	—	—	—	698
Total liabilities	6,109	2,890	640	1,893
Total stockholders' equity	$ 202,914	$ 113,226	$ 49,474	$ 289

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following information should be read in conjunction with the consolidated financial statements and related notes thereto included in this Annual Report on Form 10-K. In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties which may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties discussed in the sections entitled Item 1A. "Risk Factors" and "Forward-Looking Statements" included at the beginning of this Annual Report on Form 10-K. The risks and uncertainties can cause actual results to differ significantly from those forecast in forward-looking statements or implied in historical results and trends. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

This section of this Form 10-K generally discusses 2019 and 2018 items and year-to-year comparisons between 2019 and 2018 of the Company. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Overview

We are a clinical stage gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from skin diseases. We have developed a proprietary gene therapy platform, which we refer to as the Skin TARgeted Delivery platform, or STAR-D platform, that consists of a patented engineered viral vector based on herpes simplex virus 1, or HSV-1, and skin-optimized gene transfer technology, to develop off-the-shelf treatments for dermatological diseases for which we believe there are no known effective treatments. We are initially using the STAR-D platform to develop treatments for rare or orphan dermatological indications caused by the absence of or a mutation in a single gene, and plan to leverage our platform in the future to expand our pipeline to include other indications and skin conditions.

Our lead clinical product candidate, B-VEC (beremagene geperpavec, previously "KB103") is our proprietary gene therapy candidate therapy for the treatment of dystrophic epidermolysis bullosa, or DEB, a rare and severe genetic disease, for which there is currently no approved treatment.

In October 2019, we announced positive results from our Phase 1/2 clinical trial of B-VEC at Stanford University. Safety data from all patients showed that B-VEC was well tolerated with no serious adverse events (SAEs) reported. For more information on the B-VEC Phase 1/2 clinical trial, visit:

http://ir.krystalbio.com/news-releases/news-release-details/krystal-biotech-announces-final-update-phase-12-clinical-trial.

We anticipate commencing pivotal Phase 3 FDA trials in the first half of 2020.

The FDA and the European Medicines Agency, or EMA, have each granted B-VEC orphan drug designation for the treatment of DEB. In addition, the FDA granted Regenerative Medicine Advanced Therapy, or RMAT to B-VEC. The designation includes all the benefits of the FDA's Fast Track and Breakthrough Therapy designations and enables the ability to work more closely and frequently with the FDA to discuss surrogate or intermediate endpoints to support the potential acceleration of approval and satisfy post-approval requirements. The EMA granted PRIority MEdicines, or PRIME, eligibility for B-VEC to treat DEB. Through PRIME, the EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency. B-VEC is also eligible during the FDA marketing process to apply for a Rare Pediatric Disease Priority Review Voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

Our second pipeline candidate, KB105, is currently in a Phase 1/2 clinical trial for treatment of patients with deficient autosomal recessive congenital ichthyosis, or ARCI, which is associated with transglutaminase 1, or TGM-1. There are currently no treatments for this disease that affects approximately 20,000 patients worldwide. The FDA has granted KB105 orphan drug designation and rare pediatric designation for the treatment of ARCI. KB105 is also eligible during the FDA marketing process to apply for a Rare Pediatric Priority Review Voucher. We anticipate announcing interim clinical results from the on-going trial in 1H 2020.

We have several other product candidates in various stages of preclinical development.

We commenced operations in April 2016. In March 2017, we converted from a California limited liability company to a Delaware C-corporation, and changed our name from Krystal Biotech, LLC to Krystal Biotech, Inc. On June 19, 2018, we incorporated Krystal Australia Pty Ltd, an Australian proprietary limited company, for the purposes of undertaking preclinical and clinical studies in Australia. On April 24, 2019, the Company incorporated Jeune, Inc. in Delaware, a wholly-owned subsidiary, for the purposes of undertaking preclinical studies for aesthetic skin conditions.

On September 22, 2017, the Company completed its initial public offering, or IPO, of 4,554,000 shares of its common stock at a price to the public of $10.00 per share. Proceeds to the Company were $40.7 million, net of underwriting discounts, commissions and offering expenses.

On November 1, 2017, the Company entered into a stock purchase agreement with Epidermolysis Bullosa Medical Research Foundation, a California not-for-profit corporation ("EBMRF"), and EB Research Partnership, Inc., a New York not-for-profit corporation ("EBRP" and together with EBMRF, the "Purchasers"), pursuant to which the Company agreed to issue and sell, and the Purchasers agreed to purchase, an aggregate of 70,000 shares of the Company's common stock, par value $0.00001 per share, for a purchase price of $11.00 per share, resulting in aggregate gross proceeds to the Company of $770 thousand.

On January 16, 2018, the United States Patent and Trademark Office or USPTO granted US patent No. 9,877,990 to the Company which covers compositions comprising herpes simplex viral or HSV vectors and methods of using the same for providing prophylactic, palliative or therapeutic relief of a wound, disorder or disease of the skin in a subject.

On August 16, 2018, the Company entered into a stock purchase agreement with Frazier Life Sciences for the private placement of 625,000 shares of the Company's common stock at $16.00 per share. The private placement yielded gross proceeds of $10 million and closed on August 17, 2018.

On October 23, 2018, the Company completed a public offering of 3,450,000 shares of its common stock at a price to the public of $20.00 per share, which includes the sale of 450,000 shares of the Company's common stock pursuant to the underwriters' full exercise of their option to purchase additional shares. Net proceeds were approximately $64.3 million from the public offering after underwriter discounts, commissions and other offering expenses payable by the Company.

In January 2019, we completed the construction of our own commercial scale current good manufacturing practice or cGMP-compliant manufacturing facility, ANCORIS, to enhance supply chain control, increase supply capacity for clinical trials and ensure commercial demand is met in the event that B-VEC receives marketing approval. We intend to use our cGMP manufacturing process for all clinical and commercial production of B-VEC.

On June 27, 2019, the Company completed a public offering of 2,500,000 shares of its common stock to the public at $40.00 per share. Net proceeds to the Company from the offering were $93.8 million after deducting underwriting discounts and commissions of approximately $6.0 million, and other offering expenses payable by the Company of approximately $220 thousand. On July 3, 2019, the underwriters exercised their option to purchase an additional 353,946 shares of common stock at $40.00 per share for additional net proceeds of $13.3 million after deducting underwriting discounts and commissions of approximately $849 thousand.

On September 27, 2019, the Company announced the granting of a new patent for its lead product candidate, B-VEC, after receiving a Notice of Acceptance from IP Australia for patent application number 2016401692. This represents the company's first foreign patent and a Notice of Acceptance appeared in the Australian Official Journal of Patents on October 3, 2019. This patent covers pharmaceutical compositions comprising B-VEC, as well as to medical uses thereof, *e.g.*, in the treatment of wounds, disorders, or diseases of the skin, particularly those found in epidermolysis bullosa patients. In addition, the United States Patent and Trademark Office (USPTO) announced a new US patent for B-VEC that covers the STAR-D, for skin-targeted therapeutics, as well as methods of its use for delivering any effector of interest to the skin.

On January 21, 2020, the Company announced the appointment of Jennifer Chien to the newly created position of chief commercial officer, effective January 20, 2020. Ms. Chien has more than 20 years of commercial leadership experience in the biopharmaceutical industry, most recently having served as vice president, head of genetic diseases at Sanofi Genzyme.

On January 24, 2020, we announced the ground breaking of the second commercial gene therapy facility in Findlay Township, Pennsylvania. The Findlay-based GMP facility, named ASTRA, will have the capacity to produce commercial gene therapy medicines to treat patients suffering from debilitating rare diseases. The ASTRA facility will initially be used as a commercial back up facility for B-VEC, which is being developed for the treatment of dystrophic epidermolysis bullosa, a rare and devastating skin disorder, and expand to produce investigational and commercial material for our pipeline products. The 100,000 square foot facility will be built-out and validated with an expected completion date by early 2021.

At December 31, 2019, our cash, cash equivalents and short-term investments balance was approximately $193.7 million. Since operations began, we have incurred operating losses. Our net losses were $19.1 million and $10.9 million for the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, we had an accumulated deficit of $39.0 million. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to generate significant revenue to achieve profitability, and we may never generate revenue or enough revenue to achieve profitability.

Costs related to clinical trials can be unpredictable and therefore there can be no guarantee that we will have sufficient capital to fund our continued clinical studies of B-VEC, KB105 and planned preclinical studies for our other product candidates, or our operations. Our funds may not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch B-VEC, KB105 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize this or any other product candidates, we may be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, if at all. Our failure to raise capital when needed could have a negative effect on our financial condition and our ability to pursue our business strategy.

Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- conduct clinical studies for our B-VEC and KB105 product candidates;
- increase research and development-related activities for the discovery and development of our pipeline product candidates;
- continue our research and development efforts internally;
- manufacture clinical study materials and establish the infrastructure necessary to support and develop large-scale manufacturing capabilities;
- seek regulatory approval for our product candidates;
- add personnel to support our product development and commercialization efforts; and
- increase activities leading up to the potential commercial launch of our B-VEC, KB105 and other product candidates.

We do not expect to generate any product revenues until 2022, at the earliest, assuming we receive marketing approval for B-VEC on the schedule we currently contemplate. While we are in the process of building out our internal vector manufacturing capacity, currently all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities. As we seek to obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses as we prepare for product sales, marketing, manufacturing, and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our products.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Revenue

We currently have no approved products for commercial marketing or sale and have not generated any revenue from the sale of products or other sources to date. In the future, we may generate revenue from product sales, royalties on product sales, or license fees, milestones, or other upfront payments if we enter into any collaborations or license agreements. We expect that our future revenue will fluctuate from quarter to quarter for many reasons, including the uncertain timing and amount of any such payments and sales.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred to advance our preclinical candidates, which include:

- expenses incurred under agreements with contract manufacturing organizations, consultants and other vendors that conduct our preclinical activities;
- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies; and
- facility costs, depreciation and other expenses, which include direct expenses for rent and maintenance of facilities and other supplies.

We expense internal research and development costs to operations as incurred. We expense third party costs for research and development activities, such as the manufacturing of preclinical and clinical materials, based on an evaluation of the progress to completion of specific tasks such as manufacturing of drug substance, fill/finish and stability testing, which is provided to us by our vendors.

We expect our research and development expenses will increase as we continue the manufacture of preclinical and clinical materials and manage the clinical trials of, and seek regulatory approval for, our product candidates and expand our product portfolio. In the near term, we expect that our research and development expenses will increase as we begin our planned pivotal Phase 3 clinical trial for B-VEC, conduct our ongoing Phase 1/2 clinical trial for KB105, and incur pre-clinical expenses for our other product candidates. Due to the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration, costs and timing of this clinical trial, and, as a result, the actual costs to complete this planned clinical trial may exceed the expected costs.

General and Administrative Expenses

General and administrative expenses consist principally of professional fees associated with corporate and intellectual property legal expenses, consulting and accounting services and facility-related costs. Other general and administrative costs include stock-based compensation and travel expenses.

We anticipate that our general and administrative expenses will increase in the future to support the continued research and development of our product candidates and to operate as a public company. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of our first product candidate appears likely, we anticipate that we will increase our salary and personnel costs and other expenses as a result of our preparation for commercial operations.

Interest and Other Income (Expense), Net

Interest and other income (expense), net for year ended December 31, 2019 consisted primarily of interest earned on our cash, cash equivalents and short-term investments.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial position and results of operations is based on our financial statements, which have been prepared in accordance with US generally accepted accounting principles, or GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate estimates which include, but are not limited to, estimates related to clinical trial and contract manufacturing prepayments and accruals, stock-based compensation expense, and reported amounts of related expenses during the period. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses, current assets and other current liabilities. This process involves reviewing open contracts and commitments, communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued research and development expenses, current assets and other current liabilities as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses, prepaid assets and other current liabilities include fees paid to contract manufacturers made in connection with the manufacturing of pre-clinical and clinical trials materials.

We base our expenses related to clinical manufacturing on our estimates of the services performed pursuant to contracts with the entities producing clinical materials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under these types of contracts depend heavily upon the successful completion of many separate tasks involved in the manufacturing of drug product. In accruing service fees, we estimate the time period over which services will be performed, and the actual services performed in each period. If our estimates of the status and timing of services performed differs from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amount actually incurred.

Stock-Based Compensation

We have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718, *Compensation—Stock Compensation*, or ASC 718, to account for stock-based compensation for employees and ASC 718 and ASC 505, *Equity*, or ASC 505, for non-employees for 2018. We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant. Stock compensation related to non-employee awards is re-measured in 2018 at each reporting period until the awards are vested. Described below is the methodology we have utilized in measuring stock-based compensation expense.

Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock-based awards as of their measurement date. We recognize stock-based compensation expense over the requisite service period, which is the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are a company with a limited operating history, we utilize data from a representative group of publicly traded companies to estimate expected stock price volatility. We selected representative companies from the biopharmaceutical industry with characteristics similar to us. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment* as we do not have sufficient historical stock option activity data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. For non-employee grants, we use an expected term equal to the remaining contractual term of the award in 2018. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention of paying cash dividends. The risk-free interest rate used for each grant is based on the US Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

Under ASC 718, we elected to estimate the level of forfeitures expected to occur and record stock-based compensation expense only for those awards that we ultimately expect will vest. During the years ended December 31, 2019 and 2018, our estimated annual forfeiture rate was 10% and 0%, respectively.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Results of Operations

Years Ended December 31, 2019, 2018 and 2017

	Years Ended December 31,			Change	
(in thousands)	2019	2018	2017	2019 vs. 2018	2018 vs. 2017
Expenses					
Research and development	$ 15,616	$ 7,761	$ 3,208	$ 7,855	$ 4,553
General and administrative	6,465	4,155	1,564	2,310	2,591
Total operating expenses	22,081	11,916	4,772	10,165	7,144
Loss from operations	(22,081)	(11,916)	(4,772)	(10,165)	(7,144)
Other Expense					
Interest and other income, net	2,993	1,027	(3,148)	1,966	4,175
Total interest and other income, net	2,993	1,027	(3,148)	1,966	4,175
Net loss	$ (19,088)	$ (10,889)	$ (7,920)	$ (8,199)	$ (2,969)

Research and Development Expenses

Research and development expenses increased $7.9 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. Higher research and development expenses were due to increases in professional services related to outsourced manufacturing, in-vivo and clinical studies of $2.3 million, payroll, employee benefits and stock-based compensation of $1.9 million due to an increase in headcount as we scaled up our research and development efforts for our 2 leading product candidates, B-VEC and KB105, lab supplies of $2.2 million, and other research and development expenses of $1.5 million.

Research and development expenses increased $4.6 million for the year ended December 31, 2018 compared to the year ended December 31, 2017. Higher research and development expenses were due largely to increases in professional services related to outsourced manufacturing, in-vivo and clinical studies of $1.9 million, payroll, employee benefits and stock-based compensation of $1.5 million due to an increase in headcount as we scaled up our research and development efforts for our 2 leading product candidates, KB103 and KB105, lab supplies of $860 thousand, and other research and development expenses of $216 thousand.

General and Administrative Expenses

General and administrative expenses increased $2.3 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. Higher general and administrative spending was due largely to increases in legal and professional services of $184 thousand, payroll, employee benefits and stock-based compensation costs of $1.5 million, insurance expenses of $242 thousand, and other administrative costs of $434 thousand.

General and administrative expenses increased $2.6 million for the year ended December 31, 2018 compared to the year ended December 31, 2017. Higher general and administrative spending was due largely to increases in legal and professional services of $420 thousand, payroll, employee benefits and stock-based compensation costs of $1.6 million, insurance expenses of $270 thousand as a result of being a public company for the full year, tax and license expenses of $142 thousand as a result of increased authorized common shares for the full year, and other administrative costs of $196 thousand.

Interest and Other Income (Expense), Net

Interest and other income for the year ended December 31, 2019 was $3.0 million and consisted of interest income earned from our cash, cash equivalents, short-term and long-term investments. Interest and other income, net, for the year ended December 31, 2018 was $1.0 million and consisted of interest income earned from our cash, cash equivalents and short-term investments. This increase was due to our increased cash position in 2019 as compared to 2018.

Interest and other income for the year ended December 31, 2018 was $1.0 million and consisted of interest income earned from our cash, cash equivalents and short-term investments. Interest and other expense, net, for the year ended December 31, 2017 was $3.1 million and consisted primarily of interest expense incurred due to the beneficial conversion feature upon conversion of promissory notes to shares of preferred stock, and to a lesser degree due to interest expense on our convertible promissory notes before their conversion to shares of preferred stock, partially offset by interest earned on our cash and cash equivalents.

Liquidity and Capital Resources

Overview

At December 31, 2019 and 2018, we had accumulated deficits of $39.0 million and $20.0 million, respectively.

We believe that our cash, cash equivalents and short-term investments of approximately 193.7 million as of December 31, 2019 will be sufficient to allow the Company to fund its operations for at least 12 months from the filing date of this Form 10-K. As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and the achievement of a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through the sale of equity and debt financings and may also seek additional capital through arrangements with strategic partners. There can be no assurances that additional funding will be available on terms acceptable to the Company, if at all.

We have funded our operations principally from the sale of common stock in public and private placement offerings as outlined below:

- In June 2019, we received net proceeds of approximately $107.1 million from our public offering after deducting underwriting discounts and commissions and other offering expense payable by the Company.
- In October 2018, we received net proceeds of approximately $64.3 million from our public offering after underwriter discounts, commissions and other offering expenses payable by the Company.
- In August 2018, we closed the sale of common stock in a private placement to Frazier Life Sciences for gross proceeds of $10 million.
- In November 2017, we closed the sale of common stock in a private placement for gross proceeds of $770 thousand.
- On September 22, 2017, we received net proceeds of approximately $40.7 million from our initial public offering
- In August 2017, we closed the sale of preferred stock to a single investor for aggregate proceeds of $7.0 million, and the sale of 130,590 shares of our common stock with a party related to a member of our board of directors for aggregate proceeds of $1.0 million.
- Prior to August 2017, we had received $1.4 million in gross proceeds from the issuance of equity securities and $4.1 million in gross proceeds from debt financings.

Operating Capital Requirements

Our primary uses of capital are, and we expect will continue to be for the near future, compensation and related expenses, manufacturing costs for preclinical and clinical materials, third party clinical trial research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2019 will be sufficient to fund our planned operations and to enable us to complete our planned pivotal Phase 3 clinical trial for B-VEC and our ongoing Phase 1/2 clinical trial for KB105. In order to complete the process of obtaining regulatory approval for any of our product candidates and to build the sales, manufacturing, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, results and costs of our ongoing Phase 1/2 clinical trial for KB105;
- the progress, timing and costs of manufacturing of B-VEC for our planned pivotal Phase 3 clinical trials;
- the continued development and the filing on an Investigational New Drug, or IND, application for future product candidates;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other product candidates that we may pursue in the future, if any;
- the costs of maintaining our own commercial-scale cGMP manufacturing facility;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with the manufacturing process development and evaluation of third-party manufacturers;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, in the event we receive marketing approval for B-VEC, KB105 or any other product candidates we may develop;
- the extent to which the costs of our product candidates, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors;
- the costs of commercialization activities for B-VEC, KB105 and other product candidates if we receive marketing approval for B-VEC, KB105 or any other product candidates we may develop, including the costs and timing of establishing product sales, medical affairs, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, if any, revenue received from commercial sale of B-VEC, KB105 or our other product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;
- our current license agreements remaining in effect and our achievement of milestones under those agreements;
- our ability to establish and maintain collaborations and licenses on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

We expect that we will need to obtain substantial additional funding in order to receive regulatory approval and to commercialize B-VEC or any other product candidates, including KB105. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely affect our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of B-VEC, KB105 or our other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to B-VEC or KB105 or our other product candidates that we otherwise would seek to develop or commercialize ourselves.

Cash Flows

The following table summarizes our sources and uses of cash (in thousands):

	Years Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (18,713)	$ (9,445)
Net cash used in investing activities	(4,968)	(10,323)
Net cash provided by financing activities	107,525	73,847
Net increase in cash	$ 83,844	$ 54,079

Operating Activities

Net cash used in operating activities for the year December 31, 2019 was $18.7 million and consisted primarily of a net loss of $19.1 million adjusted for non-cash items of depreciation of $748 thousand, stock-based compensation expense of $1.2 million, loss on disposals of fixed assets of $67 thousand, amortization of right-of-use asset of $226 thousand, and cash used by net decreases in operating assets and liabilities of $1.9 million.

Net cash used in operating activities for the year ended December 31, 2018 was $9.4 million and consisted primarily of a net loss of $10.9 million adjusted for non-cash items of depreciation and stock-based compensation expense of $933 thousand and a net decrease in operating assets and liabilities of approximately $511 thousand.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2019 was $5.0 million and consisted primarily of purchases of $8.6 million of short-term available-for-sale investment securities, proceeds of $10.5 million from maturities of short-term investments, purchases of $497 thousand of long-term investments, expenditures of $6.4 million for the build-out of our GMP facility and purchases of computer and laboratory equipment.

Net cash used in investing activities for the year ended December 31, 2018 was $10.3 million and consisted primarily of purchases of $8.1 million of short-term available-for-sale investment securities, expenditures of $2.2 million for the build-out of our new GMP facility and purchases of computer and laboratory equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 was $107.5 million and was primarily from net proceeds of $107.1 million after underwriter discounts and other offering expenses payable by the Company from a follow-on public offering of 2,853,946 shares of common stock at a price of $40.00 per share, which includes the sale of 353,946 shares of the Company's common stock pursuant to the underwriters' exercise of their option to purchase additional shares.

Net cash provided by financing activities for the year ended December 31, 2018 was $73.8 million and was primarily form net proceeds of $64.3 million after underwriter discounts, commissions and other offering expenses payable by the Company from a follow-on public offering of 3,450,000 shares of common stock at a price of $20.00 per share, which includes the sale of 450,000 shares of the Company's common stock pursuant to the underwriters' full exercise of their option to purchase additional shares, and an August 2018 private placement of 625,000 shares of the Company's common stock at $16.00 per share resulting in gross proceeds of $10.0 million, partially offset by transactions costs of $450 thousand.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of payment due date by period at December 31, 2019 (in thousands):

	Total	Less than 1 year	Years 1-3	Years 4-5	More Than 5 Years
Future minimum operating lease payments (1)(2)	$ 19,943	$ 3,029	$ 2,743	$ 2,854	$ 11,317
Obligation to contract manufacturing organization	$ 3,264	$ 3,264	$ —	$ —	$ —

(1) We lease approximately 25,000 square feet of office and laboratory space at 2100 Wharton St., Suite 701, Pittsburgh, Pennsylvania. The lease expires February 2027.

(2) On December 26, 2019, we entered into a lease agreement for our second commercial gene therapy facility in the Pittsburgh, Pennsylvania area. The 100,000 square foot facility is under construction and is expected to be completed by early 2021. The lease will commence when the space is available for access, which is anticipated to be in the second half of 2020, and has an initial term that lasts until October 31, 2035. A cash contribution in the amount of $2.4 million was paid to escrow on January 21, 2020. The contribution was intended to reduce the amount of the building construction costs and had the effect of reducing the base rental rate of the lease.

Recent Accounting Pronouncements

In August 2018, the SEC issued a final rule to simplify certain disclosure requirements. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. In August and September 2018, further amendments were issued to provide implementation guidance on adoption of the SEC rule and transition guidance for the new interim stockholders' equity disclosure. The amended guidance is effective for us commencing in the first quarter of 2019. The adoption of this amended guidance resulted in us disclosing the Condensed Consolidated Statements of Stockholders' Equity in the quarterly financial statements for the year ended December 31, 2019 and 2018.

In August 2018, the FASB issued ASU 2018-13 - Fair Value Measurement (Topic 820) ("ASU 2018-13") which removes, modifies and adds disclosure requirements on fair value measurements. ASU 2018-13 removes disclosure requirements for transfers between Level 1 and Level 2 measurements and valuation processes for Level 3 measurements but adds new disclosure requirements including changes in unrealized gains/losses in other comprehensive income related to recurring Level 3 measurements. The amended guidance is effective for us beginning in the first quarter of 2020. Certain aspects may be applied prospectively while other aspects may be applied retrospectively upon the effective date. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07 - Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations. The amended guidance is effective for us beginning in the first quarter of 2019. Early adoption is permitted. The adoption of this amended guidance did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASC 842 - Leases ("ASC 842"), which replaces the existing lease accounting standards. The new standard requires a dual approach for lessee accounting under which a lessee would account for leases as finance (also referred to as capital) leases or operating leases. Both finance leases and operating leases with terms longer than 12 months will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases the lessee would recognize straight-line total lease expense. In July 2018, further amendments were issued to clarify how to apply certain aspects of the amended lease guidance and to address certain implementation issues. ASC 842 was effective for the Company beginning in the first quarter of 2019. The Company generally does not finance purchases of equipment but does lease office and lab facilities. The adoption of this amended guidance resulted in $1.1 million of right-of-use asset and $1.4 million of lease liability being recognized on the consolidated balance sheet as of January 1, 2019.

Item 7A. Qualitative and Quantitative Disclosures About Market Risk

We had cash, cash equivalents and short-term investments of approximately $193.7 million and long-term investment of $497 thousand at December 31, 2019, which consist primarily of money market funds, bank deposits, US Treasury bills and certificates of deposit. The investments in these financial instruments are made in accordance with an investment policy which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and short-term investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash, cash equivalents and short-term investments has significant risk of default or illiquidity. While we believe our cash, cash equivalents and short-term investments do not contain excessive risk, we cannot provide absolute assurance that any investments we make in the future will not be subject to adverse changes in market value. Our cash, cash equivalents and short-term investments are recorded at fair value.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Krystal Biotech, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Krystal Biotech, Inc. (“Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standard

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for lease agreements as a result of the adoption of Accounting Standards Codification Topic 842, Leases, effective January 1, 2019, under the modified retrospective method.

Basis for Opinion

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

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

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

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2017.
San Diego, California
March 10, 2020

Krystal Biotech, Inc.
Consolidated Balance Sheets

(In thousands, except shares and per share data)	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 187,514	$ 103,670
Short-term investments	6,171	8,091
Prepaid and other current assets	2,195	889
Total current assets	195,880	112,650
Property and equipment, net	8,475	3,014
Long-term investments	497	—
Right-of-use asset	2,709	—
Other noncurrent assets	1,462	452
Total assets	$ 209,023	$ 116,116
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 724	$ 888
Accrued expenses and other current liabilities	2,123	1,708
Current portion of lease liabilities	480	—
Total current liabilities	3,327	2,596
Lease liabilities	2,782	—
Other noncurrent liabilities	—	294
Total liabilities	6,109	2,890
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock; $0.00001 par value; 20,000,000 shares authorized at December 31, 2019 and 2018; 2,061,773 shares issued, and no shares outstanding at December 31, 2019 and 2018	—	—
Common stock; $0.00001 par value; 80,000,000 shares authorized at December 31, 2019 and 2018; 17,354,310 and 14,428,916 shares issued and outstanding at December 31, 2019 and 2018, respectively	—	—
Additional paid-in capital	241,951	133,183
Accumulated other comprehensive income	10	2
Accumulated deficit	(39,047)	(19,959)
Total stockholders' equity	202,914	113,226
Total liabilities and stockholders' equity	$ 209,023	$ 116,116

The accompanying notes are an integral part of these consolidated financial statements.

Krystal Biotech, Inc.
Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)	Year Ended December 31, 2019	2018
Expenses		
Research and development	$ 15,616	$ 7,761
General and administrative	6,465	4,155
Total operating expenses	22,081	11,916
Loss from operations	(22,081)	(11,916)
Other Expense		
Interest and other income, net	2,993	1,027
Net loss	(19,088)	(10,889)
Unrealized gain on available-for-sale securities	8	2
Comprehensive loss	$ (19,080)	$ (10,887)
Net loss per common share:		
Basic and diluted	$ (1.20)	$ (0.97)
Weighted-average common shares outstanding:		
Basic and diluted	15,901,083	11,203,081

The accompanying notes are an integral part of these consolidated financial statements.

Krystal Biotech, Inc.
Consolidated Statements of Stockholders' Equity

(In thousands, except shares)	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balances at January 1, 2018	10,307,247	$ —	$ 58,544	$ —	$ (9,070)	$ 49,474
Issuance of common stock	4,121,669	—	73,847	—	—	73,847
Stock-based compensation expense	—	—	792	—	—	792
Unrealized gain on investments	—	—	—	2	—	2
Net loss	—	—	—	—	(10,889)	(10,889)
Balances at December 31, 2018	14,428,916	$ —	$ 133,183	$ 2	$ (19,959)	$ 113,226
Issuance of common stock	2,925,394	—	107,529	—	—	107,529
Stock-based compensation expense	—	—	1,239	—	—	1,239
Unrealized gain on investments	—	—	—	8	—	8
Net loss	—	—	—	—	(19,088)	(19,088)
Balances at December 31, 2019	17,354,310	$ —	241,951	$ 10	$ (39,047)	$ 202,914

The accompanying notes are an integral part of these consolidated financial statements.

Krystal Biotech, Inc.
Consolidated Statements of Cash Flows

(In thousands)	Year Ended December 31, 2019	2018
Operating Activities		
Net loss	$ (19,088)	$ (10,889)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities		
Depreciation	748	141
Stock-based compensation expense	1,239	792
Loss on disposals of fixed assets	67	—
Amortization of right-of-use asset, net	226	—
Increase (Decrease) in		
Prepaids and other current assets	(891)	(321)
Accounts payable	(199)	112
Accrued expenses and other current liabilities	547	644
Other noncurrent liabilities	(1,362)	76
Net cash and cash equivalents used in operating activities	(18,713)	(9,445)
Investing Activities		
Purchases of property and equipment	(6,399)	(2,234)
Purchases of short-term investments	(8,573)	(8,089)
Proceeds from maturities of short-term investments	10,501	—
Purchases of long-term investments	(497)	—
Net cash and cash equivalents used in investing activities	(4,968)	(10,323)
Financing Activities		
Issuance of common stock, net	107,525	73,847
Net cash and cash equivalents provided by financing activities	107,525	73,847
Net increase in cash and cash equivalents	83,844	54,079
Cash and cash equivalents at beginning of year	103,670	49,591
Cash and cash equivalents at end of year	$ 187,514	$ 103,670
Supplemental Disclosures of Non-Cash Investing and Financing Activities		
Unpaid purchases of property and equipment	$ 681	$ 721

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization

Krystal Biotech, Inc. and its consolidated subsidiaries (the "Company," or "we" or other similar pronouns) commenced operations in April 2016. In March 2017, the Company converted from a California limited liability company to a Delaware C-corporation, and changed its name from Krystal Biotech LLC to Krystal Biotech, Inc. On June 19, 2018, the Company incorporated Krystal Australia Pty Ltd., an Australian proprietary limited company, for the purpose of undertaking preclinical and clinical studies in Australia. On April 24, 2019, the Company incorporated Jeune, Inc. in Delaware, a wholly-owned subsidiary, for the purpose of undertaking preclinical studies for aesthetic skin conditions.

We are a clinical-stage gene therapy company dedicated to developing and commercializing novel medicines for patients suffering from skin diseases. We have developed a proprietary gene therapy platform to develop off-the-shelf treatments for skin diseases for which we believe there are no known effective treatments. Our platform consists of a patented engineered viral vector based on the herpes simplex virus type 1 ("HSV-1") containing skin-optimized gene transfer technology, which we refer to as the Skin TARgeted Delivery ("STAR-D") platform. We are initially using our STAR-D platform to develop treatments for rare or orphan monogenic dermatological indications caused by the absence of or a mutation in a single gene. We plan to leverage our platform in the future to expand our pipeline to include non-monogenic dermatological indications and skin conditions.

Liquidity and Risks

As of December 31, 2019, the Company had an accumulated deficit of $39.0 million. With the net proceeds raised upon the close of our initial public offering ("IPO") in September 2017, and as described in Note 7 "Capitalization", a private placement in August 2018, two follow-on public offerings in October 2018 and June 2019, the Company believes that its cash, cash equivalents and short-term investments of approximately $193.7 million as of December 31, 2019 will be sufficient to allow the Company to fund its operations for at least 12 months from the filing date of this Form 10-K. As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and the achievement of a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does the Company will continue to need to raise additional capital or obtain financing from other sources. Management intends to fund future operations through the sale of equity and debt financings and may also seek additional capital through arrangements with strategic partners or other sources. There can be no assurance that additional funding will be available on terms acceptable to the Company, if at all.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to the development of technological innovations by its competitors, risks of failure in clinical studies, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to commercialize product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America or ("GAAP") as found in the Accounting Standards Codification ("ASC"), the Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB") and the rules and regulations of the US Securities and Exchange Commission (the "SEC"). All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process

often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements. Estimates are used in the following areas, among others: stock-based compensation expense, accrued research and development expenses, the fair value of financial instruments, incremental borrowing rate for lease liability, and the valuation allowance included in deferred income taxes calculations.

Segment and Geographical Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company and the Company's chief operating decision maker view the Company's operations and manage its business in one operating segment, which is the business of developing and commercializing pharmaceuticals.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents and investments. The Company's policy is to invest its cash and cash equivalents in money market funds, certificate of deposits and various bank deposit accounts. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing. The Company is exposed to credit risk in the event of default by the financial institutions to the extent of amounts recorded on the balance sheets which may be in excess of insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no financial instruments with off-balance sheet risk of loss.

Cash, Cash Equivalents and Investments

Cash and cash equivalents consist of money market funds and bank deposits. Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase.

Investments with maturities of greater than 90 days but less than one year are classified as short-term investments on the consolidated balance sheets and consist of US Treasury bills and certificates of deposit. Investments with maturities of greater than one year are classified as long-term investments on the consolidated balance sheets and consist of certificates of deposit. Accrued interest on US Treasury bills and certificates of deposit are also classified as short-term investments.

As our entire investment portfolio is considered available for use in current operations, we classify all investments as available-for-sale securities. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive loss, which is a separate component of stockholders' equity in the consolidated balance sheets.

Fair Value of Financial Instruments

Fair value is defined as 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. There is a three-level hierarchy that prioritizes the inputs used in determining fair value by their reliability and preferred use, as follows:

- *Level 1*—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- *Level 2*—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- *Level 3*—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and are unobservable.

To the extent that a valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized within Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

There have been no significant changes to the valuation methods utilized by the Company during the periods presented. There have been no transfers between Level 1, Level 2, and Level 3 in any periods presented.

The carrying amounts of financial instruments consisting of cash and cash equivalents, short-term investments, prepaid expenses, other current assets, accounts payable, accrued expenses and other current liabilities included in the Company's financial statements, are reasonable estimates of fair value, primarily due to their short maturities. Marketable securities are classified as long-term investments if the Company has the ability and intent to hold them and such holding period is longer than one year. The Company classifies all its investments as available-for-sale.

Our available-for-sale short-term and long-term investments, which consist of US Treasury bills and certificates of deposit, are considered to be Level 2. The fair value of Level 2 financial assets is determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis.

Property and Equipment, net

Property and equipment is stated at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred, while costs of major additions and betterments are capitalized. Upon disposal, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

Computer equipment and software	3 years
Lab equipment	3 to 7 years
Furniture and fixtures	3 years
Leasehold improvements	shorter of 8 years and remaining life of lease

Construction-in-progress is not depreciated until the asset is placed in service.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value may not be recoverable. An impairment loss would be recognized when estimated when future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. The Company has not recognized any impairment losses for the years ended December 31, 2019 and 2018.

Leases

We have entered into a lease agreement for our laboratory and office space. As described below under "Recent Accounting Standards," we adopted ASC 842 – Leases as of January 1, 2019. Pursuant to ASC 842, all of our leases outstanding on January 1, 2019 continued to be classified as operating leases. With the adoption of ASC 842, we recorded an operating lease right-of-use asset and an operating lease liability on our balance sheet. Right-of-use lease assets represent our right to use the underlying asset during the lease term and the lease obligation represents our commitment to make lease payments arising from the lease. Right-of-use lease assets and obligations were recognized based on the present value of remaining lease payments over the lease term. As the Company's leases do not provide an implicit rate, we have used an estimated incremental borrowing rate based on the information available at our adoption date in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term. The Company adopted the New Leasing Standards as of the effective date of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Comparative periods in the Company's financial statements will be presented in accordance with the previous guidance under ASC Topic 840, Leases. Upon adoption, the Company took advantage of the transition package of practical expedients permitted within ASC 842, which allowed the Company not to reassess previous accounting conclusions around whether arrangements are, or contain, leases, as well as to carry forward both the historical classification of leases and the treatment of initial direct costs for existing leases. In addition, the Company also has made an accounting policy election to exclude leases with an initial term of twelve months or less from its balance sheet.

Prior to our adoption of ASC 842, when our lease agreements contained tenant improvement allowances and rent escalation clauses, we recorded a deferred rent asset or liability equal to the difference between the rent expense and the future minimum lease payments due. The lease expense related to operating leases was recognized on a straight-line basis in the statements of operations over the term of each lease. In cases where the lessor granted us leasehold improvement allowances that reduced our lease expense, we capitalized the improvements as incurred and recognized deferred rent, which was amortized over the shorter of the lease term or the expected useful life of the improvements.

Research and Development Expenses

Research and development costs are charged to expense as incurred in performing research and development activities. The costs include employee compensation costs, facilities and overhead, preclinical activities and related clinical manufacturing costs, regulatory and other related costs.

The Company estimates contract research and clinical trials materials manufacturing expenses based on the services performed pursuant to contracts with research and manufacturing organizations that manufacture materials used in the Company's ongoing preclinical studies. Nonrefundable advanced payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third party service providers and the Company's estimates of accrued expenses using information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Stock-Based Compensation Expense

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation-Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock, to be recognized in the statements of operations based on their grant-date fair values. Compensation expense related to awards to employees is recognized on a straight-line basis based on the grant-date fair value over the associated service period of the award, which is generally the vesting term. Beginning in the first quarter of 2019, the Company adopted ASU 2018-07 - Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which no longer required non-employee stock options to be periodically revalued. The adoption of this amended guidance did not have a material effect on our consolidated financial statements.

The Company estimates the fair value of its stock options using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including: (i) the expected stock price volatility; (ii) the expected term of the award; (iii) the risk-free interest rate; and (iv) expected dividends. Due to the lack of sufficient history and trading volume of our Common Stock and a lack of Company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Due to the lack of Company-specific historical option activity, the Company has estimated the expected term of its employee stock options using the "simplified" method, whereby the expected term equals the arithmetic mean of the vesting term and the original contractual term of the option. Beginning in the first quarter of 2019, the expected term of non-employee stock options also used the "simplified" method. Prior to the first quarter of 2019, the expected term for non-employee awards was the remaining contractual term of the option. The risk-free interest rates are based on the US Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid and does not expect to pay dividends in the foreseeable future. The Company is also required to estimate forfeitures at the time of grant and to revise those estimates in subsequent periods if actual forfeitures differ from its estimates. Beginning in the first quarter of 2019, the Company used historical data to estimate forfeitures and recorded stock-based compensation expense only for those awards that were expected to vest. Prior to the first quarter of 2019, the forfeiture rate was estimated to be zero. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised.

Prior to the first quarter of 2019, share-based payments issued to non-employees were recorded at their fair values, and were periodically revalued as the equity instruments vested and were recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505, Equity, and were expensed ratably over the vesting term.

Income Taxes

For the year ended December 31, 2019 income taxes are recorded in accordance with FASB ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, we record deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect when the differences are expected to reverse. Valuation allowances are provided when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized. Based on the available evidence, we are unable, at this time, to support the determination that it is more likely than not that our deferred tax assets will be utilized in the future. Accordingly, we recorded a full valuation allowance as of December 31, 2019. We intend to maintain valuation allowances until sufficient evidence exists to support its reversal.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2019, the Company did not have any significant uncertain tax positions.

The Company may recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2019 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations. Company's consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions from non-owner sources. Unrealized gains (losses) on available-for-sale securities is a component of other comprehensive gains (losses) and is presented net of taxes. We have not recorded any reclassifications from other comprehensive gains (losses) to net loss during any period presented.

Recent Accounting Pronouncements

In August 2018, the SEC issued a final rule to simplify certain disclosure requirements. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. In August and September 2018, further amendments were issued to provide implementation guidance on adoption of the SEC rule and transition guidance for the new interim stockholders' equity disclosure. The amended guidance is effective for us commencing in the first quarter of 2019. The adoption of this amended guidance resulted in us disclosing the Condensed Consolidated Statements of Stockholders' Equity in the quarterly financial statements for the year ended December 31, 2019 and 2018.

In August 2018, the FASB issued ASU 2018-13 - Fair Value Measurement (Topic 820) ("ASU 2018-13") which removes, modifies and adds disclosure requirements on fair value measurements. ASU 2018-13 removes disclosure requirements for transfers between Level 1 and Level 2 measurements and valuation processes for Level 3 measurements but adds new disclosure requirements including changes in unrealized gains/losses in other comprehensive income related to recurring Level 3 measurements. The amended guidance is effective for us commencing in the first quarter of 2020. Certain aspects may be applied prospectively while other aspects may be applied retrospectively upon the effective date. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07 - Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations. The amended guidance is effective for us commencing in the first quarter of 2019. The adoption of this amended guidance did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASC 842 - Leases ("ASC 842"), which replaces the existing lease accounting standards. The new standard requires a dual approach for lessee accounting under which a lessee would account for leases as finance (also referred to as capital) leases or operating leases. Both finance leases and operating leases with terms longer than 12 months will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases the lessee would recognize straight-line total lease expense. In July 2018, further amendments were issued to clarify how to apply certain aspects of the amended lease guidance and to address certain implementation issues. ASC 842 was effective for the Company beginning in the first quarter 2019. The Company generally does not finance purchases of equipment but does lease office and lab facilities. The adoption of this amended guidance resulted in a $1.1 million of right-of-use asset and $1.4 million of lease liability being recognized on the consolidated balance sheet as of January 1, 2019.

3. Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of shares of common stock and common share equivalents outstanding for the period. Preferred stock and stock options are common share equivalents. There were 420,766 and 399,515 common stock equivalents outstanding as of December 31, 2019 and 2018, respectively, in the form of stock options and unvested restricted stock awards, that have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect would be anti-dilutive for all periods presented.

(In thousands, except share and per share data)	**Year Ended December 31,**	
	2019	**2018**
Numerator:		
Net loss applicable to common stockholders	$ (19,088)	$ (10,889)
Denominator:		
Weighted-average basic and diluted common shares	15,901,083	11,203,081
Basic and diluted net loss per common share	$ (1.20)	$ (0.97)

4. Fair Value Instruments

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category as of December 31, 2019 and 2018, respectively (in thousands):

	December 31, 2019						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities (1)	Long-term Marketable Securities (2)
Level 1:							
Cash	$ 3	$ —	$ —	$ 3	$ 3	$ —	$ —
Money market instruments	187,511	—	—	187,511	187,511	—	—
Subtotal	187,514	—	—	187,514	187,514	—	—
Level 2:							
U.S. government agency securities	1,747	6	—	1,753	—	1,753	—
Certificates of deposit	4,911	4	—	4,915	—	4,418	497
Subtotal	6,658	10	—	6,668	—	6,171	497
Total	$ 194,172	$ 10	$ —	$ 194,182	$ 187,514	$ 6,171	$ 497

	December 31, 2018						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities (1)	Long-term Marketable Securities (2)
Level 1:							
Cash	$ 1	$ —	$ —	$ 1	$ 1	$ —	$ —
Money market instruments	103,669	—	—	103,669	103,669	—	—
Subtotal	103,670	—	—	103,670	103,670	—	—
Level 2:							
U.S. government agency securities	989	8	—	997	—	997	—
Certificates of deposit	7,100	—	(6)	7,094	—	7,094	—
Subtotal	8,089	8	(6)	8,091	—	8,091	—
Total	$ 111,759	$ 8	$ (6)	$ 111,761	$ 103,670	$ 8,091	$ —

(1) The Company's short-term marketable securities mature in one year or less.
(2) The Company's long-term marketable securities mature between one and two years.

See Note 2 to these consolidated financial statements for additional discussion regarding the Company's fair value measurements.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Construction-in-progress	$ 2,431	$ 2,259
Leasehold improvements	3,179	3
Furniture & fixtures	99	99
Computer equipment and software	45	40
Laboratory equipment	3,571	779
Total property and equipment	9,325	3,180
Accumulated depreciation and amortization	(850)	(166)
Property and equipment, net	$ 8,475	$ 3,014

Depreciation expense was $748 thousand and $141 thousand for the years ended December 31, 2019 and 2018, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Accrued preclinical and clinical expenses	$ 991	$ 537
Accrued professional fees	72	41
Accrued payroll and benefits	510	348
Accrued taxes	40	154
Accrued construction in progress and laboratory equipment	491	589
Other current liabilities	19	39
Total	$ 2,123	$ 1,708

6. Commitments and Contingencies

Significant Contracts and Agreements

Lease Agreement

In May 2016, the Company signed an operating lease for laboratory and office space that commenced in June 2016 and expired on October 31, 2017 (the "2016 Lease"). The 2016 Lease was amended to increase the area leased to approximately 31,000 square feet and to extend the expiration date to February 28, 2027, including 6,000 square feet relating to a month-to-month lease that we expect to utilize through the first quarter of 2020. As mentioned above in "Recent Accounting Pronouncements" in Note 2, the adoption of ASC 842 on January 1, 2019 for the 2016 Lease, as amended, resulted in a $1.1 million of right-of-use asset and $1.4 million of lease liability being recognized on the consolidated balance sheet as of January 1, 2019.

On December 26, 2019, we entered into a lease agreement for our second commercial gene therapy facility in the Pittsburgh, Pennsylvania area. The 100,000 square foot facility is under construction and is expected to be completed by early 2021. The lease will commence when the space is available for access, which is anticipated to be in the second half of 2020, and has an initial term that expires on October 31, 2035. A cash contribution in the amount of $2.4 million was paid to escrow on January 21, 2020. The contribution was intended to reduce the amount of the building construction costs and had the effect of reducing the base rental rate of the lease.

As of December 31, 2019, future minimum commitments under the Company's operating leases were as follows (in thousands):

	Operating Leases
2020	3,029
2021	1,358
2022	1,385
2023	1,413
2024	1,441
Thereafter	11,317
Total minimum lease payments, net	19,943

The Company recorded $669 thousand and $231 thousand in rent expense for the years ended December 31, 2019 and 2018, respectively.

Clinical Supply Agreements

The Company has entered into various product manufacturing and clinical supply agreements with Contract Manufacturing Organizations ("CMOs"). The product manufacturing and clinical supply agreements provide the terms and conditions under which the CMOs will formulate, fill, inspect, package, label and test our product candidates, B-VEC and KB105 for clinic supply. The Company is obligated to make milestone payments. Additionally, certain raw materials, supplies, outsourced testing and other services for the purposes of batch production will be invoiced separately by the CMOs. The estimated remaining commitment as of December 31, 2019 under these agreements for the manufacturing of our drug product is approximately $3.6 million. The Company is also responsible for the payment of a monthly service fee for project management services for the duration of any arrangements. The Company has incurred expenses under these agreements of $4.4 and $3.1 million for the years ended December 31, 2019 and 2018, respectively.

7. Capitalization

Sale of Common Stock

On November 1, 2017, the Company entered into a stock purchase agreement (the "Agreement") with the Epidermolysis Bullosa Medical Research Foundation, a California not-for-profit corporation ("EBMRF"), and EB Research Partnership, Inc., a New York not-for-profit corporation ("EBRP" and together with EBMRF, the "Purchasers"), pursuant to which the Company issued and sold to the Purchasers an aggregate of 70,000 shares of the Company's common stock, par value $0.00001 per share, for a purchase price of $11.00 per share, resulting in aggregate gross proceeds to the Company of $770 thousand (the "Transaction"). The proceeds are to be used exclusively to complete the research plan pursuant to the

Agreement. There are redemption features whereby the Company shall repurchase all or a portion of the shares at a purchase price of $11.00 per share or the closing trading price of the common stock on the redemption request date, whichever is higher, should the Company not commence work on or before September 1, 2018 or cease commercially reasonable efforts. The Company did commence work prior to September 1, 2018. As the Company does not intend to cease commercially reasonable efforts, the remaining redemption feature is within the control of the Company and consequently the issued common stock is classified as permanent equity. The offer, sale and issuance of the shares of the Company under the Agreement are exempt from registration pursuant to Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933, as amended. The Transaction closed on November 2, 2017.

On August 16, 2018, the Company entered into a stock purchase agreement with Frazier Life Sciences for the private placement of 625,000 shares of the Company's common stock at $16.00 per share. The private placement yielded gross proceeds of $10.0 million and closed on August 17, 2018. Pursuant to the terms of the purchase agreement, the Company filed a registration statement with the SEC which became effective on October 12, 2018.

Follow-on Public Offerings

On October 23, 2018, the Company completed it's a public offering of 3,450,000 shares of its common stock at a price to the public of $20.00 per share, which includes the sale of 450,000 shares of the Company's common stock pursuant to the underwriters' full exercise of their option to purchase additional shares. The Chief Executive Officer and Chief Operating Officer each purchased 25,000 shares of the Company's common stock at $20.00 per share as part of the public offering. Net proceeds to the Company from the offering were $64.3 million after deducting underwriting discounts and commissions of approximately $4.2 million, and other offering expenses of approximately $496 thousand payable by the Company.

On June 27, 2019, the Company completed a public offering of 2,500,000 shares of its common stock to the public at $40.00 per share. Net proceeds to the Company from the offering were $93.8 million after deducting underwriting discounts and commissions of approximately $6.0 million, and other offering expenses payable by the Company of approximately $220 thousand. On July 3, 2019, the underwriters exercised their option to purchase an additional 353,946 shares of common stock at $40.00 per share for additional net proceeds of $13.3 million after deducting underwriting discounts and commissions of approximately $849 thousand. In connection with the public offering, the Company suspended its "at-the-market" equity offering program ("ATM Facility") that had previously been put in place in March 2019. This program had allowed the Company to sell shares of its common stock for up to $50.0 million in gross proceeds. Following the completion of the offering, $16.8 million remains suspended under this program .

8. Stock-Based Compensation

Options granted to employees vest ratably over a four-year period and options granted to directors of the company vest ratably over one and four-year periods. Options have a life of ten years. Commencing in the first quarter of 2019, the accounting treatment for stock options granted to non-employees was aligned with the accounting for employee stock options upon the adoption of ASU 2018-07 as described in Note 2 "Summary of Significant Accounting Policies". Prior to the first quarter of 2019, stock options granted to non-employees were accounted for using the fair value method of accounting, and were periodically revalued as the options vest, and recognized as expense over the related service period.

The following table summarizes the Company's stock option activity:

	Stock Options Outstanding	Weighted-average Exercise Price	Weighted-average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands) (1)
Balance at January 1, 2018	185,332	$ 3.91	9.0	$ 1,244
Granted	195,500	13.79		
Exercised	(4,243)	2.46		
Cancelled or forfeited	(19,500)	14.96		
Balance at December 31, 2018	357,089	$ 8.73	8.8	$ 4,302
Granted	159,500	33.04		
Exercised	(72,073)	6.08		
Cancelled or forfeited	(23,750)	20.82		
Balance at December 31, 2019	420,766	$ 17.71	8.4	$ 15,859
Exercisable at December 31, 2019	109,390	$ 7.52	7.6	$ 5,236

(1) Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2019 and the exercise price of outstanding in-the-money options.

Options for 72,073 shares of our common stock with an intrinsic value of $3,777 thousand were exercised during the year ended December 31, 2019.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards and restricted stock awards to employees and non-employees in the consolidated statements of operations for the years ended December 31, 2019 and 2018 as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development	$ 578	$ 327
General and administrative	661	465
Total stock-based compensation	$ 1,239	$ 792

Stock Options Granted to Employees. The Company recorded stock-based compensation expense related to employees' and board members' stock options of $1,195 thousand and $739 thousand for the years ended December 31, 2019 and 2018, respectively. The fair value of options granted to employees was estimated at the date of grant using the Black-Scholes valuation model with the following weighted-average assumptions for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Expected stock price volatility	72%	80%
Expected term of the award (years)	6.10	6.25
Risk-free interest rate	2%	3%
Exercise price	$ 33.36	$ 13.57
Forfeiture Rate	10%	0%
Expected dividend yield	0%	0%

The weighted-average grant-date fair value per share of options granted to employees during the years ended December 31, 2019 and 2018 was $21.72 and $9.74, respectively.

There was $4.1 million of unrecognized stock-based compensation expense related to employees' awards that is expected to be recognized over a weighted-average period of 2.22 years as of December 31, 2019.

Stock Options Granted to Non-Employees. The Company recorded stock-based compensation expense related to non-employees' stock options of $44 thousand and $53 thousand for the years ended December 31, 2019 and 2018, respectively.

There was $33 thousand of unrecognized stock-based compensation expense related to non-employees' awards that is expected to be recognized over a weighted-average period of 0.91 years as of December 31, 2019.

There were no options granted to non-employees in the year ended December 31, 2019 or 2018.

Restricted Stock Awards. The Company granted 26,213 and 16,213 restricted stock awards ("RSA"s) on June 1, 2018 to our Chief Executive Officer and Chief Operating Officer, respectively. The RSAs vest ratably over a one-year period and had completely vested as of May 31, 2019. No RSAs were outstanding as of December 31, 2019. The fair value of each restricted stock was $10.30 reflecting the closing price of our common stock on the grant date. The Company recorded stock-based compensation expense related to RSAs of $182 thousand and $255 thousand for the year ended December 31, 2019 and 2018, respectively, within general and administrative expenses in the accompanying consolidated statements of operations.

Stock options available to grant were 545,824 at December 31, 2019.

9. Income Taxes

From inception through December 31, 2016, the Company was a Limited Liability Company treated as a "pass-through" for federal and state income tax purposes, and therefore, all items of income or loss through December 31, 2016 flowed through to the members of the LLC. Effective January 1, 2017, the Company converted from an LLC to a C-corporation for federal and state income tax purposes. Prior to the conversion to a C-corporation, the Company did not record deferred tax assets or liabilities or have any net operating loss ("NOL") carryforwards for federal income tax purposes. Effective upon the conversion to a C-corporation, the Company became subject to income tax at the federal and state levels.

We did not record a current or deferred income tax expense or benefit for the years ended December 31, 2019 and 2018 due to the Valuation Allowance position. A reconciliation of income tax expense (benefit) computed at the statutory federal and state income tax rate for the year to income tax expense (benefit) as reflected in our financial statements for years ended December 31, 2019 and 2018 are as follows (in thousands):

	December 31, 2019	December 31, 2018
Federal income tax expense (benefit) at statutory rate	$ (4,008)	$ (2,287)
Change in valuation allowance	6,471	2,296
State income tax expense net of federal benefit	(1,522)	(913)
Prior period adjustment	(110)	852
Credits	(604)	(143)
Other non-deductible expenses	(223)	189
Other	(4)	6
Total tax expense (benefit)	$ —	$ —

The significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 are as follows (in thousands):

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Net operating loss carryforwards	$ 9,934	$ 4,262
Stock compensation	140	77
Lease liability	945	—
Accrued expenses	144	123
Credits	820	143
Total deferred tax assets	11,983	4,605
Valuation allowance	(10,931)	(4,460)
Deferred tax assets	1,052	145
Deferred tax liabilities:		
Depreciation	(3)	(42)
Right-of-use asset	(785)	—
Prepaid expenses	(261)	(102)
Unrealized loss on marketable securities	(3)	(1)
Total deferred tax liabilities	(1,052)	(145)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2019.

As of December 31, 2019, the Company had cumulative US federal NOL carryforwards of approximately $34.3 million. Of this amount, $5 million is available to offset future income tax liabilities and will expire in 2037, the remaining $29.3 million is available indefinitely to offset future income tax liabilities with no expiration period.

Under the provisions of the Internal Revenue Code, the NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Internal Revenue Code Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

The Company files income tax returns in the United States at the federal level and in states in which the Company conducts business activities. The federal and state income tax returns are generally subject to tax examinations for the tax year ended December 31, 2017 and 2018. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

10. Related Party Transactions

Our Chief Executive Officer and Chief Operating Officer of the Company each purchased 25,000 shares of common stock at the offering price of $20 per share in connection with our follow-on public offering in October 2018.

In December 2019 the Company advanced $420 thousand to a member of our management team to cover the personal payroll and income taxes on their taxable income from NSO exercises. This employee repaid the Company in the full amount on January 6, 2020.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Accounting Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act as of December 31, 2019. Based on that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Accounting Officer, as appropriate to allow timely discussion regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based on the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and Chief Accounting Officer, do not expect that our disclosure controls and procedures and our internal controls will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. As these inherent limitations are known features of the financial reporting process, it is possible to design into the process safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Accounting Officer have concluded that, as of December 31, 2019, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of the Independent Registered Public Accounting Firm

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

Item 9B. Other Information.

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that applies to our officers, directors and employees which is available on our internet website at www.krystalbio.com. The Code of Conduct contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services.

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List the following documents filed as a part of the report:

(1) Financial statements

The response to this portion of Item 15 is set forth under Item 8 above.

(2) Financial statement schedule.

All schedules have been omitted because they are not required or because the required information is given in the financial statements or notes thereto set forth under Item 8 above.

(3) Exhibits.

A list of exhibits filed with this report or incorporated herein by reference can be found in the Exhibit Index of this Report.

Exhibit Index

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Krystal Biotech, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 25, 2017)
3.2	Amended and Restated Bylaws of Krystal Biotech, Inc. (incorporate by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on September 25, 2017)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)
4.2	Form of Indenture (including form of Debt Securities) (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-3 (Reg. No. 333-227632), as filed with the SEC on October 1, 2018)
4.3*	Description of Common Stock
10.1#	Indemnification Agreement by and between Krystal Biotech, Inc. and each of its directors and officers listed on Schedule A thereto (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)
10.2#	Executive Employment Agreement, effective July 1, 2017, by and between Krystal Biotech, Inc. and Krish S. Krishnan (incorporated by reference to Exhibit 10.2 to the Company's Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 7, 2017)
10.3#	Executive Employment Agreement, effective May 1, 2017, by and between Krystal Biotech, Inc. and Suma M. Krishnan (incorporated by reference to Exhibit 10.3 to the Company's Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 7, 2017)
10.4#	Executive Employment Agreement, effective May 1, 2017, by and between Krystal Biotech, Inc. and Pooja Agarwal (incorporated by reference to Exhibit 10.4 to the Company's Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 7, 2017)
10.5#	Krystal Biotech, LLC 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)
10.6#	Krystal Biotech, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)

Exhibit Number	Description
10.7#	Krystal Biotech, Inc. 2017 IPO Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)
10.8#	Form of Krystal Biotech, Inc. 2017 Stock Incentive Plan Notice of Stock Option Award (incorporated by reference to Exhibit 10.8 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)
10.9#	Form of Krystal Biotech, Inc. 2017 IPO Stock Incentive Plan Notice of Stock Option Award (incorporated by reference to Exhibit 10.9 to the Company's Amendment No. 2 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 14, 2017)
10.10	Lease Agreement, dated as of May 26, 2016, by and between Wharton Lender Associates, L.P. and Krystal Biotech, LLC (incorporated by reference to Exhibit 10.10 to the Company's Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 7, 2017)
10.11	Second Amendment to Lease Agreement, dated as of February 27, 2017, by and between Wharton Lender Associates, L.P. and Krystal Biotech, LLC (incorporated by reference to Exhibit 10.11 to the Company's Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-220085), as filed with the SEC on September 7, 2017)
10.12	Investors' Rights Agreement, dated as of August 7, 2017, by and among Krystal Biotech, Inc. and the investors listed on Schedule A thereto (incorporated by reference to Exhibit 10.9 to Form S-1 (Reg. No. 333-220085), as filed with the SEC on August 21, 2017)
10.13*	Third amendment to Lease Agreement, dated as of May 31, 2018, by and between Wharton Lender Associate, L.P. and Krystal Biotech, Inc.
10.14*	Fourth amendment to Lease Agreement, dated as of October 22, 2018, by and between Wharton Lender Associate, L.P. and Krystal Biotech, Inc.
10.15*	Fifth amendment to Lease Agreement, dated as of December 10, 2018, by and between Wharton Lender Associate, L.P. and Krystal Biotech, Inc.
10.16**	Lease Agreement, dated as of December 26, 2019, by and between Northfield I, LLC and Krystal Biotech, Inc.
21.1*	Subsidiaries of Krystal Biotech, Inc.
23.1*	Consent of Mayer Hoffman McCann P.C.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Certain information in Exhibit 10.16 has been omitted pursuant to Item 601(b)(10) of Regulation S-K because it is both not material and would be competitively harmful if publicly disclosed. The Company undertakes to furnish, supplementally, a copy of the unredacted exhibit to the Securities and Exchange Commission upon request.

# Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary.

The Company has elected to not include a summary.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Pittsburgh, State of Pennsylvania, on March 10, 2020.

KRYSTAL BIOTECH, INC.

By: /s/ Krish S. Krishnan
Krish S. Krishnan
President and Chief Executive Officer

By: /s/ Kathryn A. Romano
Kathryn A. Romano
Chief Accounting Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Krish S. Krishnan and/or Kathryn A. Romano as his or her true and lawful attorney-in-fact and agent, with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Krish S. Krishnan Krish S. Krishnan	President and Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2020
/s/ Kathryn A. Romano Kathryn A. Romano	Chief Accounting Officer (Principal Financial Officer)	March 10, 2020
/s/ Suma M. Krishnan Suma M. Krishnan	Chief Operating Officer and Director	March 10, 2020
/s/ Daniel S. Janney Daniel S. Janney	Director	March 10, 2020
/s/ R. Douglas Norby R. Douglas Norby	Director	March 10, 2020
/s/ Dino A. Rossi Dino A. Rossi	Director	March 10, 2020
/s/ Kirti Ganorkar Kirti Ganorkar	Director	March 10, 2020
/s/ Julian Gangolli Julian Gangolli	Director	March 10, 2020

Exhibit 4.3

DESCRIPTION OF COMMON STOCK

General

Our authorized capital stock consists of 80,000,000 shares of common stock, $0.00001 par value per share, and 20,000,000 shares of preferred stock, $0.00001 par value per share. Our common stock is registered under Section 12(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have no other securities registered under Section 12 of the Exchange Act.

The following description summarizes the most important terms of our common stock. Because it is only a summary, it does not contain all the information that may be important to you. The description is intended as a summary, and is qualified in its entirety by reference to our second amended and restated certificate of incorporation (our "Certificate of Incorporation") and our amended and restated bylaws (our "Bylaws"). For a complete description, you should refer to our Certificate of Incorporation and Bylaws.

Common Stock

Dividend Rights

The holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our Certificate of Incorporation. Accordingly, holders of a majority of the shares of our common stock will be able to elect all of our directors. Our Certificate of Incorporation has established a classified board of directors, divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock at that time, subject to prior satisfaction of all outstanding debt and liabilities.

Anti-Takeover Provisions

The provisions of Delaware law, our Certificate of Incorporation and our Bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), regulating corporate takeovers. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder: (i) shares owned by persons who are directors and also officers; and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 of the DGCL may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws Provisions

Our Certificate of Incorporation and our Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies*. Our Certificate of Incorporation and Bylaws authorizes only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors may only be set by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- *Classified Board*. Our Certificate of Incorporation and Bylaws provide that our board of directors will be classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

  Stockholder Action; Special Meetings of Stockholders. Our Certificate of Incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock may not amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our Certificate of Incorporation and Bylaws provide that

special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, or our Chief Executive Officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our Bylaws provides advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our Bylaws also specifies certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

- *No Cumulative Voting*. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our Certificate of Incorporation does not provide for cumulative voting.

- *Directors Removed Only for Cause*. Our Certificate of Incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.

- *Amendment of Charter Provisions*. Any amendment of the above expected provisions in our Certificate of Incorporation requires approval by holders of at least two-thirds of our outstanding common stock.

- *Issuance of Undesignated Preferred Stock*. Our board of directors has the authority, without further action by the stockholders, to issue up to 20,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock will enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

- *Choice of Forum*. Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our Certificate of Incorporation or our Bylaws; any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is Meidinger Tower, 462 S. 4th Street, Louisville, KY 40202, and its telephone number is 1-502-601-6000. Our shares of common stock were issued in uncertificated form only, subject to limited circumstances.

NASDAQ Capital Market Listing

Our common stock is listed on The NASDAQ Capital Market under the symbol "KRYS."

Exhibit 10.13

THIRD AMENDMENT TO LEASE AGREEMENT

THIS THIRD AMENDMENT TO LEASE AGREEMENT (the "Third Amendment") is made as of the 31st day of May, 2018, by and between Wharton Lender Associates, L.P., ("Landlord"), and Krystal Biotech Inc. ("Tenant").

WITNESSETH:

WHEREAS, by Lease dated May 26, 2016 (the "Original Lease"), as amended by First Amendment to Lease Agreement dated July 26, 2016 and Second Amendment to Lease Agreement dated February 27, 2017 (the "Second Amendment") (the Original Lease as amended, collectively, the "Lease"), Landlord currently leases to Tenant and Tenant currently leases from Landlord certain premises consisting of approximately 5,065 rentable square feet (the "Current Premises") located on the 7th Floor of the building known as 2100 Wharton Street, Pittsburgh, Pennsylvania (the "Building"); and

WHEREAS, Landlord and Tenant now desire to amend the Lease so as to (i) expand the Current Premises by approximately 5,913 rentable square feet of area (the "Expansion Space") thereby increasing Tenant's rentable area in the Building to a total of 10,978 rentable square feet; (ii) extend the term of the Lease; (iii) provide for updates and refurbishment of the Current Premises; and, (iv) modify certain other terms of the Lease, all in accordance with the terms and provisions hereof.

NOW THEREFORE, the parties hereto, in consideration of the mutual premises contained herein, and intending to be legally bound hereby, do covenant and agree as follows:

1. Recitals. The foregoing preamble is incorporated by reference herein as if set forth at length. Capitalized terms not otherwise defined shall have the meaning given to such terms in the Lease. All references herein to the Lease shall include this Third Amendment.

2. Expansion of Current Premises; Expansion Space Commencement Date.

(a) Effective as of the Expansion Space Commencement Date (as defined below), the Premises shall be amended to comprise, in addition to the Current Premises, the Expansion Space, (consisting of approximately 5,913 rentable square feet of area on the 7th Floor of the Building), for a total of 10,978 rentable square feet of area, as outlined on Exhibit "A" attached hereto and made a part hereof. Accordingly, effective as of the Expansion Space Commencement Date (as defined below), the "Premises" shall mean a total of 10,978 rentable square feet of area on the 7th Floor of the Building, as described on Exhibit "A".

(b) Expansion Space Commencement Date. The Term of the Lease for the Expansion Space and Tenant's obligation to pay Fixed Rent and additional rent for the Expansion Space shall commence on the date of November 1, 2018 (the "Expansion Space Commencement Date")

3. Extended Term of Lease for Premises.

The Term of the Lease for the Premises is hereby extended for an additional period of seven (7) years and four (4) months (the "Extended Term"), commencing on the Expansion Space Commencement Date and ending on February 28, 2026 (the "Expiration Date").

4. Tenant's Share; Tenant's Percentage; Base Year.

(a) Commencing as of the Expansion Space Commencement Date, "Tenant's Percentage" as defined in Paragraph 1.L. of the Original Lease and "Tenant's Share", as defined in Paragraph 4.A.(ii) of the Original Lease shall mean "4.85%", and all references in the Lease to "Tenant's Share" and "Tenant's Percentage" shall mean "4.85%".

(b) Commencing as of the Expansion Space Commencement Date, "Base Year" as defined in Paragraph 1.(m) and 4.A.(v) of the Original Lease shall mean calendar year 2018 and all references in the Lease to "Base Year" shall mean calendar year 2018.

5. Fixed Rent Current Premises; Fixed Rent for Premises (being the Expansion Space plus the Current Premises for a total of 10,978 rental square feet).

(a) Fixed Rent for Current Premises. Commencing as of the date hereof and ending on the Expansion Space Commencement Date, Tenant shall continue to pay Landlord Fixed Rent for the Current Premises in accordance with the terms of the Second Amendment.

(b) Fixed Rent for Premises (being the Expansion Space and the Current Premises for a total of 10,978 rentable square feet).

Commencing on the Expansion Space Commencement Date, Tenant shall pay Landlord Fixed Rent for the Premises (being the Expansion Space and the Current Premises for a total of 10,978 rentable square feet) as follows:

LEASE PERIOD	PREMISES	$PER RENTABLE SQ FT	MONTHLY FIXED RENT INSTALLMENT	ANNUAL FIXED RENT AMOUNT
Expansion Space Commencement Date - Month 16	10,978 rsf	22.50	$20,583.75	$247,005.00
Months 17 – 28	10,978 rsf	22.95	$20,995.43	$251,945.10
Months 29 – 40	10,978 rsf	23.41	$21,416.25	$256,994.98
Months 41 – 52	10,978 rsf	23.88	$21,846.22	$262,154.64
Months 53 – 64	10,978 rsf	24.36	$22,285.34	$267,424.08
Months 65 – 76	10,978 rsf	24.85	$22,733.61	$272,803.30
Months 77 – 88	10,978 rsf	25.35	$23,188.28	$278,259.28

Fixed Rent shall be payable in equal monthly installments in advance on the first day of each calendar month during the Term without demand, notice, offset or deduction.

Notwithstanding the above, so long as Tenant is not in default under the terms of this Lease Tenant shall receive an abatement to its Fixed Rent in the total amount of $44,347.52 applied as a monthly credit of $11,086.88 per month for the first four (4) months of the Expansion Space Term of the Lease only Such abatement of Fixed Rent shall not affect Tenant’s obligation to pay additional rent or any other sums payable by Tenant as and when due under the terms of this Lease.

6. Landlord's Expansion Space Work; Substantial Completion

(a) Landlord's Expansion Space Work. Notwithstanding anything to the contrary contained in this Lease, the Expansion Space shall be delivered in its current “as-is” where-is condition except that Landlord, at its sole cost and expense, agrees to do or otherwise perform the work in or relating to the Expansion Space (the “Landlord's Expansion Space Work”) necessary to complete the work described in "Exhibit "B". In no event and under no circumstances will Landlord's Expansion Space Work entail or will Landlord be obliged to perform any work or supply any materials in excess of the work and materials described with particularity in Exhibit "B".

Notwithstanding anything to the contrary contained in the Lease, Tenant specifically agrees that the following items are excluded from Landlord's Expansion Space Work and shall be performed at Tenant's sole cost and expense (i) all of Tenant's Expansion Space Work (as defined below) (ii) all work items that need to be completed in conjunction with Tenant's Expansion Space Work or are contingent upon the completion of Tenant's Expansion Space Work; and (iii) all furniture costs including, but not limited to, moving and installation costs, lab equipment, data service and telecommunication wiring, cabling and systems (collectively, the "Excluded Items").

(b) Landlord's Expansion Space Work shall be deemed to be Substantially Completed when the work shown on Exhibit "B" attached hereto and made a part hereof has been completed except for: (i) any improvements or work to be performed by Tenant; and (ii) such items of finishing and construction of a nature which are not necessary to make the Expansion Space reasonably tenantable for Tenant's use as stated herein; and (iii) all of Tenant's Expansion Space Work and all Excluded Items; and (iv) items not completed because of delay by Tenant in furnishing or receiving any drawings or approvals or within the time set forth in any agreement between Landlord and Tenant; or changes in the work to be performed by Landlord which are requested by Tenant after Landlord's approval of Tenant's plans; or the performance of any work or activity in the Expansion Space by Tenant or any of its employees, agents or contractors .

The following shall be deemed Tenant's Delay: (i) Tenant fails to timely provide the necessary approvals to Landlord; or (ii) Tenant otherwise unreasonably delays the Substantial Completion of Landlord's Work. If a Tenant Delay occurs, Rent shall commence on the date upon which Landlord's Work would have been Substantially Completed had the above-described delays by Tenant not occurred.

(c) Tenant acknowledges that Landlord's Expansion Space Work will not be sufficient to allow the Expansion Space to be used for Tenant's purposes. Landlord and Tenant understand that additional work will be required, and Tenant agrees to perform all such additional work at Tenant's sole cost and expense pursuant to Paragraph 8 below

(d) Landlord's Expansion Space Work shall be completed within thirty (30) days from full execution of this Third Amendment. Tenant shall have access to the Expansion Space upon completion of Landlord's Expansion Space Work.

7. Condition of Premises/Landlord's Current Premises Work. Notwithstanding anything contained in the Lease to the contrary, Tenant's continued possession of the Current Premises for the Extended Term shall be in its current "as-is" where is condition with the exception that Landlord agrees to do or otherwise perform at its cost and expense that work in or relating to the Current Premises (the "Landlord's Current Premises Work") necessary to complete the work described in Exhibit "C". Within ten (10) days from Tenant's execution of this Third Amendment, Tenant shall relocate all of its business operations from the office portion of the Current Premises to the Temporary Space (as defined below). Landlord's Current Premises Work shall be done in a good and workmanlike manner using the materials set forth in Exhibit "C". In no event and under no circumstances will Landlord's Current Premises Work entail or will Landlord be obliged to perform any work or supply any materials in excess of the work and materials described in Exhibit "C". All work in the Premises other than Landlord's Current Premises Work and Landlord's Expansion Space Work shall be performed at Tenant's sole cost and expense.

Notwithstanding anything to the contrary contained herein, Landlord shall use commercially reasonable efforts to Substantially Complete Landlord's Current Premises Work prior to the Expansion Space Commencement Date. In the event that solely and directly due to Landlord's Current Premises Work, changes to the common areas are required and necessary under the applicable laws for ADA compliance, Landlord shall be responsible for such changes. Notwithstanding the foregoing, if Tenant's Expansion Space Work triggers or causes modifications to be performed to the Premises or the common areas to comply with applicable laws and regulations (including fire, ADA compliance, changes to the corridors, etc.), such modifications shall be performed at Tenant's sole cost and expense.

8. Tenant's Expansion Space Work. Except for Landlord's Expansion Space Work as set forth above, Tenant agrees to do or otherwise perform at Tenant's sole cost and expense, all work that is necessary in order for Tenant to open and conduct its business in the Expansion Space ("Tenant's Expansion Space Work").

(a) Tenant’s Plans. Tenant shall provide, at Tenant's sole cost and expense, all of the plans, specifications and drawings necessary to design and construct Tenant’s Expansion Space Work, including all required mechanical, electrical and plumbing drawings, the location and installation of all equipment, risers, disconnects, ducts, utility and HVAC distribution, and other Tenant installations (collectively, the "Tenant's Plans"). Tenant’s Plans shall be prepared by Tenant’s architect at Tenant's sole cost and expense. Within ten (10) business days after Landlord's receipt, Landlord shall in writing approve Tenant’s Plans or deny Tenant's Plans and specify what changes are necessary for such approval. Landlord’s approval or denial shall not be unreasonably withheld or delayed. Landlord’s review of Tenant’s Plans shall not impose any obligation or liability on Landlord, its agents or representatives, and Landlord’s approval of Tenant’s Plans shall not serve as a representation or warranty as to the accuracy of Tenant’s Plans or as to compliance with any laws, codes, regulations or ordinances. Landlord shall approve Tenant's Plans prior to Tenant commencing any of Tenant's Expansion Work.

(b) Tenant’s Expansion Space Work shall be performed, at Tenant’s sole cost and expense, by a bona fide union general contractor and bona fide union subcontractors, architects and engineers selected by Tenant, but subject to Landlord’s approval, which approval shall not be unreasonably withheld or delayed. Landlord shall have the right to bid on Tenant’s Expansion Space Work. Landlord shall have the right to approve all contractors and subcontractors and the performance of Tenant's Expansion Space Work. All contractors and subcontractors performing the Tenant’s Expansion Space Work shall comply in all respects with all applicable laws, codes and regulations and with the terms of this Paragraph 8 and the terms of the Lease, Tenant’s Plans, and with the rules and regulations applicable to the Lease. Landlord reserves the right to specify certain contractors for structural and mechanical alterations (e.g., roof contractor, electricians, plumbers, etc.). Tenant’s Expansion Space Work shall not interfere with or affect the common areas or structural components of the Building or any B mechanical systems, HVAC, electrical, plumbing, gas, elevator or other building mechanical systems serving other tenants and occupants of the Building. Tenant shall perform or cause to be performed Tenant’s Expansion Space Work in a manner which shall not commercially unreasonably interfere with or interrupt the business operations or premises of other tenants in the Building, except as may be approved by Landlord. All of the costs and expense of Tenant's Expansion Space Work and other matters relating to the work and/or installations to be made at the Premises shall be borne by Tenant.

9. Expansion Space Tenant Improvement Allowance.

Landlord shall provide Tenant with a construction improvement allowance up to the total amount of Two Hundred Fifty Thousand and 00/100 Dollars ($250,000.00) (the “Expansion Space Tenant Improvement Allowance”), to be applied solely toward the cost of design, construction and refurbishment of Tenant’s Expansion Space and for no other purpose whatsoever. The Tenant Improvement Allowance shall be paid by Landlord, at Landlord’s option, either (i) directly to Tenant as a reimbursement within thirty (30) days after receipt by Landlord of paid invoices from the contractor or subcontractors performing Tenant’s Expansion Space Work, lien waivers and architect’s certification of completion of work; or (ii) directly to the persons or entities performing Tenant’s Expansion Space Work within thirty (30) days after receipt by Landlord of a written sign- off from Tenant with attached invoices from the contractor or subcontractors performing Tenant’s Expansion Space Work, lien waivers and architect’s certification of completion of work. No credit shall be given to Tenant for any unused allowance.

Tenant shall be solely responsible for all costs and expenses of Tenant’s Expansion Space Work, Tenant’s Plans, fixtures, and for all costs and expenses of Tenant’s furniture, cables, data wiring, telephone, computer equipment and related equipment, telecommunication, data and computer wiring and all associated work and, in the event that Landlord is performing Tenant’s Expansion Space Work, to the extent that the cost of Tenant’s Expansion Space Work is determined by Landlord to be in excess of the Expansion Space Tenant Improvement Allowance, Tenant shall pay to Landlord, within thirty (30) days of receipt of invoice, all sums in excess of the Expansion Space Tenant Improvement Allowance. In the event any such sums are not paid by Tenant to Landlord within such ten (10) day period, Landlord may, in its sole discretion, cause Tenant’s Expansion Space Work to cease until such sums are paid; provided, however, that Tenant’s obligation to pay Rent shall not be affected and shall continue during any such periods of cessation of Tenant’s Expansion Space Work.

10. Leasing of Temporary Space. Notwithstanding anything in Paragraph 2.(a) above to the contrary, in order to accommodate Tenant's requirement for office space prior to the Expansion Space Commencement Date, Tenant shall have the right to lease, temporary office space consisting of approximately 9,000 rentable square feet on the 3rd Floor of the Building described as Suite 310 (the "Temporary Space"). Tenant shall have the right to occupy the Temporary Space for the period commencing on the date of this Third Amendment, provided, however, that Landlord shall have the right to relocate the Temporary Space to another space in the Building upon ten (10) days prior written notice to Tenant. The Tenant's leasing of the Temporary Space shall be under the same terms and conditions of this Lease, except that: (i) Fixed Rent for the Temporary Space shall be abated solely for the first three (3) months only commencing on the date that is earlier to occur of: (a) the date that is ten (10) days from the date of Tenant's execution of this Third Amendment; or (b) the date Tenant commences occupying all or a portion of the Temporary Space (the "Temporary Space Commencement Date"); and (ii) the Temporary Space shall be delivered to Tenant in its current "as-is", "where is" condition. In addition, Tenant shall be responsible, at Tenant's sole cost and expense, for the costs of all utilities and janitorial expenses for the Temporary Space. Notwithstanding the foregoing, in the event that Tenant elects to remain in the Temporary Space beyond the date that is three (3) months from the date of the Temporary Space Commencement Date, Tenant shall pay Landlord Fixed Rent for the Temporary Space in advance on the first day of each calendar month of Tenant's occupancy of the Temporary Space, without demand, notice, offset or deduction in the amount of $9,000.00 per month for each of the months 4, 5 and 6, and $18,000.00 per month for each of the months 7 until the date that Tenant vacates the Temporary Space, provided that in the event that Landlord has not Substantially Completed Landlord's Current Premises Work except due to any Tenant's Delay, Tenant shall continue to pay $9,000.00 per month for each of months 7 until the date that Landlord has Substantially Completed Landlord's Current Premises Work. Unless otherwise agreed by the parties in writing, Tenant shall vacate the Temporary Space no later than fifteen (15) days from the date of Substantial Completion of Landlord's Current Premises Work and Landlord's Expansion Space Work. Upon Tenant's vacation of Temporary Space, Tenant shall deliver such space to Landlord in the same condition in which it was delivered to Tenant except for normal wear and tear. Notwithstanding anything contained in this Lease, Tenant's leasing of the Temporary Space does not affect the Term of the Lease and Tenant shall take possession of the Expansion Space upon the Expansion Space Commencement Date.

11. Assignment and Subletting. Effective as of the Expansion Space Commencement Date, the following words shall be added in the first sentence, on the third line of Section 15.A of the Original Lease after the word "consent" and before the words "(a) assign, which shall not be commercially unreasonably withheld or delayed for office use only".

12. Vehicle Parking. Commencing as of the Expansion Space Commencement Date, Section 5 of the Second Amendment shall be deleted in its entirety, and the same shall be null and void and of no force or effect, and shall be replaced with the following:

> "During the Extended Term, subject to the Parking Rules set forth in Exhibit B to the Original Lease, as modified by Landlord from time to time (the "Rules"), Tenant shall be entitled to use up to seventeen (17) unreserved parking spaces in the parking facility of the Property, subject to availability, at the rate of One Hundred Forty and 00/Dollars ($140.00) per month per parking space. Tenant shall pay Landlord, as additional rent, without demand, notice, offset or deduction, the foregoing rate per parking space per month for each month of the Expansion Space Term hereof for each of the Parking Spaces utilized by Tenant. Notwithstanding the foregoing, so long as Tenant is not in default under the terms of the Lease, seven (7) of the foregoing unreserved parking spaces shall be provided at no charge."

13. Broker. Tenant represents to Landlord, that Tenant has not dealt with any real estate broker, salesperson, or finder in connection with this Third Amendment except for Hanna Langholz Wilson Ellis and CBRE, Inc., ("Broker") 600 Grant Street, Suite 4800, Pittsburgh, PA 15219. Unless otherwise agreed by the parties, Landlord shall be responsible for the payment of commission to the Broker based upon Landlord's separate agreement with such Broker. Landlord and Tenant hereby agree to indemnify and hold harmless the other party and their respective agents and employees, from and against any and all liabilities and claims for commissions and fees arising out of a breach of the foregoing representation.

14. Full Force and Effect. Except as specifically set forth herein, the terms, covenants and conditions of the Lease shall remain in full force and effect. The Lease and this Third Amendment shall not be further modified or amended, except in writing signed by both Landlord and Tenant. This Third Amendment sets forth the entire understanding of the parties with respect to the matters set forth herein and there are no other rights, including but not limited to, any renewals, extensions, expansions, purchases, rights of first refusal, allowances, etc., granted under the Lease or this Third Amendment. Landlord and Tenant hereby ratify and affirm all of the remaining terms and conditions of the Lease. Landlord and Tenant hereby acknowledges that, as of the date of this Third Amendment, neither party is not in default of any of the terms and conditions of the Lease.

15. Provisions Binding. All rights and liabilities herein given to or imposed upon the parties to this Third Amendment shall extend to, and be binding upon and inure to the benefit of, the parties hereto and their respective heirs, successors and assigns.

16. Confidentiality. Tenant and Tenant's representative agree that it shall maintain in confidence and shall not divulge to any third party (except as may be required by law) any of the items, covenants and conditions of the Lease and this Third Amendment, including without limitation, any information related to the rental rate, the length of the Term, and any other terms and conditions thereof. Tenant further agrees to take commercially reasonable precautions to prevent the unauthorized disclosure of any such information to any third parties. Tenant's obligations under this Section 15 shall survive the termination of the Lease.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment to Lease Agreement on the day and year first above written.

LANDLORD:
WHARTON LENDER ASSOCIATES, LP,
a Pennsylvania Limited Partnership By:
WHARTON LENDER PROPERTIES,
LLC, a Pennsylvania Limited Liability
Company, its General Partner

By:	/s/ Larry walsh
Name:	**Larry Walsh**
Title:	**Chief Operating Officer**

TENANT:
KRYSTAL BIOTECH INC., a Delaware
Company

By:	/s/ Tony Riley
Name:	Tony Riley
Title:	Chief Financial Officer

EXHIBIT A

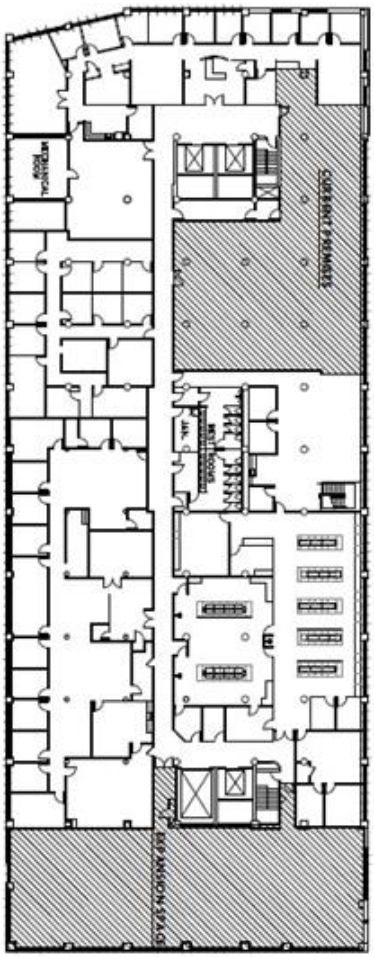
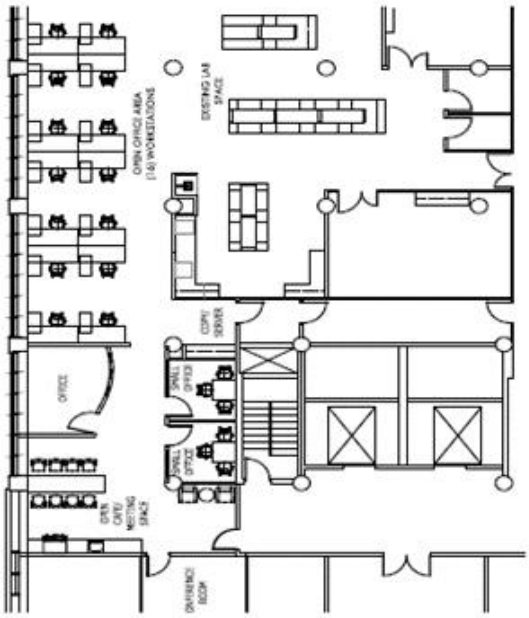


EXHIBIT B
LANDLORD'S EXPANSION SPACE WORK

Landlord will deliver the Expansion Premises in shell condition with the following work Complete:

- The ceiling, lighting, flooring, base and any interior wall will be removed.
- All electrical will be removed back to the junction box.
- VAV boxes, sprinkler lines will remain.

Exhibit C
Landlord’s Existing Space Work



Entrance Doors:
Existing entry doors shall remain.

Demising Partitions:
Drywall construction consisting of 3-5/8" steel studs 24" off center with one layer 5/8" gypsum wall board on each side of steel stud. Partitions shall extend to underside of structure and shall include sound attenuating batt insulation.

Interior Partitions:
Drywall construction consisting of 3-5/8" steel studs at 24" on-center with one layer 5/8" wall board on each side extending 6 inches through the acoustical ceiling grid to separate room from open ceiling area. Partitions shall include sound attenuating batt insulation.

Interior Doors & Glass Sidelites/ Glass Partitions:
New 7’ solid core wood veneer stained doors (stain color T.B.D.) with hollow metal door jambs shall be installed for Conference Room, Two Small Offices and single Office.
Provide tempered glass partition Two Small Offices and single Office. Glass partitions shall have 1” top and bottom channel with clear glass caulked into opening and between glass panes. Office doors and Conference Rooms shall receive tempered glass lite. All doors shall have building standard non-locking stainless steel lever pulls, except for wood entrance doors and Storage Rooms. Notwithstanding the forgoing, Tenant shall indicate which, if any, doors need locking mechanisms.

Ceilings:
Existing ceilings shall be removed in Open Café, Open Office, Office and Small Offices. No new acoustical ceilings will be installed. Structural deck shall be exposed along with ductwork, conduit, wires, cabling, support items, etc.- all will be painted.

Lighting:

Lighting in Office area shall receive Finelite Series 16 LED direct/ indirect linear pendant fixtures. New undercabinet LED strip lighting shall be installed on one wall of casework within Existing Lab. Existing direct/ indirect linear pendant fixtures in the Lab shall be relamped with new brighter LED lamps.

Carpet:
Carpet to be selected by Tenant from Building Standard Carpet Tile selections: Building Standard Carpet Tile Selections:

Style	Style #	Style	Style #
basic tile	5T121	captivate tile	59554
primary tile	5T123	link tile	59105
catalyst tile	59579	linage tile	59106
hybrid tile	59580	undertone tile	5T157
transparent tile	59563	gradient tile	59534
diffuse tile	59575	simplicity tile	59344
disperse tile	59576	rotate tile	5T105
tangle tile	5T018	copy tile	5T103
tempt tile	5T019	construct tile	5T104
shine tile	59328	prisma tile	59463
glimmer tile	59329	connect tile	59342
clear tile	59564	color form tile	5T112
centric tile	5T124	augment tile	5T064
surround tile	5T125	hype tile	5T065
allure tile	59327	peto II 26 tile	59371
glaze tile	59562	repartee tile	59387
reverse tile	5T069	color frame tile	5T081
shape tile	5T070	mirror image tile	59466
direction tile	5T071	focus tile	59455
vast tile	5T009	emotion tile	59343
infinite tile	5T010	balance tile	59340
scape tile	5T080	beam of light tile	59465
realm tile	5T078	applied tile	5T004
momentum iv tile	59502	vibrant tile	5T001
straightforward tile	59224	visible tile	5T002
wander tile	5T039	absorbed tile	5T003
embark tile	5T040	charisma tile	59561
field tile	5T079	fringe tile	5T038
peto II 20 tile	59369	trace tile	5T005
tinge tile	5T156	sculpt tile	5T007
byline tile	59113	mesh tile	5T044
intrigue tile	59558	achromatic tile	5T107

LVT
Luxury Vinyl Tile shall be installed in Lunch Areas and Server Closet and in areas or in rooms (such as a section of the Training Room) as directed by tenant. Tile shall be selected from Building Standard selections: Shaw Native Origins, Emerge, Jeogori and Crete.

Lab Flooring:
Existing flooring to remain in Lab.

Base:
New 4” vinyl base shall be installed in Office Areas in a color T.B.D. to coordinate with flooring and paint finishes.

Paint:
Premises shall receive two (2) coats eggshell finish in colors approved by Tenant. No more than ten (10) colors shall be used within Suite Premises.

Casework:
New plastic laminate custom casework shall installed in Open Cafe. Pulls shall be Berenson 0802-2BPN-P. New plastic laminate coat rod and shelves shall be installed in Coat Rooms.

Switches:
New occupancy sensor switches shall be installed in rooms and overhead occupancy sensors shall be installed in open areas and corridors.

Duplex Outlets/ Floor Outlets:
Provide one (1) floor outlet in each Conference room under conference room table. Install duplex outlets within partitions in all rooms and open areas to work with tenant equipment and furniture layout. Outlets shall be on common shared circuits- except for copiers, microwaves, lab equipment and refrigerators. Furniture feeds shall be installed in office area to feed workstations.

Data/ Telephone Outlets:
Tenant is responsible for phone and data cabling and system. Lessee-installed phone system must use fire rated telephone cable. Cabling will need to be concealed in areas receiving Open Ceilings.

Window Treatment:
All existing blinds shall be removed. New roller shades shall be install throughout.

Plumbing:
Landlord to provide and install new sink (Elkay CR2521) and faucet (American Standard 4275.551.295 with separate sprayer) in Open Cafe. Water lines shall be installed for refrigerators and dishwashers. Appliances shall be purchased by Tenant and delivered to building.

HVAC:
Existing ductwork shall remain and be reworked/ supplied with new as needed to work with new floor plan. Thermostats shall be placed to work with new floor plan and furniture layout.

Fire Protection:
Existing sprinkler system shall remain and be adjusted to work with new floor plan and new exposed ceiling.

Fire Alarm system:
Fire alarm locations shall be adjusted to work with new floor plan. New locations shall be coordinated with new floor plan and furniture layout.

Signage:
Tenant’s name shall be lettered on Building’s First Floor Directory adjacent to elevators and on the 7th Floor directory. Tenant shall be permitted to install signage either on entry doors or adjacent to entry doors. Signage needs to be reviewed and approved by Landlord prior to fabrication and installation.

Notes:

1. A construction supervision fee will apply to all nonstandard work not identified as part of Exhibit C shown above.

2. No credit will be given for items listed in Exhibit C but not used on project.

3. Landlord shall provide Construction Drawings for review, approval and comment within twenty (20) business days of fully executed lease document. Construction Drawings will further detail items covered in Exhibit C of this lease and include Partition Plan, Reflected Ceiling Plan, Power and Communication Plan, Finish Plan and all necessary Interior Elevations and Details. Tenant will review Construction Drawings within five (5) business days. If Tenant does not provide any changes within five (5) business days from the date Landlord has provided these drawings to Tenant, Landlord deems the drawings approved by Tenant. Any and all changes requested by Tenant shall be consistent with this Exhibit C.

4. Equipment, furniture and workstations are shown on this drawing for reference and coordination purposes only. All equipment, furniture and workstations shall be installed at Tenant’s sole cost and expense.

Exhibit 10.14

FOURTH AMENDMENT TO LEASE AGREEMENT

THIS FOURTH AMENDMENT TO LEASE AGREEMENT (the "Fourth Amendment") is made as of the 22nd day of October, 2018, by and between Wharton Lender Associates, L.P., ("Landlord"), and Krystal Biotech Inc., ("Tenant").

WITNESSETH:

WHEREAS, by Lease dated May 26, 2016 (the "Original Lease"), as amended by First Amendment to Lease Agreement dated July 26, 2016, Second Amendment to Lease Agreement dated February 27, 2017 (the "Second Amendment") and Third Amendment to Lease Agreement dated May 31, 2018 (the "Third Amendment") (the Original Lease as amended, collectively, the "Lease"), Landlord currently leases to Tenant and Tenant currently leases from Landlord certain premises consisting of approximately 10,978 rentable square feet (the "Seventh Floor Premises") located on the 7th Floor of the building known as 2100 Wharton Street, Pittsburgh, Pennsylvania (the "Building"); and

WHEREAS, Landlord and Tenant now desire to amend the Lease so as to (i) expand the Seventh Floor Premises by approximately 6,003 rentable square feet of area (the "Sixth Floor Premises") thereby increasing Tenant's rentable area in the Building to a total of 16,981 rentable square feet; and, (ii) modify certain other terms of the Lease, all in accordance with the terms and provisions hereof.

NOW THEREFORE, the parties hereto, in consideration of the mutual premises contained herein, and intending to be legally bound hereby, do covenant and agree as follows:

1. Recitals. The foregoing preamble is incorporated by reference herein as if set forth at length. Capitalized terms not otherwise defined shall have the meaning given to such terms in the Lease. All references herein to the Lease shall include this Fourth Amendment.

2. Expansion of Seventh Floor Premises; Sixth Floor Premises Commencement Date.

(a) Effective as of the Sixth Floor Premises Commencement Date (as defined below), the Premises shall be amended to comprise, in addition to the Seventh Floor Premises, the Sixth Floor Premises, (consisting of approximately 6,003 rentable square feet of area on the 6th Floor of the Building), for a total of 16,981 rentable square feet of area, as outlined on Exhibit "A" attached hereto and made a part hereof. Accordingly, effective as of the Sixth Floor Premises Commencement Date (as defined below), the "Premises" shall mean a total of 16,981 rentable square feet of area consisting of 10,973 rentable square feet on the 7th Floor and 6,003 rentable square feet on the 6th Floor of the Building, as described on Exhibit "A".

(b) Sixth Floor Premises Commencement Date; Expiration Date. The Term of the Lease for the Sixth Floor Premises and Tenant's obligation to pay Fixed Rent and additional rent for the Sixth Floor Premises shall commence on the date that Landlord's delivers possession of the Sixth Floor Premises to the Tenant (the "Sixth Floor Premises Commencement Date"). The expiration date of the Sixth Floor Premises Term shall be February 28, 2026 (the "Expiration Date").

3. Condition of Sixth Floor Premises. Notwithstanding anything contained in the Lease to the contrary: (i) Landlord shall deliver the Sixth Floor Premises to Tenant and Tenant accepts delivery and possession of the Sixth Floor Premises in its current "as- is" where is condition; and (ii) Tenant shall perform, at Tenant's sole cost and expense, all work and modifications to the Sixth Floor Premises that is necessary or desired; and (iii) any and all costs for work required in the Premises shall be at Tenant's sole cost and expense.

4. Tenant's Share; Tenant's Percentage. Commencing as of the Sixth Floor Premises Commencement Date, "Tenant's Percentage" as defined in Paragraph 1.L. of the Original Lease and "Tenant's Share", as defined in Paragraph 4.A.(ii) of the Original Lease shall mean "7.51%", and all references in the Lease to "Tenant's Share" and "Tenant's Percentage" shall mean "7.51%".

5. Fixed Rent for the Sixth Floor Premises. Commencing on the Sixth Floor Premises Commencement Date, Tenant shall pay Landlord Fixed Rent for the Sixth Floor Premises (being 6,003 rentable square feet) as follows:

LEASE PERIOD	PORTION OF PREMISES	$PER RENTABLE SQ FT	MONTHLY FIXED RENT INSTALLMENT	ANNUAL FIXED RENT AMOUNT
Sixth Floor Premises Commencement Date to 2/29/20	6,003 rsf Sixth Floor Premises	22.50	$11,255.63	$135,067.50
3/1/20 – 2/28/21	6,003 rsf Sixth Floor Premises	22.95	$11,480.74	$137,768.85
3/1/21 – 2/28/22	6,003 rsf Sixth Floor Premises	23.41	$11,710.85	$140,530.23
3/1/22 – 2/28/23	6,003 rsf Sixth Floor Premises	23.88	$11,945.97	$143,351.64
3/1/23 – 2/29/24	6,003 rsf Sixth Floor Premises	24.36	$12,186.09	$146,233.08
3/1/24 – 2/28/25	6,003 rsf Sixth Floor Premises	24.85	$12,431.21	$149,174.55
3/1/25 – 2/28/26	6,003 rsf Sixth Floor Premises	25.35	$12,681.34	$152,176.05

Fixed Rent shall be payable in equal monthly installments in advance on the first day of each calendar month during the Term without demand, notice, offset or deduction.

Notwithstanding the above, so long as Tenant is not in material default under the terms of this Lease, Tenant shall receive an abatement to its Fixed Rent in the total amount of $45,022.52 applied as a monthly credit of $11,255.63 per month for the first four (4) months of the Sixth Floor Premises Term of the Lease only. Such abatement of Fixed Rent shall not affect Tenant’s obligation to pay additional rent or any other sums payable by Tenant as and when due under the terms of this Lease.

6. Utilities; Janitorial; Cleaning. Notwithstanding anything to the contrary contained in the Lease, Tenant shall be responsible, at Tenant's sole cost and expense, for providing: (i) cleaning and janitorial services in a first class manner and keeping with the standards of the Building, including but not limited to garbage and rubbish removal on a daily basis and the costs of dumpsters and services thereof, in the entire portion of the Premises that is used or occupied for non-administrative office uses including laboratory functions; and (ii) all extraordinary utilities usage, costs and expenses (e.g., above standard office usage) used in the entire portion of the Premises that is used for non- administrative office uses including laboratory functions.

7. Vehicle Parking. Commencing as of the Sixth Floor Premises Commencement Date, Section 12 of the Third Amendment shall be deleted in its entirety, and the same shall be null and void and of no force or effect, and shall be replaced with the following:

"Commencing as of the Sixth Floor Premises Commencement Date until the Expiration Date, subject to the Parking Rules set forth in Exhibit B to the Original Lease, as modified by Landlord from time to time (the "Rules"), Tenant shall be entitled to use up to twenty-six (26) unreserved parking spaces in the parking facility of the Property, subject to availability, at the rate of One Hundred Forty and 00/Dollars ($140.00) per month per parking space. Tenant shall pay Landlord, as additional rent, without demand, notice, offset or deduction, the foregoing rate per parking space per month for each month of the Expansion Space Term hereof for each of the Parking Spaces utilized by Tenant. Notwithstanding the foregoing, so long as Tenant is not in material default under the terms of the Lease, eleven (11) of the foregoing unreserved parking spaces shall be provided at no charge."

8. Tenant's Generator; Insurance. Within thirty (30) days from the Sixth Floor Commencement Date, Landlord and Tenant agree to execute a mutually satisfactory separate Generator License Agreement for the existing and additional electrical generator to be installed by Tenant in or near the Building. It is understood that there will not be a license fee charged by Landlord for the generators, but that all costs, expenses, and liability with regards to the generators shall be at Tenant's sole cost, expense and liability and Tenant releases, remises, discharges and acquits the Landlord along with their agents, representatives, assigns, predecessors, successors, insurers, sureties and mortgage lenders from any and all claims which the Tenant may have against any of them arising from the generators. In addition, Tenant agrees to indemnify, defend and hold harmless Landlord and their respective representatives from and against all claims, actions, losses, liabilities, costs and expenses of any nature whatsoever (including attorneys' and other legal fees and costs) arising from or relating to the generators. Tenant shall deliver to Landlord a certificate of insurance naming Landlord as additional insured and satisfactory to Landlord covering the generators and Tenant's contractual obligations of indemnification with respect to the generators. The Generator License Agreement will set forth the specific terms and conditions relating to the location, permits, approvals, operation, removal, insurance, and liability associated with the electrical generators.

9. Broker. Tenant represents to Landlord, that Tenant has not dealt with any real estate broker, salesperson, or finder in connection with this Fourth Amendment except for Landlord's Broker, CBRE, Inc., ("Broker") 600 Grant Street, Suite 4800, Pittsburgh, PA 15219. Unless otherwise agreed by the parties, Landlord shall be responsible for the payment of commission to the Broker based upon Landlord's separate agreement with such Broker. Tenant hereby agrees to indemnify and hold harmless the Landlord and its respective agents and employees, from and against any and all liabilities and claims for commissions and fees arising out of a breach of the foregoing representation.

10. Full Force and Effect. Except as specifically set forth herein, the terms, covenants and conditions of the Lease shall remain in full force and effect. The Lease and this Fourth Amendment shall not be further modified or amended, except in writing signed by both Landlord and Tenant. This Fourth Amendment sets forth the entire understanding of the parties with respect to the matters set forth herein and there are no other rights, including but not limited to, any renewals, extensions, expansions, purchases, rights of first refusal, allowances, etc., granted under the Lease or this Fourth Amendment. Landlord and Tenant hereby ratify and affirm all of the remaining terms and conditions of the Lease. Tenant hereby acknowledges that, as of the date of this Fourth Amendment, Landlord is not in default of any of the terms and conditions of the Lease.

11. Provisions Binding. All rights and liabilities herein given to or imposed upon the parties to this Fourth Amendment shall extend to, and be binding upon and inure to the benefit of, the parties hereto and their respective heirs, successors and assigns.

12. Confidentiality. Tenant and Tenant's representative agree that it shall maintain in confidence and shall not divulge to any third party (except as may be required by law) any of the items, covenants and conditions of the Lease and this Fourth Amendment, including without limitation, any information related to the rental rate, the length of the Term, and any other terms and conditions thereof. Tenant further agrees to take commercially reasonable precautions to prevent the unauthorized disclosure of any such information to any third parties. Tenant's obligations under this Section 12. shall survive the termination of the Lease.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Fourth Amendment to Lease Agreement on the day and year first above written.

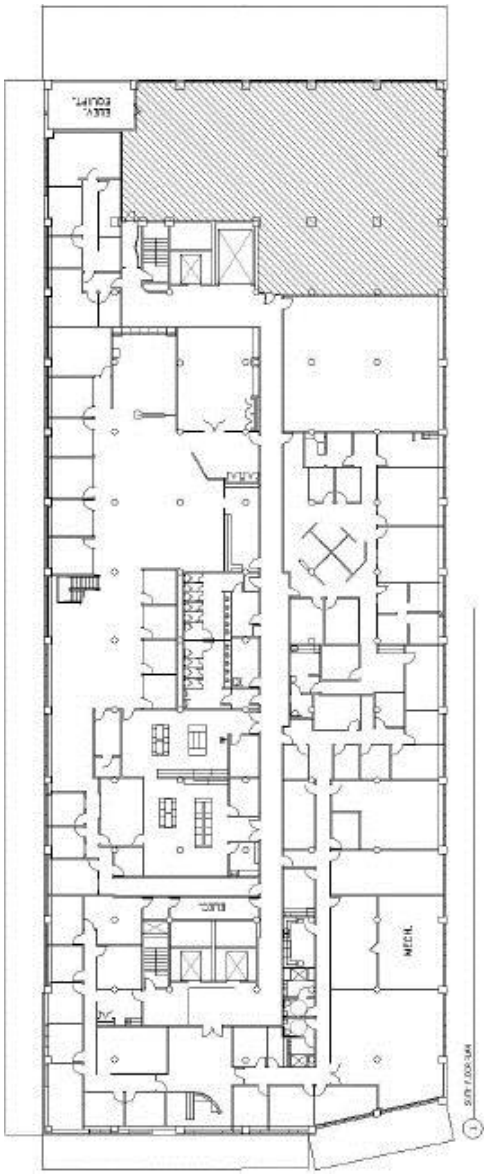
LANDLORD:
WHARTON LENDER ASSOCIATES, LP,
a Pennsylvania Limited Partnership By:
WHARTON LENDER PROPERTIES,
LLC, a Pennsylvania Limited Liability
Company, its General Partner

By: /s/ Larry Walsh
Name: **Larry Walsh**
Title: **COO**

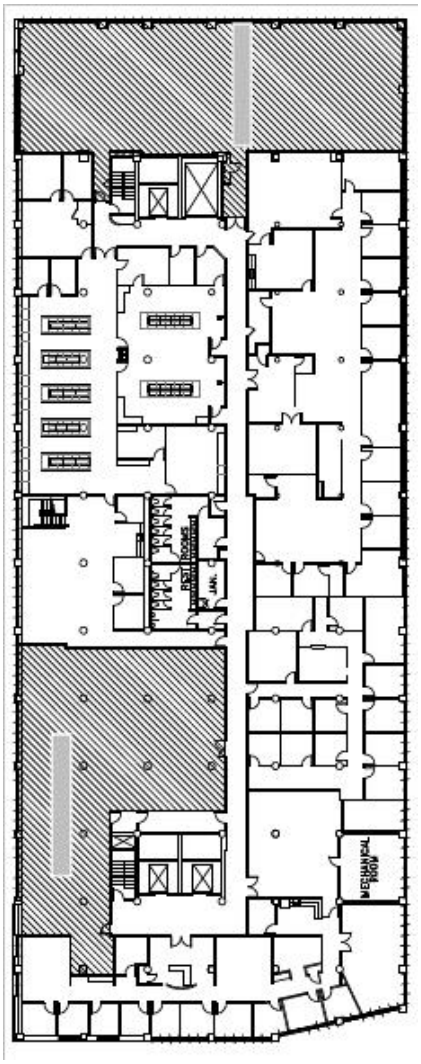
TENANT:
KRYSTAL BIOTECH INC., a Delaware Corporation

By: /s/ Tony Riley
Name: Tony Riley
Title: CFO

EXHIBIT "A"



6th Floor Premises



7th Floor Premises

Exhibit 10.15

FIFTH AMENDMENT TO LEASE AGREEMENT

THIS FIFTH AMENDMENT TO LEASE AGREEMENT (the "Fifth Amendment") is made as of the 10th day of December, 2018, by and between Wharton Lender Associates, L.P., a Pennsylvania limited partnership ("Landlord"), and Krystal Biotech Inc. a Delaware corporation formerly known as Krystal Biotech, LLC, a California limited liability company, ("'Tenant").

WITNESSETH:

WHEREAS, by Lease dated May 26, 2016 (the '•Original Lease"), as amended by First Amendment to Lease Agreement dated July 26, 2016, Second Amendment to Lease Agreement dated February 27, 2017 (the "Second Amendment"), Third Amendment to Lease Agreement dated May 31, 2018 (the "Third Amendment"), and Fourth Amendment to Lease Agreement dated October 22, 2018 (the •'Fourth Amendment'") (the Original Lease as amended, collectively, the "Lease"), Landlord currently leases to Tenant and Tenant currently leases from Landlord certain premises (the "Existing Premises") consisting of a total of 16,981 rentable square feet, being 10,978 rentable square feet (the "Seventh Floor Premises") located on the 7th Floor and 6,003 rentable square feet (the 'Sixth Floor Premises") on the 6th Floor, all in the building known as 2100 Wharton Street, Pittsburgh, Pennsylvania (the "Building"); and

WHEREAS, Landlord and Tenant now desire to amend the Lease so as to (i) lease to Tenant an additional 14,398 rentable square feet of area on the 3rd Floor of the Building (the "Third Floor Premises"). thereby increasing Tenant's rentable area in the Building to a total of 25,376 rentable square feet of office space in the Building (upon Tenant's vacation of the Sixth Floor Premises); (ii) provide for the termination of the leasing and vacation of the Sixth Floor Premises; (iii) extend the Term of the Lease; and (iv) modify certain other terms of the Lease, all in accordance with the terms and provisions hereof.

NOW THEREFORE, the parties hereto, in consideration of the mutual premises contained herein, and intending to be legally bound hereby, do covenant and agree as follows:

1. Recitals. The foregoing preamble is incorporated by reference herein as if set forth at length. Capitalized terms not otherwise defined shall have the meaning given to such terms in the Lease. All references herein to the Lease shall include this Fifth Amendment.

2. Third Floor Premises; Third Floor Premises Commencement Date.

(a) Effective as of the Third Floor Premises Commencement Date (as defined below) and the Sixth Floor Vacate Date (as defined below), the Premises shall be amended to comprise, in addition to the Existing Premises, the Third Floor Premises, consisting of approximately 14,398 rentable square feet of area on the 3rd Floor of the Building), for a total of 25,376 rentable square feet of area, as outlined on Exhibit “A" attached hereto and made a part hereof. Accordingly, effective as of the Third floor Premises Commencement Date (as defined below) and the Sixth Floor Vacate Date, the “Premises" shall mean a total of 25,376 rentable square feet of area consisting of I 0,978 rentable square feet on the 7111 Floor and 14,398 rentable square feet on the yd floor of the Building, as described on Exhibit “A". Tenant shall vacate the 6,003 rentable square feet of the Sixth Floor Premises on the Sixth Floor Vacate Date as per Section 3 below. During the time period between the Third Floor Premises Commencement Date until the Sixth Floor Vacate Date, Premises shall mean a total of 31,379 rentable square feet consisting of 10,978 rentable square feet on the 7th Floor and 14,398 rentable square feet on the 3rd Floor and 6,003 rentable square feet on the Sixth Floor of the Building.

(b) Third Floor Premises Commencement Date; Expiration Date. The Term of the Lease for the Third Floor Premises and Tenant's obligation to pay Fixed Rent and additional rent for the Third Floor Premises shall commence on the date that is one hundred eighty (180) days after Landlord has Substantially Completed Landlord's Base Building Work (as defined below) (the “Third Floor Premises Commencement Date”). Landlord shall provide written notice to Tenant stating the Third Floor Premises Commencement Date.

3. Vacation of the Sixth Floor Premises.

(a) Notwithstanding anything in the contrary contained in the Lease, (Tenant shall vacate the 6,003 rentable square feet of the Sixth Floor Premises on the Third Floor Commencement Date and leave it in the condition required under the Lease (the "Sixth Floor Vacation Date"). Notwithstanding the foregoing sentence, upon prior written notice to Landlord, Tenant may continue to occupy the Sixth Floor Premises on a month-to-month basis after the Third floor Premises Commencement Date occurs, in which case, the Sixth Floor Vacation Date shall be the date that is thirty (30) days after either party gives notice of termination to the other party of the leasing of the Sixth Floor Premises only. As of the Sixth Floor Vacation Date, the Lease shall be terminated solely as to the Sixth Floor Premises, and Landlord shall take possession of the Sixth Floor Premises, and Landlord may subsequently lease or otherwise utilize the Sixth Floor Premises on such terms and conditions as Landlord shall deem proper, in its sole and absolute discretion, without obtaining the consent of Tenant.

(b) Effective as of the Sixth Floor Vacation Date, the "Premises" shall mean a total of 25,376 rentable square feet of area in the Building, being 14,398 rentable square feet on the 3rd Floor of the Building and 10,978 rentable square feet on the 7th Floor of the Building.

4. Extended Term of Lease for Premises.

The Term of the Lease for the Premises (beingl4,398 rentable square feet on the 3rd Floor of the Building and I 0,978 rentable square feet on the 7th Floor of the Building) is hereby extended for an additional period of one (I) year (the "Extended Term"), commencing on March 1, 2026 (the "Extended Term Commencement Date") and ending on February 28, 2027 ("the Expiration Date").

5. Fixed Rent.

(a) Fixed Rent for the Existing Premises. Commencing on the date hereof until the Sixth Floor Vacation Date, Tenant shall continue to pay Fixed Rent for the Existing Premises (being 16,981 rentable square feet consisting of 10,978 rentable square feet on the 7th Floor and 6,003 rentable square feet on the 6th floor) in accordance with the terms of the Original Lease, Third Amendment and Fourth Amendment.

(b) Fixed Rent for the Third Floor Premises. Commencing on the Third Floor Premises Commencement Date, Tenant shall pay Landlord Fixed Rent for the Third Floor Premises (being 14,398 rentable square feet) as follows:

LEASE PERIOD	PORTION OF PREMISES	$PER RENTABLE SQ FT	MONTHLY FIXED RENT INSTALLMENT	ANNUAL FIXED RENT AMOUNT
Third Floor Premises Commencement Date to 2/29/20	14,398 rsf Third Floor Premises	22.50	$26,996.25	$323,955.00
3/1/20 – 2/28/21	14,398 rsf Third Floor Premises	22.95	$27,536.18	$330,434.10
3/1/21 – 2/28/22	14,398 rsf Third Floor Premises	23.41	$28,088.10	$337,057.18
3/1/22 – 2/28/23	14,398 rsf Third Floor Premises	23.88	$28,652.02	$343,824.24
3/1/23 – 2/29/24	14,398 rsf Third Floor Premises	24.36	$29,227.94	$350,735.28
3/1/24 – 2/28/25	14,398 rsf Third Floor Premises	24.85	$29,815.86	$357,790.30
3/1/25 – 2/28/26	14,398 rsf Third Floor Premises	25.35	$30,415.78	$364,989.30

Notwithstanding the above, so long as Tenant is not in material default under the terms of this Lease, Tenant shall receive an abatement to its Fixed Rent in the total amount of $111,510.00 applied as a monthly credit of $9,292.50 per month for the first twelve (12) months of the Third Floor Premises Term of the Lease only. Such abatement of Fixed Rent shall not affect Tenant's obligation to pay additional rent or any other sums payable by Tenant as and when due under the terms of this Lease.

(c) Fixed Rent for the Premises. For the Extended Terms, Tenant shall pay to Landlord fixed Rent for the Premises (being 25,376 rentable square feet consisting of 14,398 rentable square feet on the 3rd Floor and 10,978 rentable square feet on the 7th Floor) at the annual rate(s) as follows:

LEASE PERIOD	PORTION OF PREMISES	$PER RENTABLE SQ FT	MONTHLY FIXED RENT INSTALLMENT	ANNUAL FIXED RENT AMOUNT
3/1/26 – 2/28/27	25,376 rsf Premises	25.86	$54,685.28	$656,223.36

All Fixed Rent shall be payable in equal monthly installments in advance on the first day of each calendar month during the Term without demand, notice, offset or deduction.

6. Tenant's Share: Tenant's Percentage.

(a) Commencing as of the Third Floor Premises Commencement Date, “Tenant's Percentage" as defined in Paragraph l .L. of the Original Lease and "Tenant's Share", as defined in Paragraph 4.A.(ii) of the Original Lease shall mean "9.03%". and all references in the Lease to "Tenant's Share" and "Tenant's Percentage" shall mean “9.03%".

(b) Commencing as of the date of January 1, 2020, “Tenant's Percentage" as defined in Paragraph I .L. of the Original Lease and "Tenant's Share", as defined in Paragraph 4.A.(ii) of the Original Lease shall mean “11.22%", and all references in the Lease to "Tenant's Share" and "Tenant's Percentage" shall mean “11.22%".

7. Condition of the Premises. Notwithstanding anything contained in the Lease to the contrary, except solely for Landlord's Base Building Work (as defined below): (i) Landlord shall deliver the Third Floor Premises to Tenant and Tenant accepts delivery and possession of the Third Floor Premises in its current ••as-is" where is condition; and (ii) Tenant shall perform, at Tenant's sole cost and expense, all work and modifications to the Third Floor Premises that is necessary or desired; and (iii) Tenant's continued possession of the Premises shall be in its current “as-is" where is condition; and (iv) any and all costs for work required in the Premises shall be at Tenant's sole cost and expense.

8. Landlord's Base Building Work.

A. Notwithstanding anything contained in the Lease to the contrary, the Premises shall be delivered in its current “as-is" condition except that Landlord agrees to do or otherwise perform that work in or relating to the Third Floor Premises necessary to complete the work described in Exhibit ”B” attached hereto and made a part hereof (the "Landlord's Base Building Work"). In no event and under no circumstances will Landlord's Work entail or will Landlord be obliged to perform any work or supply any materials in excess of the work and materials described with particularity in Exhibit "B". All work in the Premises other than Landlord’s Work, shall be performed by Tenant at Tenant's sole cost and expense.

Within ten (10) days after the date of the Lease, Tenant will provide Landlord with all specifications and/or approval of Landlord's plans that are required for Landlord to perform Landlord's Base Building Work.

B. The Third Floor Premises shall be deemed to be Substantially Completed when the work shown on Exhibit "B" attached hereto and made a part hereof has been completed except for the Excluded Landlord Work Items (as defined below) and: (i) any improvements or work to be performed by Tenant including Tenant's Work; and (ii) items not completed because of: (a) delay by Tenant in furnishing or receiving any drawings or approvals within the time set forth in any agreement between Landlord and Tenant; or (b) changes in the work to be performed by Landlord which are requested by Tenant after approval of Tenant's plans; or (c) delays, not caused by Landlord, in obtaining materials required for installation or work in the Premises, provided that Tenant shall be notified of Landlord's good faith estimate of the anticipated delay promptly after discovery thereof by Landlord, and shall be given an opportunity to specify alternative materials in requirements; or (d) interference by Tenant or any of its employees, agents or contractors.

Notwithstanding anything to the contrary in the foregoing, Tenant specifically agrees that the following items are deemed to be “Excluded Landlord Work" Items: (i) all work items that need to be completed in conjunction with Tenant's Work, or are contingent upon the completion of Tenant's Work; and (ii) any work related to the replacement of the roof.

Tenant acknowledges and agrees that Landlord's Base Building Work will not be sufficient to allow the Third Floor Premises to be used for Tenant's purposes. Tenant understands that additional work will be required, and Tenant agrees to perform all such additional work at Tenant's sole cost and expense.

9. Tenant’s Work. Tenant agrees to do or otherwise perform at Tenant's sole cost and expense, all work that is necessary in order for Tenant to open and conduct its business in the Third Floor Premises (“Tenant’s Work"').

(a) Tenant’s Plans. Tenant shall provide, at Tenant's sole cost and expense, all of the plans, specifications and drawings necessary to design and construct Tenant's Work, including all required mechanical, electrical and plumbing drawings, the location and installation of all equipment, risers, disconnects, ducts, utility and HVAC distribution, and other Tenant installations (collectively, the "Tenant's Plans"). Notwithstanding the foregoing, Landlord shall provide at Landlord's expense, the test-fit drawings for the non-lab portion of the Third Floor Premises. All such drawings shall be prepared by Landlord's space planner (the “Space Planner") at Landlord's sole cost and expense. Tenant's Plans shall be prepared by Tenant and shall be subject to the prior written approval of Landlord. Landlord’s review of Tenant's Plans shall not impose any obligation or liability on Landlord, its agents or representatives. and Landlord's approval of Tenant's Plans shall not serve as a representation or warranty as to the accuracy of Tenant's Plans or as to compliance with any laws. codes, regulations or ordinances. Landlord shall approve Tenant's Plans prior to Tenant commencing any of Tenant's Work.

(b) Tenant's Work shall be performed. at Tenant's sole cost and expense, by a bona fide union general contractor and bona fide union subcontractors, architects and engineers selected by Tenant. Landlord shall have the right to approve all contractors and subcontractors, and the performance of Tenant's Work, and all such contractors and subcontractors performing such work, shall comply in all respects with all applicable laws, codes and regulations and with the terms of this Paragraph 29 and the terms of Paragraph 12 of the Original Lease, Tenant's Plans. and with the rules and regulations attached to the Lease; provided, however, that Landlord will not unreasonably withhold approval of said contractors and subcontractors if proof of proper licensure and insurance is demonstrated to Landlord. Tenant's Work shall not interfere with or affect the common areas or structural components of the Building or any building or any building mechanical systems, HVAC, electrical, plumbing, gas, plumbing, elevator or other building operating systems serving other tenants and occupants of the Building. Tenant shall perform or cause to be performed Tenant's Work in a manner which shall not interfere with or interrupt the business operations or premises of other tenants in the Building, except as may be approved by Landlord. Tenant shall commence Tenant's Work within ten (10) days following Landlord's written approval of Tenant's Plans therefor. All of the cost and expense of Tenant's Work and other matters relating to work and/or installations to be made at the Premises shall be borne by Tenant.

(c) Notwithstanding anything to the contrary in the forgoing, Landlord shall provide construction administration services for the non-lab portion of Tenant's Work, subject to a separate statement of work, as approved by Landlord and Tenant.

10. Vehicle Parking. Commencing as of the Third Floor Premises Commencement Date, Section 7 of the Fourth Amendment shall be deleted in its entirety, and the same shall be null and void and of no force or effect, and shall be replaced with the following:

"Commencing as of the Sixth Floor Premises Commencement Date until the Expiration Date, subject to the Parking Rules set forth in Exhibit B to the Original Lease, as modified by Landlord from time to time (the "Rules"), Tenant shall be entitled to use up to thirty-seven (37) unreserved parking spaces in the parking facility of the Property, subject to availability, at the rate of One Hundred Forty and 00/Dollars ($140.00) per month per parking space. Tenant shall pay Landlord, as additional rent, without demand, notice, offset or deduction, the foregoing rate per parking space per month for each month of the Expansion Space Terms hereof for each of the Parking Spaces utilized by Tenant. Notwithstanding the foregoing, so long as Tenant is not in material default under the terms of the Lease, sixteen (16) of the foregoing unreserved parking spaces shall be provided at no charge."

11. Tenant’s Generator; Insurance. Within thirty (30) days from the date of this Fifth Amendment, Landlord and Tenant agree to execute a mutually satisfactory separate Generator License Agreement for the existing and additional electrical generator to be installed by Tenant in or near the Building. It is understood that there will not be a license fee charged by Landlord for the generators, but that all costs, expenses, and liability with regards to generators installed by Tenant shall be at Tenant's sole cost, expense and liability and Tenant releases, remises, discharges and acquits the Landlord along with their agents, representatives, assigns, predecessors, successors, insurers, sureties and mortgage lenders from any and all claims which the Tenant may have against any of them arising from generators installed by Tenant. In addition, Tenant agrees to indemnify, defend and hold harmless Landlord and their respective representatives from and against all claims, actions, losses, liabilities, costs and expenses of any nature whatsoever (including attorneys• and other legal fees and costs} arising from or relating to generators installed by Tenant. Tenant shall deliver to Landlord a certificate of insurance naming Landlord as additional insured and satisfactory to Landlord covering generators installed by Tenant and Tenant's contractual obligations of indemnification with respect to the generators. The Generator License Agreement will set forth the specific terms and conditions relating to the location, permits, approvals, operation, removal, insurance, and liability associated with the electrical generators.

12. Broker. Tenant represents to Landlord, that Tenant has not dealt with any real estate broker, salesperson, or finder in connection with this Fifth Amendment except for Landlord's Broker, CBRE, Inc., (“Broker") 600 Grant Street, Suite 4800, Pittsburgh, PA 15219. Unless otherwise agreed by the parties, Landlord shall be responsible for the payment of commission to the Broker based upon Landlord's separate agreement with such Broker. Tenant hereby agrees to indemnify and hold harmless the Landlord and its respective agents and employees, from and against any and all liabilities and claims for commissions and fees arising out of a breach of the foregoing representation.

13. Full Force and Effect. Except as specifically set forth herein, the terms, covenants and conditions of the Lease shall remain in full force and effect. The Lease and this Fifth Amendment shall not be further modified or amended, except in writing signed by both Landlord and Tenant. This Fifth Amendment sets forth the entire understanding of the parties with respect to the matters set forth herein and there are no other rights, including but not limited to, any 'renewals, extensions, expansions, purchases, rights of first refusal, allowances, etc., granted under the Lease or this Fifth Amendment. Landlord and Tenant hereby ratify and affirm all of the remaining terms and conditions of the Lease. Tenant hereby acknowledges that, as of the date of this Fifth Amendment, Landlord is not in default of any of the terms and conditions of the Lease.

14. Provisions Binding. All rights and liabilities herein given to or imposed upon the parties to this Fifth Amendment shall extend to, and be binding upon and inure to the benefit of, the parties hereto and their respective heirs, successors and assigns.

15. Confidentiality. Tenant, Tenant's representative, Landlord, and Landlord's representative agree that it shall maintain in confidence and shall not divulge to any third party {except as may be required by law) any of the items, covenants and conditions of the Lease and this Fifth Amendment, including without limitation, any information related to the rental rate, the length of the Term, and any other terms and conditions thereof. Tenant and Landlord further agree to take commercially reasonable precautions to prevent the unauthorized disclosure of any such information to any third parties. Tenant's and Landlord's obligations under this Section 14. shall survive the termination of the Lease.

(SIGNATURE PAGE FOLLOWS)

IN WITNESS WHEREOF, the parties hereto have executed this Fifth Amendment to Lease Agreement on the day and year first above written.

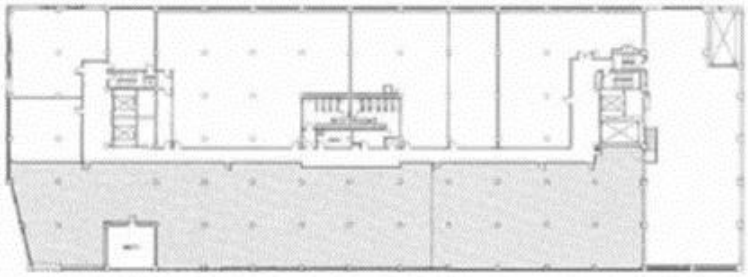
LANDLORD:
WHARTON LENDER ASSOCIATES, LP,
a Pennsylvania Limited Partnership
By: WHARTON LENDER PROPERTIES, LLC, a Pennsylvania Limited Liability Company, its General Partner

By: _____
Name: Larry Walsh
Title: COO

TENANT:
KRYSTAL BIOTECH INC., a Delaware corporation f/k/a KRYSTAL BIOTECH, LLC, a California limited liability company

By: _____
Name: Tony Riley
Title: CFO

EXHIBIT "A"
THIRD FLOOR PREMISES



SEVENTH FLOOR PREMISES

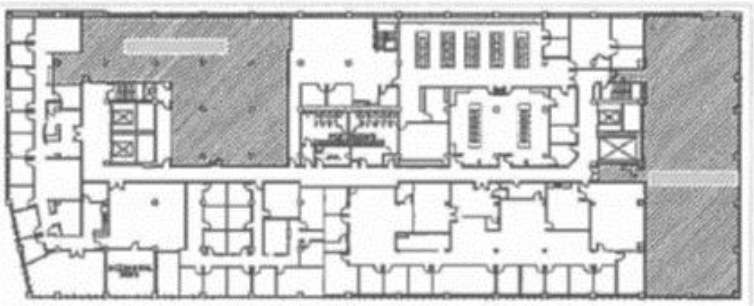


EXHIBIT “B”

LANDLORD'S BASE BUILDING WORK

Landlord will deliver the Third Floor Premises in shell condition with the following work Complete:

•The ceiling. lighting, flooring, base and any interior wall will be removed.

•All electrical will be removed back to the junction box.

•VA V boxes, sprinkler lines will remain.

Certain information indicated with [**] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LEASE DOCUMENTATION

TENANT:	**KRYSTAL BIOTECH, INC.**
ADDRESS:	**2100 Wharton Street, Suite 701** **Pittsburgh, PA 15203**

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LEASE AGREEMENT

THIS LEASE AGREEMENT "***Lease***" is entered into this 26th day of December 2019 ("***Effective Date***"), between NORTHFIELD I, LLC, an Ohio limited liability company ("***Landlord***") and KRYSTAL BIOTECH, INC., a Delaware corporation ("***Tenant***").

1. DEFINITIONS AND CERTAIN BASIC PROVISIONS

1.1.	Landlord:	Northfield I, LLC
1.2.	Landlord's Address:	c/o Al. Neyer, LLC 302 West Third Street, Suite 800 Cincinnati, OH 45202 Attn: Legal Services Email: lkoth@neyer.com
	With copy to:	c/o Al. Neyer, LLC 302 West Third Street, Suite 800 Cincinnati, OH 45202 Attn: Asset Management Email: jcheung@neyer.com
1.3.	Tenant:	Krystal Biotech, Inc.
1.4.	Tenant's Address:	2100 Wharton Street, Suite 701 Pittsburgh, PA 15203 Attn: Tony Riley Email: triley@krystalbio.com and 2100 Wharton Street, Suite 701 Pittsburgh, PA 15203 Attn: Josh Suskin Email: jsuskin@krystalbio.com
	With copy to:	Jonathan P. Altman, Esq. Sherrard, German & Kelly, P.C. 535 Smithfield Street, Suite 300 Pittsburgh, PA 15222 Email: jpa@sgkpc.com

1.5. Premises: The Property (as defined below), together with a building to be constructed thereon containing approximately 100,000 rentable square feet of space (currently expected to be comprised of approximately 86,015 rentable square feet of industrial warehouse, production and distribution space and approximately 13,985 rentable square feet of office space) ("***Building***"), together with all improvements located on the Property (including, without limitation all utility systems located within or otherwise serving the Building and a parking lot containing at least 200 parking spaces located on the Property) and all appurtenances thereto, including but not limited to, rights of ingress, egress and regress to the Premises. The Premises are shown on the site plan attached hereto as Exhibit A. The rentable square footage contained within the Building shall be subject to confirmation after the Lease Commencement Date in accordance with the remeasurement provisions set forth in Section 3.1 below.

1.6. Property: Approximately 10 acres located on International Drive, Findlay Township, Allegheny County, Coraopolis, Pennsylvania, 15108, more fully described in the Legal Description attached hereto as Exhibit A-1.

1.7. Lease Term: The term of this Lease ("***Lease Term***") shall be for a period of Fifteen (15) years plus a part of a month, if any, from the Lease Commencement Date (as defined herein) to the first day of the first full calendar month in the Lease Term.

1.8. Renewal Terms: Tenant shall have three (3) consecutive renewal options (each a "***Renewal Term***"), the first two of which shall be for a period of five (5) years each, and the third of which shall be for a period of up to a maximum of four (4) years and eleven (11) months. Each Renewal Term shall be exercisable upon Tenant providing Landlord with at least nine (9) months prior written notice. The Base Rent for each Renewal Term shall be the Base Rent in the last year of the preceding Lease Term plus the increase in average annual CPI Increases (as defined below) for the prior three (3) years. The annual escalations for each Renewal Term shall be equal to the CPI Increases established in the first year of the then current Renewal Term. The foregoing notwithstanding, in no event shall any Renewal Term Base Rent be less than the Base Rent in the last year of the preceding Lease Term. As used herein, the phrase "***CPI Increases***" means the annual increase in The United States Department of Labor, Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers (CPI-U), Midwest – Size Class B/C (December 1996=100).

1.9. Lease Commencement Date: The Lease Term shall commence upon the date of Substantial Completion ("***Lease Commencement Date***"). "***Substantial Completion***" shall mean the date Landlord delivers the Premises to Tenant with Landlord's Work (as defined herein) substantially completed in accordance with the work letter attached hereto and made a part hereof as Exhibit B ("***Work Letter***"), except for Punch List Items (as defined in the Work Letter) and otherwise (a) in compliance with all applicable federal, state and local laws, statutes, ordinances, codes, orders rules, regulations and other requirements of governmental agencies having authority over the Property (collectively, "***Applicable Law(s)***") and (b) in a condition that is suitable for a certificate of occupancy to be issued, subject only to the completion of Tenant's Work. The Lease Commencement Date will be officially established by execution of a written statement in the form attached hereto as Exhibit C. The "***Estimated Lease Commencement Date***" is November 1, 2020.

Should Landlord fail to (1) deliver the Premises to Tenant with the Initial Delivery Conditions (as defined on Exhibit B-4 attached hereto) satisfied (as applicable, the "***Initial Delivery Date***") by August 24, 2020 (the "***Estimated Initial Delivery Date***") or (2) to achieve Substantial Completion of Landlord's Work by the Estimated Lease Commencement Date, in either case for reasons other than Force Majeure (defined in Section 28 below) or a Tenant Delay (defined below), Tenant shall be entitled to the following abatement rights: (i) one day of Rent for each calendar day of delay up to and including the sixtieth (60th) day of such delay; (ii) two days of Rent for each calendar day of delay, from the sixty-first (61st) day of such delay up to and including the one hundred twentieth (120th) day of such delay; and (iii) three days of Rent for each calendar day of delay from the one hundred twenty-first (121st) day of such delay and beyond, until the Initial Delivery Date or Lease Commencement Date (as applicable) occurs.

"***Tenant Delay***" means any actual delay that Landlord encounters in the performance of the Landlord's Work, to the extent that such delay is caused by any act or omission by Tenant or its employees, agents, licensees, contractors or any other party acting on behalf of Tenant which substantially interferes with the performance of Landlord's Work such that Landlord is delayed in the performance of Landlord's Work as a direct result of such act or omission by Tenant or its employees, agents, licensees, contractors or any other party action on behalf of Tenant. In order for Landlord to claim an event of Tenant Delay, Landlord must provide written notice to Tenant within ten (10) days of the date on which Landlord actually learns of the act or omission and the resulting delay, which notice specifies Landlord's reasonable determination of the cause of the delay and (if known and completed) the duration of the delay. In the event a Tenant Delay causes a delay in the Lease Commencement Date, Tenant shall commence payment of Rent on the date which would be the Lease Commencement Date if not for Tenant Delay.

1.10. Early Access Period: Upon Tenant's request to Landlord and Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed, and provided that Tenant's access to the Premises shall not unreasonably interfere with Landlord's performance of Landlord's Work, Tenant shall have access to the Premises prior to the Lease Commencement Date for the purposes of commencing all work necessary for Tenant to open for business at the Premises (including, without limitation, all of the items enumerated on Exhibit B-3) ("***Tenant's Work***") including, but not limited to, MEP installation, and otherwise to install trade fixtures and personal property at the Premises ("***Early Access Period***"). Tenant shall provide proof of Tenant's Insurance as described in Section 12.3 of this Lease prior to entering the Premises to conduct any of Tenant's Work. No Base Rent or Additional Rent will be payable during the Early Access Period.

1.11. Base Rent: Base Rent shall be defined per the following schedule:

TIME PERIOD (Months)	**ANNUAL BASE RENT**	**MONTHLY BASE RENT**
1 – 12	$ 763,000.00	$ 63,583.33
13 – 24	$ 778,260.00	$ 64,855.00
25 – 36	$ 793,825.20	$ 66,152.10
37 – 48	$ 809,701.70	$ 67,475.14
49 – 60	$ 825,895.74	$ 68,824.64
61 – 72	$ 842,413.65	$ 70,201.14
73 – 84	$ 859,261.93	$ 71,605.16
85 – 96	$ 876,447.16	$ 73,037.26
97 – 108	$ 893,976.11	$ 74,498.01
109 – 120	$ 911,855.63	$ 75,987.97
121 – 132	$ 930,092.74	$ 77,507.73
133 – 144	$ 948,694.60	$ 79,057.88
145 – 156	$ 967,668.49	$ 80,639.04
157 – 168	$ 987,021.86	$ 82,251.82
169 – 180	$ 1,006,762.30	$ 83,896.86

1.12. Base Rent Commencement Date: The Base Rent shall commence on the Lease Commencement Date which is anticipated to be on or before November 1, 2020.

1.13. Additional Rent: Additional Rent for the first year of the Lease Term is estimated to be Two and 24/100 Dollars ($2.24) per rentable square foot per annum, payable in twelve (12) equal monthly installments as set forth in Section 4.2 of this Lease, and shall commence on the Lease Commencement Date.

1.14. Security Deposit: One Million Five Hundred Twenty-Six Thousand Dollars ($1,526,000.00). Provided that no Tenant Default exists under any of the terms of this Lease, the then-remaining Security Deposit shall be released to Tenant as follows:

(a) Within fifteen (15) days after the date upon which (i) the Initial Delivery Date has occurred and (ii) Tenant has caused the portion of the slab required to be installed by Tenant in accordance with item 17 set forth in Exhibit B-3 attached hereto, Landlord's specifications therefor and accepted by Landlord, Landlord shall return Two Hundred Thousand Dollars ($200,000.00) of the Security Deposit to Tenant;

(b) Within fifteen (15) days after the date upon which Tenant has submitted evidence to Landlord of Tenant's achievement for at least twenty-four (24) consecutive months of (i) a Fixed Charge Coverage Ratio (as defined below) of at least 1.50 to 1.00 and (ii) a Debt to EBITDA Ratio (as defined below) of no more than 3.00 to 1.00, Landlord shall return an amount equal to (i) the Security Deposit remaining less (ii) an amount equal to the following six (6) months of Rent; and

(c) Any remaining Security Deposit shall be returned to Tenant upon Tenant's achievement of a long-term credit rating of Baa3 or above from Moody's Investor Service and BBB- from Standard & Poor's Financial Services for a period of twenty-four (24) consecutive months.

As used herein, "***Fixed Charge Coverage Ratio***" means, as of the end of each calendar month, (i) the sum of EBITDA (as defined below) *plus* fixed charges before tax, *divided by* (ii) the sum of fixed charges before tax *plus* interest expense.

As used herein, "***Debt to EBITDA Ratio***" means, as of the end of each calendar month, the ratio of (i) the aggregate amount of Debt *divided by* (ii) EBITDA. As used herein, "***Debt***" means, as of the end of each calendar month, the aggregate outstanding principal amount of all debt owed by Tenant. As used herein, "***EBITDA***" means, as of the end of each calendar month, Tenant's net profit before tax *plus* interest expense (net of capitalized interest expense), depreciation expense and amortization expense.

Each of the Fixed Charge Coverage Ratio and the Debt to EBITDA Ratio tests shall be calculated on a semi-annual basis, on June 30th and December 31st. Tenant shall furnish to Landlord within sixty (60) days of each testing date the calculation for each test, certified in writing by an authorized representative of Tenant as true, complete and correct.

1.15. Permitted Use: Tenant and its affiliates shall be permitted to utilize the Premises for any function related to the production, storage or distribution of pharmaceutical products and products ancillary thereto, and any administrative functions related thereto; *provided* such use conforms to all applicable zoning requirements of the appropriate governmental authority sufficient to entitle Tenant to an occupancy permit from such governmental authority. Any use other than this must be approved in advance in writing by Landlord. Tenant hereby represents and warrants to Landlord that Tenant will ensure compliance with all of the terms of this Lease by any Tenant affiliate utilizing the Premises.

Each of the foregoing definitions and basic provisions shall be construed in conjunction with and limited by the references thereto in the other provisions of this Lease.

2. FUNDAMENTAL EXHIBITS TO LEASE

The following exhibits attached to this Lease are incorporated herein by this reference:

Exhibit A:	Site Plan of Premises
Exhibit A-1:	Property Legal Description
Exhibit B:	Work Letter
Exhibit B-1:	Plans and Specifications for Landlord's Work
Exhibit B-2:	Schedule for Landlord's Work
Exhibit B-3:	Description of Tenant's Work
Exhibit B-4:	Initial Delivery Conditions
Exhibit C:	Lease Commencement Date Memorandum
Exhibit D:	Rules and Regulations
Exhibit E:	Landlord Ground Lease
Exhibit F:	Form of SNDA
Exhibit G:	Form of Landlord Ground Lease NDA
Exhibit H:	Form of Memorandum of Lease

3. GRANT, PREMISES AND TERM

3.1. Grant and Premises

Landlord leases to Tenant and Tenant leases from Landlord upon the terms and conditions set forth herein, the Premises more fully described in Section 1.5 of this Lease. Landlord leases the Property pursuant to a ground lease between Landlord and The Allegheny County Airport Authority ("***Ground Lessor***") of even date herewith, a copy of which is attached hereto as Exhibit E ("***Landlord Ground Lease***"). Tenant agrees that it shall not take any action that would violate or cause a default under the Landlord Ground Lease.

This Lease is subject to, and contingent upon, Landlord's ability to obtain committed financing in the amount of at least $5,929,328 (the "***Financing Amount***") for its completion of the Landlord's Work contemplated herein. If Landlord is unable to obtain committed financing equal to or greater than the Financing Amount from a lender on commercially reasonable terms, Landlord shall have the right to terminate this Lease upon written notice to Tenant, which notice must be given to Tenant no later than January 15, 2020. Landlord shall use its best efforts to satisfy this financing contingency on or before January 15, 2020. Furthermore, if Landlord is unable to obtain final land use approvals from Findlay Township, which are required in order for Landlord to proceed with commencing construction of the Premises as contemplated by this Lease, on or before February 15, 2020, Landlord and/or Tenant shall have the right to terminate this Lease upon written notice to the other party, which notice must be given to the other party no later than February 20, 2020. Landlord shall use its best efforts to satisfy this land use approval contingency on or before February 15, 2020. Notwithstanding anything herein to the contrary, if Landlord or Tenant terminates this Lease in accordance with the terms set forth in this paragraph, (i) Landlord shall, at Tenant's election, provide Tenant with a signed copy of a commercially reasonable assignment of the Landlord Ground Lease, within three (3) days after any written notice of termination is delivered hereunder, (ii) Landlord shall, at Tenant's election and upon receipt of a commercially reasonable release and waiver executed by Tenant therefor, assign (or cause the assignment) to Tenant all plans, drawings and specifications related to Landlord's Work, (iii) Landlord shall immediately return the Security Deposit to Tenant, (iv) Landlord shall cause the Escrow Agent (as defined in the Work Letter) to return Tenant's Cash Contribution to Tenant within ten (10) business days after the date of such termination, and (v) Landlord shall (and shall cause its affiliate, Al. Neyer, LLC to) release Tenant from any and all liabilities and obligations otherwise contemplated by that certain Letter of Indemnification dated October 3, 2019 between Al. Neyer, LLC and Tenant. This paragraph shall survive the termination of the Lease.

After construction of the Building, Landlord will direct a third-party architect, who is not affiliated with Landlord and who shall be jointly selected by Landlord and Tenant, to measure the square footage within Building utilizing the American National Institute Publication ANSI Z65.1-1998, as promulgated by the Building Owners and Managers Association. After such measurement is complete and accepted as accurate by Landlord and Tenant, the parties shall execute the Lease Commencement Date Memorandum in the form of Exhibit C, attached hereto and made a part hereof, confirming the rentable square footage of the Building, and, if the rentable square footage of the Building is less than 100,000, the Base Rent schedule (starting with $7.63 rate per RSF, with 2% annual increases) and the Purchase Price for Tenant's exercise of the Purchase Option shall be adjusted accordingly.

3.2. Park Common Areas

The Premises are leased together with the rights granted to Landlord under the Landlord Ground Lease to use, in common with other tenants in the Northfield Industrial Park ("***Park***"), and their respective agents, invitees and employees all exterior areas and facilities (including, without limitation, sidewalks, driveways and landscaped areas) in the Park which are made available by the owner of the Park to Tenant and other tenants within the Park and/or to the general public, in common ("***Park Common Areas***").

3.3. Roof

Tenant shall have the non-exclusive right to place communications equipment such as an antenna, dish or other device on the roof of the Building on the following terms and conditions: (a) prior to installation, Landlord shall have the right to approve Tenant's plans and proposed location for any such installation in Landlord's reasonable discretion; (b) such installation shall not void any warranty relating to the roof of the Building, or if required by the warranty, Tenant shall use the roof contractor required by the warranty for such installation; and (c) at the end of the Lease Term, Tenant shall remove Tenant's communications equipment and repair any damage to the roof of the Building caused by such removal. Tenant shall have the right to use the roof of the Building, subject to Applicable Laws (if any) and subject to Landlord's prior approval of Tenant's plans for any such use, such approval not to be unreasonably withheld, conditioned or delayed, which approval may include a screening plan to be paid for by Tenant. Landlord shall not grant any other party the right to use the rooftop for telecommunications equipment other than Tenant. Tenant shall be solely responsible for and agrees to promptly make any repairs or replacements to the roof necessitated by any use of the roof by Tenant or any of Tenant's agents, employees, contractors or invitees (collectively, "***Tenant's Agents***") pursuant to this Section 3.3. In no event shall any party other than Tenant be permitted to place signage on the Building's rooftop.

3.4. Term

The Lease Term shall be for the period set forth in Section 1.7 of this Lease and the Lease Term shall begin on the Lease Commencement Date specified in Section 1.9 of this Lease. When the Lease Commencement Date has been established, Landlord and Tenant shall execute, acknowledge and deliver a written statement specifying the dates of commencement and termination of the Lease Term in the form attached hereto as Exhibit C.

4. RENT; ADDITIONAL RENT; OTHER CHARGES

4.1. Rent

The term "***Rent***" shall include Base Rent, Additional Rent and any other amount due from Tenant to Landlord. Tenant shall pay Base Rent to Landlord without notice of demand and (except as otherwise expressly set forth in this Lease) without setoff or deduction for any reason at Landlord's address set forth in Section 1.2 of this Lease or at such other place, or by wire transfer of immediately available funds, as Landlord may, at its discretion, from time to time designate, as rental for the Premises. In addition to the Base Rent, Tenant shall pay as Additional Rent during the Lease Term and any extension or renewal thereof, all Operating Expenses, Taxes and Landlord's Insurance (as those terms are defined below) related to the Premises. In addition, Tenant shall pay any and all sums of money or charges required to be paid by Tenant under the terms of this Lease whether designated Additional Rent or not, and such amounts, if not paid when due, shall be collectible with the next installment of Base Rent thereafter falling due as provided herein and shall be subject to all provisions of this Lease and of Applicable Laws.

Base Rent and Additional Rent shall be payable in advance on the first day of each calendar month during the Lease Term hereof commencing on the Lease Commencement Date. Rent for partial months shall be prorated. The first monthly payment of Base Rent shall include any prorated rental for the period from the Lease Commencement Date to the first day of the first full calendar month in the Lease Term. If Tenant shall fail to timely pay the foregoing Rent to Landlord and such failure continues for more than ten (10) days after Tenant receives written notice thereof from Landlord, Landlord may, in addition to all other rights and remedies which Landlord may have, assess a "late charge" on such past-due amount equal 1.5% of the amount that is past-due for that month; *provided*, *however*, that Landlord shall not be required to give such written notice more than one (1) time per calendar year before assessing any such late charge.

4.2. Additional Rent

Tenant's obligation to pay Additional Rent shall commence on the Lease Commencement Date. Within ninety (90) days after the end of each calendar year, Landlord shall furnish Tenant with a statement of the actual amount of Tenant's Additional Rent reflecting the actually incurred Operating Expenses, Taxes and Landlord's Insurance expenses for such period. If the total amount paid by Tenant under this Section for any calendar year shall be less than the actual amount due for Tenant for such year as shown on such statement, Tenant shall pay to Landlord the difference between the amount paid by Tenant and the actual amount due, such deficiency to be paid within thirty (30) days after the furnishing of each such statement; and if the total amount paid by Tenant hereunder for any such calendar year shall exceed such actual amount due from Tenant for such calendar year, such excess shall be credited against the next installment(s) of Additional Rent.

4.3. Operating Expenses

"***Operating Expenses***" shall mean all expenses, costs and disbursements of every kind and nature which Landlord shall pay or become obligated to pay because of, or in connection with, the ownership, operation, repair and maintenance of the Premises, including but not limited to: the maintenance and repair of the landscaping, parking, sidewalks and roadway facilities and retaining walls located in or on the Property, non-capitalized repairs, line painting, sealing, and removal of snow, ice, trash, rubbish and refuse from parking and roadway areas, parking area and walkway lighting and utilities for the same (if separately metered), repair and replacement of parking area lights (including the repair and replacement of light bulbs and poles) and walkway lights.

Operating Expenses shall include, but not be limited to, all expenses incurred by Landlord in connection with the Landlord Ground Lease, including, but not limited to, the expenses associated with any detention pond utilized by the Premises. Subject in all respects to the Landlord's Construction Warranties (as defined in Section 7 below) and any warranties referred to in the Work Letter, Operating Expenses shall include Building-related maintenance, repair, cleaning, snow and ice removal, planting, replanting, landscaping, painting and power washing of exterior walls, tuck-pointing of exterior walls, glass panel sealing, exterior security lights and utilities for the same (if separately metered), gutters, downspouts, minor roof repair and maintenance and repair of lawn sprinkler systems, water and sewage charges for Building maintenance or operation (if separately metered), worker's compensation insurance, wages, unemployment taxes, social security taxes, employee benefits, personal property taxes, fees for required licenses and permits, supplies, reasonable depreciation of equipment, and a property management fee equal to two percent (2%) of the Base Rent payable by Tenant during any calendar year. Operating Expenses shall further include amortization of the costs of capital expenditures and reasonable financing charges for (a) items that are primarily for the purpose of reducing or avoiding increases in Operating Expenses in Landlord's good faith estimate, (b) replacing, modifying and/or adding improvements or equipment mandated by any Applicable Laws enacted or which take effect after the date of this Lease and any repairs, disposals or removals necessitated thereby (including, but not limited to, the cost of complying with Applicable Laws), or (c) any other cost or expense necessary to carry out Landlord's maintenance, repair, replacement and other obligations under this Lease; *provided*, *however*, that the cost of any such permitted capital expenditure shall be amortized on a straight line basis, at a rate of six percent (6%), over the GAAP useful life thereof, and Landlord shall only pass through the annual amount stemming from such amortization.

Notwithstanding the foregoing, Operating Expenses shall <u>not</u> include any of the following expenses:

(i) costs for which Landlord is entitled to be reimbursed by a third-party (including, without limitation, by Ground Lessor or any insurer, tenant or condemnor) and is actually reimbursed by such third-party;

(ii) costs incurred in connection with the sale, financing or refinancing (or attempted sale, financing or refinancing) of the Property or any other portion of the Park including, without limitation, commissions, marketing costs, interest, principal, points and fees on debts or amortization on any mortgage or mortgages or any other debt instrument encumbering the Property or any other portion of the Park or planned to encumber the Property or any other portion of the Park;

(iii) legal fees, accounting expenses, leasing commissions, allowances, buy-out amounts, tenant improvement costs, advertising expenses, promotional expenses, any management fee in excess of the amount set forth in the first paragraph of this Section 4.3 above, and other costs of a similar nature incurred in the leasing of space at the Property or elsewhere at the Park;

(iv) ground rent or any other payments paid under any present or future ground or underlying lease (including but not limited to the Landlord Ground Lease) and/or grant affecting the Park, Property and/or the Premises (other than payments which, independent of such ground or underlying lease, would constitute an Operating Expense hereunder);

(v) depreciation on any aspect or component of the Premises other than as expressly provided in this Section 4.3;

(vi) legal fees arising out of disputes or negotiations with any tenant, if applicable;

(vii) costs incurred due to a breach of this Lease by Landlord or any violation of any Applicable Laws by Landlord, unless directly related to Tenant's use of the Premises;

(viii) costs arising from the presence of any Hazardous Material or violation of Environmental Laws as of or prior to the Lease Commencement Date or otherwise caused by any party other than Tenant or any of Tenant's Agents;

(ix) costs for any structural or foundation repair or replacement that is not a capital repair or replacement pursuant to the first paragraph of this Section 4.3 above;

(x) costs of roof replacement that is not a capital replacement pursuant to the first paragraph of this Section 4.3 above;

(xi) tap-in fees, impact fees or fees or charges or which Landlord is solely responsible under this Lease;

(xii) costs related to Landlord's Work or the satisfaction of Landlord's Construction Warranties;

(xiii) costs incurred in connection with casualty or condemnation repairs or restorations; and/or

(xiv) should Landlord fail to maintain the insurance coverages required by this Lease, costs that have not been reimbursed to Landlord but would have been reimbursed to Landlord by an insurance provider had Landlord maintained the insurance coverages required by this Lease.

4.4. Taxes

"***Taxes***" shall mean all taxes, fees, service payments and assessments levied upon the Premises and its appurtenances and upon the real property upon which the same are constructed, but shall *not* include: (a) any income, occupational, franchise, estate, inheritance or other taxes which shall not be denoted specifically as real estate taxes; or (b) any taxes applicable to a period of time before or after the Lease Term. If at any time a tax or excise on rents, or other tax, however described, is levied or assessed against Landlord on account of the rent reserved hereunder, the same shall be included within the terms "***Taxes***" for the purposes hereof. Taxes shall also include all reasonable costs and expenses incurred by Landlord in seeking a reduction of any taxes and assessments. Tenant will pay all Taxes incurred by Landlord with respect to the Property. Tenant shall have the right to appeal the assessed value of the Property and/or the Building throughout the Lease Term, at Tenant's sole cost and expense. Tenant may initiate proceedings to contest any Taxes. If notice of any increased assessment relative to the Property or the Building is sent to or received by Landlord, Landlord shall immediately, but no later than thirty (30) days after its receipt, forward the notice to Tenant at both of the addresses set forth in Section 1.4 of this Lease. If required by Applicable Law, Landlord shall join in any such proceedings initiated by Tenant, provided that Tenant shall pay all costs and expenses, charges, interest and penalties in connection therewith, including reasonable costs and expenses incurred by Landlord. Tenant shall continue to reimburse Landlord under this Section for all Taxes which Landlord is or becomes obligated to pay during the pendency of any such proceedings. Upon conclusion of such proceedings, Tenant shall be entitled to a credit for Tenant's share of any Taxes refunded to Landlord as a result of any such proceedings.

4.5. Insurance

"***Landlord's Insurance***" shall mean all premiums for fire and extended coverage, liability and property damage insurance maintained with respect to the Premises by Landlord pursuant to Section 12.2 below. Notwithstanding the foregoing provisions, for each calendar year during the Lease Term, Tenant shall reimburse Landlord for Landlord's Insurance premiums with respect to the Premises for such calendar year, which shall be paid in accordance with Section 12.2. Tenant's payment obligation for Landlord's Insurance shall be conditioned upon Landlord's delivery to Tenant of a copy of Landlord's Insurance policies' respective declaration pages documenting the type, amount and cost of Landlord's Insurance being provided (broken out on a per location basis, as and to the extent necessary), and proof of payment for premiums due thereon.

4.6. Tenant's Audit Rights

(a) Tenant shall have the right, upon not less than thirty (30) days' written notice to Landlord, and not more than one time each calendar year, to audit at Tenant's cost, Landlord's books and records with respect to Operating Expenses, Taxes and/or Landlord's Insurance for any given calendar year. Landlord shall cooperate with Tenant in providing Tenant reasonable access to its books and records at the office where Landlord maintains its records of Operating Expenses, Taxes and/or Landlord's Insurance (or shall provide such books and records to Tenant electronically, at Tenant's option) during normal business hours for this purpose, upon at least thirty (30) days' prior written notice delivered to Landlord. Tenant shall pay the reasonable fees and expenses related to such audit, unless the audit determines that Landlord overstated Operating Expenses, Taxes and/or Landlord's Insurance by more than four percent (4%), in which case Landlord, within thirty (30) days after demand from Tenant, shall pay such fees and expenses.

(b) In the event that any audit discloses an underpayment of Operating Expenses, Taxes and/or Landlord's Insurance by Tenant, then Tenant, within thirty (30) days of such audit, shall remit the amount of the underpayment to Landlord. In the event that any such audit discloses an overpayment by Tenant, then Tenant shall provide Landlord with a copy of such audit together with written request for Landlord to reimburse Tenant for such overpayment (together, a "***True-Up Request***"). Landlord shall, within thirty (30) days of receiving any such True-Up Request from Tenant, either (i) remit the amount of overpayment to Tenant, or (ii) notify Tenant in writing ("***Contest Notice***") of its election to contest the audit results set forth in such True-Up Request in accordance with Section 4.6(c) below.

(c) If Landlord timely delivers any Contest Notice in accordance with Section 4.6(b) above, Landlord and Tenant shall thereafter diligently and in good faith attempt to amicably determine the appropriate payments related to Operating Expenses, Taxes and/or Landlord's Insurance with respect to the year for which Tenant has submitted a True-Up Request, for a period of thirty (30) days after Landlord's delivery of such Contest Notice. If, despite the parties' diligent and good faith efforts, Landlord and Tenant have not reached agreement with respect to such matters within the aforementioned 30-day period, Landlord and Tenant shall thereafter proceed to a baseball-style arbitration, wherein Landlord and Tenant shall apply to the American Arbitration Association for the designation of a qualified third-party arbitrator ("***Arbitrator***"). Within ten (10) days of the designation of the Arbitrator, Landlord and Tenant shall each submit a written proposal to the Arbitrator setting forth its calculation of the applicable Operating Expense, Taxes and/or Landlord's Insurance true-up for the designated calendar year, as well as its calculation methodology for determining such Operating Expenses, Taxes and/or Landlord's Insurance. The Arbitrator shall select either the Landlord's or the Tenant's proposed calculation without modification. The Arbitrator's selection shall be final and binding on both Landlord and Tenant. The fees of the Arbitrator, and any costs associated with applying the American Arbitration Association for designation of the Arbitrator, shall be equally split by Landlord and Tenant. All notices required to be delivered pursuant to this Section shall be delivered in accordance with the notice requirements set forth in Section 27 below.

(d) If Landlord fails to remit the entire amount of any such overpayment to Tenant within thirty (30) days after the date such overpayment has either been deemed accepted by Landlord pursuant to Section 4.6(b) above or finally determined pursuant to Section 4.6(c) above, then Tenant may offset any such past-due amount set forth in such audit against the Base Rent payment(s) next coming due, until such past-due amount has been fully recouped by Tenant.

4.7. Utilities

Beginning on the Lease Commencement Date and continuing during the Lease Term, Tenant shall transfer all utility service to Tenant's name and Tenant shall be solely responsible for and shall promptly pay all charges for telephone service, electricity, gas, water, sewage and all other utilities used upon or furnished to the Premises and separately metered. To the extent that any utility services supplied to the Premises are billed directly to Landlord, Tenant shall reimburse Landlord, within thirty (30) days after Landlord's delivery to Tenant of an invoice therefor, for that portion of such utility services that is attributable directly to Tenant's use of the particular utility service. In no event shall Landlord be liable in damages or otherwise for any interruption or failure in the supply of such utilities, or if either the quantity or character of such utilities supplied is changed or is no longer available or suitable for Tenant's requirements.

4.8. Taxes – Other

Tenant shall pay before delinquency any and all taxes and assessments, licenses, sales, business, occupation or other taxes, fees or charges levied, assessed or imposed upon its business operations in the Premises during the Lease Term. Tenant shall pay before delinquency any and all taxes and assessments levied, assessed or imposed upon its trade fixtures, leasehold improvements, merchandise and other personal property in, on or upon the Premises. In the event any taxes, fees or charges referred to in this Section shall be assessed, levied or imposed upon or with the business or property of Landlord, such assessment, fees or charges shall be paid by Tenant to Landlord within thirty (30) days after receipt of Landlord's written request for such payment (which request shall be accompanied by a detailed invoice therefor).

4.9. Renewal Rent

If Landlord and Tenant cannot agree on the Base Rent for a Renewal Term within thirty (30) days after negotiations begin, the parties agree to enter into a "***Baseball Arbitration***" process in which each will appoint an MAI real estate appraiser whose instruction shall be to agree to the accurate calculation of CPI Increases (as defined in Section 1.8 above). Thereafter, if those two (2) appraisers are unable to agree within thirty (30) days on the applicable CPI Increases to be utilized for the calculation of Base Rent for any applicable Renewal Term, then they will jointly appoint a third appraiser, subject to the approval of Landlord and Tenant. The value determined by the third appraiser according to the factors set forth in Section 1.8 will be binding on Landlord and Tenant, unless it is either lower or higher than the lower or higher respectively of the other two (2) appraisals, in which case, the middle of the three (3) appraisals will control. If appraisals are required, Landlord and Tenant will share the cost of all appraisals. In no event shall the appraisal process exceed ninety (90) days after Tenant's initial written notice to Landlord of Tenant's election to renew.

5. SECURITY DEPOSIT

Within three (3) business days after the execution of this Lease, Tenant shall pay to Landlord the Security Deposit as set forth in Section 1.14 as security for the performance of Tenant's obligations under this Lease, which Security Deposit shall be subject to scheduled decreases in accordance with Section 1.14. In the event of a Tenant Default under this Lease, Landlord may apply such part of the Security Deposit as may be necessary to cure such Tenant Default. Should Landlord so apply all or part of the Security Deposit, Landlord shall notify Tenant of such application at least ten (10) days in advance, and Tenant shall, within fifteen (15) days after receipt of Landlord's written demand, redeposit with Landlord an amount equal to that so applied so that Landlord will have the full Security Deposit (less any amounts previously returned in accordance with Section 1.14 above) on hand. Within thirty (30) days after any reduction set forth in Section 1.14 above, and provided a Tenant Default does not then exist, Landlord shall refund to Tenant the applicable portion of the Security Deposit. In the event Landlord fails to refund to Tenant such applicable portion of the Security Deposit within such 30-day period and no dispute exists between Landlord and Tenant with regard to any Tenant Default and/or the Security Deposit, Tenant may elect to offset an amount equal to the applicable portion of the Security Deposit to be returned to Tenant against the next installment(s) of Base Rent owed hereunder, until such amount is fully recouped by Tenant. In the event of a sale of the Premises, Landlord shall transfer the Security Deposit to the purchaser. Following Landlord's written notice to Tenant accompanied by documentation signed by Landlord and such purchaser evidencing that the Lease and Security Deposit have been assigned to and assumed by any such purchaser in writing, Landlord shall thereafter be released by Tenant from any liability for the return of the Security Deposit.

6. USE AND OCCUPANCY

6.1. Use of Premises

The Premises are to be used solely for the purposes set forth in Section 1.15 of this Lease and for no other business or purpose without the prior written consent of Landlord. Tenant shall not do or permit to be done in or about the Premises anything which is illegal or unlawful. Other than with respect to Landlord's Work, Tenant shall obtain all permits, licenses, certificates or other authorizations and any renewals, extensions or continuances of the same required in connection with the lawful and proper use of the Premises and shall pay when due all taxes upon its merchandise, stock, fixtures, equipment and leasehold improvements in the Premises. Neither a failure on the part of Tenant to procure such permits, licenses, certificates or other authorizations, nor the revocation of the same, shall in any way affect the liability of Tenant for payment of Rent herein reserved or the performance or observance of any of the covenants or conditions herein contained on Tenant's part to be performed and observed. Tenant shall (and shall cause its affiliates and their respective employees to) observe the Rules and Regulations attached as Exhibit D or such other reasonable rules and regulations applicable to the Premises, as the same may be imposed by Landlord from time to time, but only to the extent that Landlord has provided a written copy of same to tenant at least thirty (30) days in advance. Tenant shall comply with all Applicable Laws applicable to the use and occupancy of the Premises and Property. Without limiting the generality of the foregoing, except as otherwise expressly permitted under the terms of this Lease, Tenant shall not display anything outside of the Premises nor operate any loud speakers without the specific written consent of Landlord.

Tenant shall be permitted to install, at Tenant's sole cost and expense, access control equipment to limit and monitor access to the Premises during normal business hours and after-hours, provided, however, that Landlord shall always retain the ability to access the Premises in the case of an emergency situation.

6.2. Continuous Occupancy

Tenant shall have the right to vacate the Premises so long as Tenant continues to pay Rent as required hereunder and maintains the Premises in good condition as described in Section 8.2 herein.

7. LANDLORD'S WORK

(a) Landlord shall perform, or cause to be performed, the work contemplated by Exhibits B, B-1 and B-2 (collectively, "***Landlord's Work***") at Landlord's sole expense (except as otherwise expressly set forth in the Work Letter), and in compliance with all Applicable Laws. Landlord shall be responsible, at its sole cost and expense, for obtaining all necessary permits for the performance of Landlord's Work in compliance with all Applicable Laws. Landlord and Tenant shall cooperate with each other in good faith to ensure that mutual access is coordinated between their agents or contractors in a reasonable manner to allow each to complete its Landlord's Work and Tenant's Work, respectively, without interference or delay.

(b) Landlord hereby warrants the Landlord's Work as follows (collectively, "***Landlord's Construction Warranties***"): (i) For a period of one (1) year beginning on the Lease Commencement Date, Landlord, at its sole cost and expense, shall warrant the Landlord's Work has been constructed in a good and workmanlike manner, in compliance with the plans and specifications attached hereto and made a part hereof as Exhibit B-1 ("***Plans and Specifications***"), and in accordance with the Schedule attached hereto and made a part hereof as Exhibit B-2 ("***Schedule***") and the same will be free of all defects; and (ii) For a period of eighteen (18) months beginning on the Lease Commencement Date, Landlord, at its sole cost and expense, shall warrant the paved areas of the Property from any defects in construction. Notwithstanding anything to the contrary contained herein, Landlord's Construction Warranties will not include any maintenance which is the responsibility of the Tenant as set forth in Section 8.2 below.

(c) Unless otherwise agreed to in writing by Tenant, it is the Landlord's responsibility to secure soil borings, topographical surveys, geotechnical and foundation recommendations and tests from licensed local professionals, including surveyors and engineers, as shall be necessary or appropriate to construct Landlord's Work, using the best engineering practices and conforming to all requirements of Applicable Laws.

8. REPAIRS

8.1. Landlord Responsibility

Landlord, at Landlord's sole cost and expense, but subject to the provisions of Section 4.3 above and the Work Letter, shall keep or cause to be kept in as good repair as same are in upon Substantial Completion of Landlord's Work or, with respect to the floor slab, upon Substantial Completion of Tenant's Work (which may include the replacement of): the foundations, the roof and the structural soundness of the floors, and the exterior walls (excluding the interior surface of the exterior walls and excluding the exterior and interior portions of all windows, doors, plate glass and showcase); the exterior water, sewage, gas and electrical services up to the point of entry to the Building; the exterior areas of the Property including, without limitation, the sidewalks and parking areas; the base building heating and air conditioning systems (but not specialized HVAC systems installed by Tenant in support of specific business operations within the Building) whether located inside or outside of the Building, except for ordinary maintenance and repairs which shall be the responsibility of Tenant, as well as wiring and cabling servicing the Building (but only to the point where such cabling enters and connects to the Building, and not from such point of connection to the Tenant's equipment); and Landlord shall make all repairs and restorations made necessary by fire or other peril covered by the standard extended coverage endorsement on fire insurance policies as further described in Section 12; *provided*, *however*, that Tenant shall reimburse Landlord upon demand for the cost of repairing any damage to the Premises or Building caused by the negligence or the willful misconduct of Tenant, its employees, agents or invitees. Landlord shall cooperate with Tenant in connection with enforcing all third-party warranties on construction, materials and/or equipment, for the benefit of Tenant. Notwithstanding the foregoing, (i) Landlord shall only be responsible for the portion of the floor slab installed by Landlord, and (ii) Landlord shall not be responsible for the repairs to the floor slab caused by Tenant or anyone acting on Tenant's behalf.

8.2. Tenant Responsibility

Except (a) to the extent covered pursuant to either of Landlord's Construction Warranties or any insurance policy required to be maintained by Landlord pursuant to the terms of this Lease, or (b) repairs caused by the negligence or willful misconduct by Landlord, any of Landlord's affiliates, or any of their respective agents, employees, invitees or contractors: Tenant shall, in all other respects, keep or cause to be kept in good repair and in a neat, clean and tenantable condition, normal wear, tear and casualty excepted, the interior of the Premises, including but not limited to the interior surface of the exterior walls, the exterior and interior portions of all windows, doors, plate glass and showcases, and all plumbing, lighting fixtures, pipes and equipment, floor coverings, ceilings, walls and plasterings. Tenant shall provide ordinary maintenance for the heating and air conditioning systems and provide for maintenance service contracts on said systems which are reasonably satisfactory to Landlord; and to make all other repairs not specifically required to be made by Landlord under Section 8.1. Landlord represents that, as of the Lease Commencement Date, the mechanical systems of the Premises installed by Landlord as part of Landlord's Work shall be in good working condition and otherwise meet the standards set forth in the Work Letter.

9. ACCESS AND CONFIDENTIALITY

9.1. Landlord Access

Subject to Landlord's Entrance Requirements (as defined below), Landlord has the right to enter the Premises periodically and shall have access to the Premises at reasonable hours for inspection or in connection with the improvement or repair of utility lines and related systems and HVAC systems or equipment serving the Premises. As used herein, the phrase "***Landlord's Entrance Requirements***" means: *except in case of emergency*, (a) Landlord shall provide Tenant with not less than 24 hours' notice prior to any entrance by Landlord, (b) Landlord shall not materially interfere with Tenant's operations on the Premises without first obtaining Tenant's written consent, (c) Landlord shall have a Tenant representative escort Landlord or its representative(s) or agent(s) while in the Premises, and (d) at all times Landlord shall follow Tenant's protocols established by Tenant to facilitate the physical safety of those in the Premises and to protect any proprietary information or trade secrets related to Tenant's operations. In all events Landlord shall use commercially reasonable best efforts to minimize any disruption to Tenant's operations on the Premises. All entrances of Landlord and any of its representatives and/or agents shall be subject to Landlord's Entrance Requirements.

9.2. Tenant Access

Tenant shall have access to the Premises twenty-four (24) hours a day, seven (7) days a week

10. ALTERATIONS TO PREMISES; SIGNS

(a) Material Structural Alterations. Tenant shall not make any alterations, additions or improvements to the Premises which materially or adversely impact the roof or structure of the Building (each, a "***Material Structural Alteration***") without first obtaining Landlord's written consent in accordance with the following: Tenant shall notify Landlord of any Material Structural Alteration that Tenant wishes to complete (each, a "***Alteration Notice***"). Landlord shall have ten (10) business days to review any such Alteration Notice and give consent to such Material Structural Alteration, which consent shall not be unreasonably withheld, conditioned or delayed. If Landlord fails to provide Tenant with a written response to any Alteration Notice within the aforementioned 10-business day period, Landlord shall be deemed to have provided its consent thereto, Tenant may thereafter proceed with such Material Structural Alteration, and Landlord shall not be permitted to raise subsequent issues or requirements in respect of the Material Structural Alteration proposed by such Alteration Notice. Landlord shall be deemed to have acted reasonably in withholding consent to an Alteration Notice *only* if the proposed Material Structural Alteration would: (i) void, in whole or in part, any warranty pertaining to any item for which Landlord is responsible to maintain pursuant to Section 8.1 above, as reasonably determined by Landlord in good faith and substantiated in writing to Tenant (unless Tenant uses Landlord's contractor for such work, in which case this clause (i) shall not be a valid basis for Landlord to withhold, condition or delay consent); (ii) materially or adversely impact the structural soundness of the Building, as determined by Landlord's structural engineer and substantiated in writing to Tenant; or (iii) violate any Applicable Law.

(b) All Other Alterations. Except as otherwise expressly set forth in Section 10(a) above, Tenant, without Landlord's prior consent and at its sole cost and expense, shall have the right, but shall not be obligated, prior to and during the Lease Term, to improve, alter and renovate the Premises in any manner which Tenant deems necessary or desirable to adapt the same for the conduct of its business operations, including, without limitation, the following items (which the parties agree are not Material Structural Alterations): painting; decorating; redecorating; installing non-load-bearing partitions, pass-through windows, counters, shelving, floor coverings, wall coverings, drop ceilings and/or light fixtures. Tenant shall be responsible for ensuring ADA compliance within the Premises. The parties further acknowledge and agree that Tenant's business needs at the Premises may necessitate or otherwise make desirable the installation of additional HVAC units, installation of one or more generator(s), increasing electrical service, modifying plumbing service, and/or installing one or more new clean room(s). Landlord hereby acknowledges and agrees that Tenant shall not be required to seek or obtain Landlord's consent with respect to, nor shall Landlord have any rights in respect of evaluating, any of the items enumerated in the previous sentence, so long as they would not materially or adversely impact the roof or structure of the Building.

(c) Additional Requirements re: Alterations. Tenant shall perform (or cause to be performed) all alterations, additions and improvements to the Premises (whether a Material Structural Alteration or otherwise) in a good and workmanlike manner, and otherwise in accordance with Applicable Laws. All alterations, additions and improvements made by Tenant, whether or not such changes were approved by Landlord, shall become the property of Landlord upon the making thereof and shall be subject to the terms of Section 19.1 herein upon the expiration or earlier termination of this Lease. Except as otherwise expressly set forth in Section 19.2 below, Tenant shall not be required to remove any alterations, additions or improvements at the expiration or earlier termination of this Lease, except for the following "***Specialized Alterations***": (i) Tenant's trade fixtures; (ii) Tenant's interior and exterior signage; (iii) alterations which penetrate floor slabs by more than two (2) inches, or otherwise adversely affect any of the MEP systems serving the Building or any structural aspect of the Building; (iv) alterations which are likely to adversely affect the safety of the Building and/or future occupants; (v) alterations that are prohibited by any ground lease, mortgage, deed or other instrument encumbering the Premises; (vi) safes or vaults or other installations which would be unusually difficult or expensive to remove; and (vii) any other alteration, addition or improvement that Landlord notifies Tenant in writing, prior to the installation thereof, must be removed at the expiration or earlier termination of this Lease. Any damage to the Premises in connection with the making of alterations, additions and improvements by Tenant or in connection with the placement, direction, maintenance, painting or removal of any signs on the Premises or Property shall be repaired by Tenant at Tenant's sole cost and expense.

(d) Signs. Notwithstanding the foregoing, Tenant shall be permitted to install Tenant's any signage it desires on the Premises, whether on the interior or outside of the Building (but not outside the Premises), provided (i) such signage shall comply in all respects with the requirements of Applicable Law and (ii) the size, location, materials, method of installation and method of removal of such signage shall be approved in advance by Landlord, whose approval shall not be unreasonably withheld, delayed or conditioned. Electricity for such signage shall be separately metered to the Premises and paid by Tenant. Upon termination of this Lease, Tenant shall be responsible for the removal of any Tenant signage and Tenant shall responsible for the cost to repair any damage as a result of the removal of Tenant signage, if applicable.

11. DAMAGE OR DESTRUCTION

11.1. Damage or Destruction

If the Building is damaged or destroyed by fire, earthquake, casualty or other risk required to be insured against pursuant to Section 12.2 below or as otherwise required by Applicable Law, Tenant shall give Landlord prompt notice of the occurrence of any such event. Within thirty (30) days after the date Landlord receives notice from Tenant of the applicable casualty event, Landlord shall prepare a written estimate of the time period required to repair and restore the damaged portions of the Core and Shell of the Building ("***Estimate***") and deliver such Estimate to Tenant. Unless terminated pursuant to Section 11.2 below, this Lease shall remain in full force and effect, and Landlord, at its sole cost and expense, shall promptly repair the damage or destruction related to the Core and Shell of the Building and restore the Core and Shell of the Building to substantially that condition existing immediately prior to such damage or destruction. If Tenant remains in occupancy of the Premises, Landlord shall exercise such repair and restoration efforts in a manner so as not to interfere unreasonably with the use and occupancy of the Premises by Tenant for the conduct of its business operations. Until the completion of Landlord's repair and restoration pursuant to this Section, Tenant's obligation to pay Rent and other amounts payable by Tenant hereunder shall be abated as of the date of the damage or destruction in proportion to the extent that the value of the Premises for the use and occupancy thereof by Tenant for the conduct of its business operations shall be reduced, in Tenant's reasonable judgment. As used herein, the term "***Core and Shell***" means all items of Landlord's Work, all external walls or the Building, the roof and roof membrane of the Building, all utility lines serving the Building (stubbed into the Building (whether up through the slab or through the walls or roof of the Building), but not any lines within the interior of the Building), and the floor slab within the Building.

11.2. Rights of Termination

Landlord's and Tenant's respective rights to terminate this Lease pursuant to events described in Section 11.1 above shall be governed as follows:

(a) If the Premises shall be damaged or destroyed to the extent of more than fifty percent (50%) of the full replacement cost of the Core and Shell of the Building, and the repair and restoration of any such damage or destruction shall not be completed within 180 days after the date of the damage or destruction, then either party may elect to terminate this Lease by delivery of notice to the other party within thirty (30) days after the date of such damage or destruction.

(b) If Landlord fails to deliver an Estimate within the 30-day period set forth in Section 11.1 above, Tenant may elect to terminate this Lease by delivery of notice to Landlord within thirty (30) days after the expiration of the 30-day period set forth in Section 11.1 above; *provided, however*, that if Landlord provides an Estimate after such 30-day period set forth in Section 11.1 above but before Tenant exercises its right to terminate hereunder, Tenant shall not have the right to terminate this Lease pursuant to this Section 11.2(b).

(c) Upon delivery of any notice pursuant to Section 11.2(a) or Section 11.2(b) above, this Lease shall terminate as of the date of the damage or destruction unless otherwise provided in such notice, and Tenant and Landlord shall have no further liabilities or obligations hereunder other than Tenant's obligation to pay Rent accrued hereunder as of the date of such termination.

12. INDEMNITY AND INSURANCE

12.1. Indemnity

(a) To the fullest extent permitted by Applicable Law, and subject in all respects to Section 13 below, Tenant shall defend, indemnify and hold harmless the Landlord from and against all claims, losses, costs, expenses, fines, penalties including attorneys' fees, court costs, consultant and expert expenses, arising out of or relating to any act, omission, breach of any provision of this Lease, or negligence or intentional act of Tenant or any of Tenant's Agents or subtenants except to the extent that any of the foregoing is attributed to the negligence or intentional act of Landlord or any of its affiliates or any of their respective agents, employees, invitees or contractors.

(b) To the fullest extent permitted by Applicable Law, and subject in all respects to Section 13 below, Landlord shall defend, indemnify and hold harmless the Tenant from and against all claims, losses, costs, expenses, fines, penalties including attorneys' fees, court costs, consultant and expert expenses, arising out of or relating to any act, omission, breach of any provision of this Lease, or negligence or intentional act of Landlord or any of Landlord's licensees, agents, employees, invitees or contractors except to the extent that any of the foregoing is attributed to the negligence or intentional act of Tenant or any of its affiliates or any of Tenant's Agents.

(c) The indemnification obligations created by this Section shall be expressly conditioned upon the indemnified party (i) delivering to the indemnifying party prompt notice of any event giving rise to such indemnification obligation and (ii) providing the indemnifying party the opportunity to defend itself from and against any losses which are the subject of such indemnification obligation. Landlord and Tenant acknowledge and agree that the indemnification obligations of this Section shall survive the expiration or earlier termination of this Lease.

12.2. Landlord's Insurance

Landlord shall maintain throughout the Lease Term the following types of insurance:

a. Commercial General Liability Insurance covering the Premises with limits of no less than $1,000,000 per occurrence and $2,000,000 aggregate for personal injury, bodily injury, sickness or death or for damage or destruction of property to the extent directly related to the Premises.

b. All Risk or Special Peril property insurance covering the full replacement cost value of the Premises and the potential loss of rental income for at least a six-month time period.

Such insurance policies shall be issued by insurance companies authorized to do business in the Commonwealth of Pennsylvania, and each shall be rated at least A- by AM Best. Such insurance coverages shall name Tenant as additional insured. Landlord's requirements to provide the aforementioned insurance in no way limits Landlord's obligations to indemnify the Tenant pursuant to the indemnity provisions expressly set forth in this Lease. Landlord shall furnish to Tenant, not less than fifteen (15) days before the date the insurance is to be obtained by Landlord hereunder, and thereafter at least fifteen (15) days before the expiration of each policy, evidence of insurance (on ACORD 25, ACORD 28 or other form reasonably acceptable to Tenant), showing Tenant as an additional insured thereunder, and evidence of payment of all premiums and other expenses owed in connection with said insurance policies.

12.3. Tenant's Insurance

Tenant shall, at its own cost and expense, maintain throughout the Lease Term the following types of insurance:

(a) Automobile Liability including coverage for all owned, leased, hired and non-owned vehicles with a minimum limit of One Million and xx/100 Dollars ($1,000,000.00) per accident including Landlord, Landlord's lender(s), and Al. Neyer, LLC, as additional insureds.

(b) Commercial General Liability including Contractual Liability, Personal Injury Liability and Products/Completed Operations Liability with minimum limits of One Million and xx/100 Dollars ($1,000,000.00) per Occurrence, Three Million and xx/100 Dollars ($3,000,000.00) General Aggregate. The required limit may be provided in a single policy or in combination with an Umbrella or Excess Liability Policy. Landlord, Landlord's lender(s) and Al. Neyer, LLC shall be included as additional insureds and such insurance shall be primary and non-contributing with any similar insurance available to the Landlord.

(c) All Risk or Special Peril property insurance covering the full replacement cost value of Tenant's leasehold improvements and other property including property of others in or about the Premises and Tenant's potential loss of income as a result of fire or other casualty. Such insurance shall include the Landlord, Landlord's lender(s) and Al. Neyer, LLC as additional insureds with respect to leasehold improvements made to the Property.

(d) Statutory Workers' Compensation to comply with the laws of the Commonwealth of Pennsylvania. Coverage shall also include Employers' Liability Insurance with minimum limits of One Million and xx/100 Dollars ($1,000,000.00) per Occurrence for Bodily Injury, One Million and xx/100 Dollars ($1,000,000.00) per Occurrence for Bodily Injury by Disease and One Million and xx/100 Dollars ($1,000,000.00) Policy Limit for Disease. The policy shall be endorsed to waive subrogation rights against the Landlord and Al. Neyer, LLC.

A certificate of insurance as evidence of the required coverage shall be provided to the Landlord prior to occupancy of the Premises. At least ten (10) days prior to the expiration of any required coverage, a new certificate shall be provided to the Landlord. The policies shall be endorsed to provide thirty (30) days prior written notice of cancellation, non-renewal or material change of any of the required coverages. Such insurance shall be provided by insurance companies authorized to do business in the Commonwealth of Pennsylvania. The requirements to provide minimum amount of insurance in no way limit the liability of the Tenant for its obligations to indemnify the Landlord and Al. Neyer, LLC pursuant to the indemnity provisions expressly set forth in this this Lease.

13. WAIVER OF SUBROGATION

Landlord and Tenant shall have no liability to one another, or to any insurer, by way of subrogation or otherwise, on account of any loss or damage to their respective property, regardless of whether such loss or damage is caused by the negligence of Landlord or Tenant, arising out of any of the perils or casualties insured against by the property insurance policies carried, or required to be carried, by the parties pursuant to this Lease. The insurance policies obtained by Landlord and Tenant pursuant to this Lease shall permit waivers of subrogation that the insurer may otherwise have against the non-insuring party.

14. LIENS

Tenant will keep the Premises and the Property free and clear of all mechanics' and materialmen's liens and other liens on account of work done for or by Tenant or persons claiming under it. Any such liens filed against the Premises or the Property shall be discharged by Tenant at its expense within thirty (30) days after Landlord's notice to Tenant of either a filing thereof or within thirty (30) days of the actual filing if prior to the filing Landlord notifies Tenant that it has received a notice of intent to file a mechanics' lien from Tenant's contractor or any of its subcontractors. Should any such lien be filed against the Premises or the Property, and Tenant has filed to discharge the same in accordance with the foregoing, Landlord may, upon prior written notice to Tenant, elect to obtain the release of such lien and any sums expended by Landlord shall be immediately repaid to Landlord by Tenant together with interest at the rate of eighteen percent (18%) per annum.

15. ASSIGNMENT, SUBLETTING, MORTGAGING

(a) Except as otherwise expressly set forth herein, Tenant shall not voluntarily, involuntarily or by operation of law, assign, transfer, mortgage or otherwise encumber all or any part of Tenant's interest in this Lease, or sublet the Premises or any part thereof to a third party without first obtaining Landlord's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), and any attempt to so assign, transfer, mortgage, encumber or sublet to a third party without Landlord's written consent shall be null and void; and if any such

assignment, transfer, mortgage or encumbrance is made with the written consent of Landlord, Tenant shall nevertheless remain liable to Landlord for payment of Rent and any other charges according to the terms hereof and for due performance of all the terms, covenants and conditions of this Lease. If Tenant is a corporation, then any transfer of this Lease by merger, consolidation, dissolution, sale, acquisition or liquidation or any change in the ownership of, or power to vote the majority of, its outstanding voting stock, or a sale of substantially all of Tenant's assets, shall constitute an assignment for the purposes of this paragraph and is permitted without consent of Landlord, but Tenant shall endeavor to provide Landlord with notice of such transfer. If written consent is once given by Landlord to any such assignment or subletting, such consent shall not operate as a waiver of the necessity for obtaining Landlord's written consent to any subsequent assignment or subletting. Any request for Landlord's consent to any proposed assignment or sublease (other than a permitted assignment) shall be accompanied by an administrative fee in the amount of One Thousand and 00/100 Dollars ($1,000.00), payable by Tenant, which shall be deemed sufficient to cover Landlord's attorneys' fees. Said fee shall be due and payable as Additional Rent, whether or not the request is approved.

Notwithstanding the foregoing, Tenant shall have the right, without Landlord's consent but upon prior notice to Landlord to (i) assign this Lease to any affiliate or wholly owned subsidiary with an equal or greater net worth (tested as of the date of such proposed transfer), and/or (ii) sublet all or any portion of the Premises to an affiliate or wholly owned subsidiary.

Any profits resulting from a sublet or assignment by Tenant shall be retained 100% by Tenant.

(b) If Landlord conveys the Premises during the Lease Term, Landlord shall inform Tenant by notice given in accordance with Section 27 hereof. Tenant shall have no obligation to recognize a successor landlord unless and until such successor landlord shall have provided Tenant with a copy of the assignment and assumption of lease agreement in which the successor landlord assumes the obligations of the Landlord under the Lease. Tenant shall have no obligation to pay to the successor landlord Rent or any other amounts coming due under the Lease unless and until such successor landlord shall have provided Tenant with a proper notice address and a completed IRS Form W-9, so that Tenant may make the necessary changes to its accounts payable system and other records to effect the new payee. Landlord hereby agrees to remit to successor landlord any payments made by Tenant to Landlord subsequent to its transfer to the successor landlord but prior to Tenant's modification of its accounts payable system, and indemnifies Tenant for any such payments made, received by Landlord and not remitted to successor landlord. Landlord hereby covenants to Tenant that it shall not sell all or any portion of the Premises prior to the Lease Commencement Date, other than as expressly contemplated in Section 25 below.

16. PRIORITY OF LEASE

Tenant covenants and agrees, on the terms and conditions provided in this Section, that this Lease shall be subordinate to the lien of any institutional mortgage or deed of trust ("***Mortgage***") which may hereafter be made covering the Premises or any portion or portions thereof, provided that each mortgagee or beneficiary shall execute and deliver to Tenant a subordination, non-disturbance and attornment agreement ("***SNDA***") substantially in the form attached hereto as Exhibit F, stating (in addition to other reasonable terms, if any) in substance that (a) if no Tenant Default exists hereunder, the right of possession of Tenant to the Premises shall not be affected or disturbed by any mortgagee in the exercise of any of its rights under a Mortgage or the note secured thereby, and any sale of the Premises pursuant to the exercise of any rights and remedies under a Mortgage or otherwise shall be made subject to Tenant's right of possession to the Premises under this Lease; and (b) Tenant shall attorn to any mortgagee or purchaser at a foreclosure sale (a "***Purchaser***") upon acquisition of title to the Premises by a mortgagee or Purchaser and notice to Tenant thereof, and this Lease shall continue in full force and effect between Tenant and such mortgagee or Purchaser. Upon Tenant's receipt and approval of the SNDA from a mortgagee or beneficiary from time to time, Tenant covenants and agrees to attorn to such mortgagee or beneficiary upon foreclosure and shall use reasonable efforts to execute the SNDA within thirty (30) days after Landlord's request.

Without limiting the generality of the foregoing, within ten (10) days after the closing of Landlord's financing on this Lease, but in no event later than the Lease Commencement Date, Landlord shall deliver to Tenant (i) an SNDA executed by Landlord and each mortgagee and beneficiary of each mortgage encumbering the Premises and (ii) a Non Disturbance and Attornment Agreement in the form attached hereto as Exhibit G ("***NDA***") executed by Landlord and the Ground Lessor with respect to the Landlord Ground Lease. If Landlord shall fail to obtain the SNDA or the NDA prior to the expiration of such thirty (30) day period, or if the form thereof shall not be reasonably acceptable to Tenant, then Tenant may deem such failure a Landlord Default (as defined in Section 20.2 below).

17. QUIET ENJOYMENT

Subject to the terms of the Landlord Ground Lease, Landlord covenants and agrees that Tenant shall have the peaceful and quiet possession, use and enjoyment of the Premises and every part thereof (not to be abrogated by any ground lease, mortgage or other matter to which this Lease is or shall become subordinate in accordance with the provisions of Section 16 above) for the conduct of its business operations during the Lease Term, in the whole of the Premises, without hindrance by Landlord or any party whatsoever.

18. ESTOPPEL CERTIFICATE

Tenant shall from time to time, but not more often than twice per calendar year execute, acknowledge and deliver to Landlord, its lender(s), ground lessor or a purchaser of the Property, within thirty (30) days of receipt of Landlord's written request therefor, a statement in writing certifying: (a) that this Lease is unmodified and in full force and effect (or if there has been any modification hereof that the same is in full force and effect as modified and stating the nature of the modification or modifications); (b) that to the best of its knowledge Landlord is not in default under this Lease (or if any such default exists the specific nature and extent thereof); (c) the date to which Rent and other charges have been paid in advance, if any; and (d) any other information regarding this Lease or Tenant's occupancy of the Premises as required by a commercially reasonable estoppel certificate and reasonably requested by Landlord or its lender(s), ground lessor or a purchaser of the Property. In the event Tenant fails to deliver such reasonably requested statement or estoppel certificate within thirty (30) days of receipt of such request, any such statement or estoppel certificate previously provided by Landlord in accordance with the above shall be deemed to be correct.

19. FIXTURES AND PERSONAL PROPERTY; SURRENDER

19.1. Surrendering of Premises

Upon the expiration or earlier termination of this Lease, Tenant shall surrender the Premises to Landlord in substantially the same condition that the Premises was delivered to Tenant as of the date of Substantial Completion (unless otherwise mutually agreed in writing between Landlord and Tenant) and with the floor slab (including the slab installed by Landlord and the slab installed by Tenant) in good condition and repair, normal wear and tear and casualty excepted; *provided*, *however*, Tenant agrees that it shall remove from the Premises (i) all movable fixtures, furniture and equipment as contemplated by Section 19.2 below, and (ii) any Specialized Alterations (whether performed as part of the Tenant's Work or afterwards) required to be removed pursuant to Section 10 above.

19.2. Removal of Tenant Property

Trade fixtures, furniture and other personal property installed or placed but not affixed in the Premises at the cost of Tenant shall be the property of Tenant unless otherwise specified in this Lease and Tenant shall remove the same prior to the termination of this Lease. Tenant shall, at its own cost and expense, completely repair any and all damage to the Premises resulting from or caused by such removal. If Tenant fails to remove all or any of such property, Landlord may, at Landlord's option, retain all or any of such property and title thereto shall thereupon vest in Landlord, or Landlord may remove from the Premises and dispose of in any manner all or any of such property, in which latter event Tenant shall, upon demand, pay to Landlord the actual expense of such removal and disposition and the cost of repair of any and all damage to the Premises resulting from or caused by such removal.

20. DEFAULT AND REMEDY

20.1. Tenant Default and Remedy

If any one or more of the following events shall occur and be continuing (after the expiration of the applicable notice and cure period), each a "***Tenant Default***": (a) Rent and any other charges due under this Lease, or any part thereof, shall at any time be past due in arrears and unpaid for more than ten (10) business days after receiving written notice from Landlord describing such failure, *provided*, *however*, Landlord shall not be required to give such written notice more than one (1) time per calendar year before late payment is considered a Tenant Default, or (b) Tenant shall default in the performance of any of the other covenants and agreements of this Lease, and shall fail to remedy such default within thirty (30) days after Tenant has received written notice of such default from Landlord, *provided*, *however*, if Tenant exercises good faith diligent efforts within such thirty (30) day period to cure the failure specified in Landlord's notice, but shall not be able to do so because of Force Majeure, then any such failure shall not be considered to be a Tenant Default, so long as Tenant shall continue to exercise in good faith such diligent efforts to cure such failure and shall do so within a reasonable period of time, or (c) Tenant shall make an assignment for the benefit of its creditors, or (d) Tenant shall file a voluntary petition in bankruptcy, be adjudicated bankrupt or take the benefit of any insolvency act, or (e) Tenant shall be dissolved voluntarily or involuntarily, or (f) the interest of Tenant shall be sold under execution or other legal process, or (g) a receiver or trustee is appointed for the property of Tenant, then, and in any one or more of such events, Landlord, at its option, may do any one or more or all of the following:

(i) Terminate this Lease and re-enter into and upon the Premises and have, repossess, and enjoy the same with all of the improvements then located thereon as if this Lease had not been made, in which event this Lease and everything therein contained on the part of Landlord to be kept and performed shall cease and be utterly void, without prejudice, however, to Landlord's right of action for unpaid Rent and/or breach of this Lease.

(ii) Without terminating this Lease, to relet all or any part of the Premises upon such terms as Landlord may, from time to time, elect, and apply the net proceeds towards Tenant's obligations hereunder; notwithstanding the foregoing, Tenant agrees, regardless of whether Landlord has relet the Premises, to (A) immediately vacate the Premises upon request from Landlord and (B) pay to Landlord the Rent herein agreed to be paid by Tenant, less the proceeds of reletting, if any, plus Landlord's documented out-of-pocket cost of tenant improvements, leasing commissions and any and all other reasonable costs related to reletting the Premises. Landlord shall be obligated in such event to exercise in good faith diligent efforts to mitigate its damages by reletting the Premises for the highest rent reasonably obtainable under the circumstances.

(iii) Charge a late payment fee as expressly contemplated in Section 4.1 above.

(iv) Seek to enjoin such default and/or have the right to invoke any right allowed at law or in equity, by statute or otherwise, as if re-entry, summary proceedings or other specific remedies were not provided for in this Lease. The rights and remedies of Landlord upon a default by Tenant shall be cumulative and not exclusive of any other right or remedy available to Landlord.

Notwithstanding anything to the contrary set forth in this Lease, in the event of any monetary Tenant Default described in Section 20.1(a) above, Landlord shall not be permitted to exercise any of the remedies set forth in Sections 20.1(i), 20.1(ii) or 20.1(iv) above unless said Tenant Default remains uncured for more than five (5) business days after delivery of written notice to Tenant regarding any such Tenant Default. For the sake of clarity, the aforementioned 5-business day notice and cure period shall apply to each and every monetary Tenant Default, and shall not be limited to any particular number of monetary Tenant Defaults occurring over the course of any particular period of time.

Notwithstanding anything to the contrary in this Lease, (A) Landlord shall have no right to place a lien on any of Tenant's personal property, furniture, fixtures or equipment, and (B) Landlord shall not be permitted to engage in any self-help remedies (even if permitted by Applicable Laws) to evict or "lock out" Tenant from the Premises, take possession of any of Tenant's property or any similar action. Landlord acknowledges and agrees that it may proceed to enforce any of its remedies under this Lease with the appropriate notice and cure periods provided herein.

Without limiting any of Landlord's rights at law or in equity, should this Lease be terminated as provided herein:

(1) Tenant shall pay to Landlord all Rent to the date upon which this Lease is terminated; and

(2) Tenant shall be liable for and will pay to Landlord, as damages, any deficiency between: (i) the Rent that would have been payable hereunder for the period which otherwise would have constituted the unexpired portion of the Lease Term; and (ii) the net amount, if any, of rents collected under any reletting effected pursuant to this Section 20 for any part of such period (first deducting from the rents collected under any such reletting all of Landlord's expenses in connection with the termination of this Lease or Landlord's re-entry, including all repossession costs, brokerage commissions, legal expenses, attorneys' fees, alteration costs and other expenses of preparing the Premises for such reletting). Such deficiency shall be paid in monthly installments by Tenant on the days specified in this Lease for the payment of installments of Base Rent, and if Tenant does not pay such deficiency by the due date, interest shall accrue on such amount (and Tenant shall pay to Landlord) at the highest rate allowed by law (but not to exceed eighteen percent (18%) per annum). Landlord will be entitled to recover from Tenant each monthly deficiency as the same will arise and no suit to collect the amount of the deficiency for any month will prejudice Landlord's right to collect the deficiency for any prior or subsequent month by a similar proceeding or otherwise. A suit or suits for the recovery of such deficiencies may be brought by Landlord from time to time at its election.

20.2. Landlord Default and Remedy

Landlord shall in no event be in default in the performance of any of the covenants, conditions or provisions in this Lease unless and until Landlord shall have failed to perform such obligation within thirty (30) days (or such additional time as is reasonably required to correct any such default and Landlord diligently prosecutes said cure to completion) after notice by Tenant to Landlord properly specifying wherein Landlord has failed to perform any such covenant, condition or provision. Upon a Landlord default, Tenant shall have all rights and remedies afforded Tenant hereunder or by law or equity. Notwithstanding the foregoing, if any such Landlord default relating to an issue with the roof of the Building creates a material disruption to Tenant's business operations at the Premises or otherwise creates a condition that is dangerous to person or property, following a second written notice to Landlord and email notice to lkoth@neyer.com, Tenant may, no sooner than twenty-four (24) hours of Landlord cure any such Landlord default and bill Landlord for its reasonable out-of-pocket costs incurred in connection therewith (the "***Cure Costs***"). If, within thirty (30) days after Landlord's receipt of Tenant's invoice for the Cure Costs, Landlord fails to (a) in good faith dispute the Cure Costs invoiced to Landlord or (b) reimburse Tenant for the Cure Costs, then upon at least fifteen (15) days' prior written notice to Landlord, Tenant shall be permitted to offset an amount equal to the Cure Costs against the next installment(s) of Base Rent owed by Tenant hereunder until such Cure Costs have been fully recouped by Tenant. If Landlord does in good faith contest the Cure Costs, then Tenant shall not have the right to offset the undisputed portion of the Cure Costs until a court of applicable jurisdiction determines the correct amount of such Cure Costs, *provided, however*, that all the equitable portion of Tenant's costs related to such filing with, and determination of, the court, including reasonable attorney's fees, (collectively, "***Tenant's Enforcement Costs***") shall be added to the Cure Costs which Tenant may offset.

20.3. Warrant of Attorney to Confess Judgment

Tenant hereby authorizes and empowers any attorney or attorneys of any Court of the Commonwealth of Pennsylvania, upon the happening of any Tenant Default hereunder and if such Tenant Default remains uncured for more than fifteen (15) days after Landlord provides Tenant with a separate written notice that Landlord intends to confess judgement hereunder, to appear for Tenant and as attorney for Tenant to sign an agreement for entering an amicable action of ejectment for possession of the Premises, and to confess judgment therein against Tenant in favor of Landlord, whereupon a Writ of Possession may immediately be issued for the possession of the Premises, without any prior writ or proceeding whatsoever and for so doing, this Lease or a copy hereof verified by affidavit shall be a sufficient warrant. Landlord may bring such amicable action of ejectment before or after the institution of any other litigation arising out of this Lease.

21. NON-WAIVER OF DEFAULTS

No waiver of any default by Landlord or Tenant hereunder shall be implied from any omission by Tenant or Landlord to take any action on account of such default if such default persists or is repeated, and no express waiver shall affect any default other than the default specified in the express waiver, and that only for the time and to the extent therein stated. The acceptance by Landlord of Rent, and the payment by Tenant of Rent, in either case with knowledge of the breach of any of the covenants of this Lease by the other party, shall not be deemed a waiver of any such breach. One or more waivers of any breach of any covenant, term or condition of this Lease shall not be construed as a waiver of any subsequent breach of the same covenant, term or condition. The consent or approval by Landlord to or of any act by Tenant requiring Landlord's consent or approval shall not be deemed to waive or render unnecessary Landlord's consent or approval to or of any subsequent similar acts by Tenant.

22. ENVIRONMENTAL / SITE REPRESENTATIONS AND INDEMNITIES

22.1. Hazardous Material

"***Hazardous Material***" means: (i) "hazardous substances" or "toxic substances" as those terms are defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. ∋ 9601, et seq., or the Hazardous Materials Transportation Act, 49 U.S.C. ss 1801, all as currently amended and amended after this date; (ii) "hazardous wastes," as that term is defined by the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. ∋∋ 6901, et seq., as currently amended and amended after this date; (iii) crude oil or any faction thereof which is liquid at standard conditions of temperature and pressure (60 degrees Fahrenheit and 14.7 pounds per square inch absolute); (iv) any radioactive material, including any source, special nuclear or by-product material as defined at 42 U.S.C. ∋∋ 2011, et seq., as currently amended and amended after this date; (v) asbestos in any form or condition; and (vi) polychlorinated byphenyls (PCB's) or substances or compounds containing PCB's.

22.2. Environmental Laws

"***Environmental Laws***" shall mean all applicable federal, state, and local laws, regulations, and ordinances relating to public health and safety and protection of the environment, including those statutes, laws, regulation and ordinances identified in Section 22.1 all as amended and modified from time to time.

22.3. Contamination

"***Contamination***" means the presence of Hazardous Material(s) in concentrations which require remediation under applicable Environmental Laws.

22.4. Tenant Representations

Tenant represents, warrants and covenants the following to Landlord that as of the Lease Commencement Date and during the entre Lease Term:

(a) Other than the initial certificate of occupancy and related permits, Tenant shall have obtained and complied, and will continue to obtain and comply with, all governmental permits required by applicable Environmental Laws relating to the use or operation of the Premises.

(b) Tenant shall not have permitted and will not permit to occur any release or disposal of Hazardous Material, on, in, under, or from the Premises. Tenant, however, will be permitted to generate, manufacture, store, treat and transport, in compliance with all Environmental Laws, those Hazardous Materials used in Tenant's business. Tenant agrees to provide Landlord with Material Safety and Data Sheets for all Hazardous Materials used in Tenant's business.

(c) Tenant will notify Landlord of all written complaints, claims, citations, demands, inquiries, reports, notices or spills or releases of Hazardous Materials relating to compliance with Environmental Laws within five (5) business days of Tenant's receipt thereof. To the extent possible, Tenant will promptly cure and resolve any such actions and proceedings that result from any Contamination caused solely by Tenant or any of Tenant's Agents. Tenant will keep the Premises free of any lien imposed pursuant to any Environmental Law for any Contamination caused solely by Tenant or Tenant's Agents.

(d) If Tenant fails to undertake to cure a violation of any of the foregoing warranties, representations, and covenants within a reasonable time, Landlord may cause the removal of any Contamination from the Premises in accordance with Environmental Laws. As to Contamination caused solely by Tenant or Tenant's Agents, the reasonable costs of any remediation of said Contamination required by Environmental Laws will be Additional Rent under this Lease, and such reasonable costs will become due and payable within thirty (30) days after written demand by Landlord, but only if Tenant fails to undertake to comply with this paragraph within a reasonable time.

(e) Tenant agrees to indemnify, defend, and hold Landlord and Landlord's affiliates, shareholders, directors, officers, employees, and agents free and harmless from and against all losses, liabilities, obligations, penalties, claims, litigation, demands, defenses, costs, judgments, suits, proceedings, damages (including consequential damages), disbursements or expenses of any kind (including reasonable attorneys' fees and investigation costs, whether defending or prosecuting any litigation, claim or proceeding) that may at any time be imposed upon, incurred by, or asserted or awarded against Landlord in connection with or arising from or out of:

1. any Contamination which has been caused solely by Tenant or Tenant's Agents on, in, or under or affecting all or any portions of the Premises;

2. any misrepresentation, inaccuracy or breach of any warranty, covenant or agreement contained (other than (e)(1) above) or referred to in this Section of the Lease by Tenant;

3. any violation or claim of violation by Tenant or Tenant's Agents of any Environmental Law (other than (e)(1) or (e)(2) above) that Tenant does not diligently undertake to resolve within a reasonable time.

This indemnification shall survive the termination of this Lease and shall be in full force and effect for five (5) years after the termination of the Lease, after which time, it shall be null, void, and of no force and effect.

The acts set forth in (e)(1), (e)(2), and (e)(3) for which indemnification is provided are hereinafter referred to as "***Predicate Acts***". To the extent that any of the Predicate Acts are caused, in whole or in part, by the acts or omissions of Landlord or any other person or party (other than Tenant or Tenant's Agents), then Tenant's obligation under this paragraph providing for indemnity shall be limited to the degree and percent that Tenant's acts or omissions contributed to the Predicate Acts and Tenant shall be responsible only for that portion of the costs which would not otherwise have been incurred were it not for Tenant's Predicate Acts, and Tenant shall not be liable for any consequential damages of any kind. As of execution of the Lease, Landlord represents that to the best of its knowledge the Premises are not in violation of the above referenced hazards.

22.5. Landlord Representations

Landlord represents, warrants and covenants to Tenant, and each of its respective officers, directors, employees, affiliates and successors (collectively, "***Tenant Entities***"), as follows:

(a) Landlord currently leases the Property pursuant to the Landlord Ground Lease and, upon completion, Landlord shall own the Building and Improvements pursuant to and subject to the Landlord Ground Lease and the easements, restrictions and encumbrances of record pertaining to the Property;

(b) Landlord shall timely pay, when and as due, all base rent, additional rent and other charges payable by Landlord to Ground Lessor under the Landlord Ground Lease.

(c) Except as otherwise expressly provided herein, Landlord shall fully and timely perform its covenants and obligations under the Landlord Ground Lease, including, but not limited to keeping in full force and effect all insurance required of Landlord as tenant under the Landlord Ground Lease.

(d) Landlord hereby grants to Tenant the right to receive all of the benefits with respect to the Premises which are to be provided by Ground Lessor under the Landlord Ground Lease (if any). The parties contemplate that Ground Lessor shall, in fact, perform its obligations under the Landlord Ground Lease and in the event of any default or failure of such performance by Ground Lessor, Landlord agrees that it will, upon notice from Tenant, make demand upon Ground Lessor to perform its obligations under the Landlord Ground Lease and Landlord will take appropriate legal action to enforce the Ground Lease.

(e) Landlord grants and demises to Tenant the non-exclusive use and benefit of all easements, licenses, rights-of-way, and privileges granted to Landlord under the Landlord Ground Lease. Landlord shall not agree to an amendment or modification to the Landlord Ground Lease which would have a material adverse effect on this Lease, Tenant's occupancy of the Premises or its use of the Premises, unless Landlord shall first obtain Tenant's prior written approval thereof. Tenant's prior written approval shall not be required for an amendment or modification to the Landlord Ground Lease which would make an immaterial and non-economic change or correct an error. In addition, in the event an amendment or modification would have any material adverse effect on Tenant, Landlord shall not, without Tenant's prior written consent, (i) waive any of its rights under the Landlord Ground Lease, or (ii) grant any consents thereunder. In no event shall Landlord subordinate the Landlord Ground Lease to any future mortgage, deed of trust or ground lease, without the prior written consent of Tenant. Tenant agrees that Landlord may obtain leasehold financing on the Landlord Ground Lease so long as Tenant receives the NDA as contemplated by Section 16 prior to closing on any such financing. If Landlord shall default under this Section then, in addition to all other rights and remedies of Tenant as a result thereof, shall include, without limitation, the right to bring suit in the name of Landlord and/or Tenant to enforce the Landlord Ground Lease and Landlord shall cooperate with Tenant in so doing.

(f) Landlord has full power and authority to enter into this Lease and to lease the Premises to Tenant.

(g) The Premises will be suitable for Tenant's Permitted Use and Landlord's Work shall be performed in a good and workmanlike manner in accordance with all Applicable Laws, and in accordance with all applicable zoning regulations and any covenants binding the owner personally or running with the Property upon which the Building is to be constructed.

(h) To the best of Landlord's knowledge, there is no physical or environmental condition existing in, on, under or surrounding the Premises that violates applicable Environmental Laws.

(i) To the best of Landlord's knowledge, there has been no release or threatened release of Hazardous Materials in, on, under or onto the Premises.

(j) To the best of Landlord's actual knowledge, there is no Contamination in, on, under or surrounding the Premises, including, without limitation, Contamination relating to the presence of PCBs, solvents, mold or microbial matter.

(k) To the best of Landlord's knowledge, there is no asbestos, asbestos-containing material or lead-based paint in, on or under the Premises or any of the structures situated thereon.

(l) To the best of Landlord's knowledge, there is no condition existing in, on, under or surrounding the Premises that could reasonably be expected to result in a soil vapor intrusion or other indoor air quality in any present or future structure(s) on the Premises.

Landlord agrees to indemnify, defend, and hold Tenant and Tenant Entities free and harmless from and against all losses, liabilities, obligations, penalties, claims, litigation, demands, defenses, costs, judgments, suits, proceedings, damages (including consequential damages), disbursements or expenses of any kind (including reasonable attorneys' fees and investigation costs, whether defending or prosecuting any litigation, claim or proceeding) that may be imposed upon, incurred by, or asserted or awarded against Tenant in connection with or arising from or out of (i) any physical or environmental condition existing in, on, under or surrounding the Premises as of the Effective Date or the Lease Commencement Date, including, without limitation the presence of any Contamination or Hazardous Materials, (ii) any breach by Landlord of any covenant or obligation contained in this Section 22.5 and/or (iii) any Contamination or violation of any Environmental Law not directly caused by Tenant, the Tenant Entities or one acting on Tenant's behalf and at Tenant's direction.

23. HOLD OVER TENANCY

Provided that no Tenant Default then exists, if, without the execution of a new lease or nine (9) months prior written extension notice to Landlord, Tenant shall hold over after the expiration of the Lease Term, Tenant shall have the right to retain possession of the Premises for up to one hundred thirty-five (135) days after expiration of the Lease Term without the possibility of eviction and upon the same terms and conditions of the Lease; *provided*, *however*, that during such tenancy, Tenant agrees to pay to Landlord 125% of the monthly installment of Base Rent which was payable in the month immediately preceding the month in which the expiration or termination occurs ("***Preceding Rent***"). If Tenant remains in possession of the Premises after such 135-day holdover period, Tenant shall pay, as liquidated damages for each day of such hold over period, 150% of the Preceding Rent and the hold over period will constitute a month-to-month tenancy which may be terminated by Landlord or Tenant upon thirty (30) days prior written notice to the other. Notwithstanding anything herein to the contrary, if: (i) Tenant holds over after the expiration or termination of the Term for a period of time in excess of the aforementioned 135-day period; ***and*** (ii) Landlord has executed a lease with another tenant ("***Replacement Tenant***") whereby Landlord has agreed to lease some or all of the Premises to such Replacement Tenant; ***and*** (iii) Landlord provides written notice to Tenant, prior to the expiration of the aforementioned 135-day period, that a lease has been fully executed with a Replacement Tenant for some or all of the Premises; ***and*** (iv) such Replacement Tenant terminates its lease with Landlord as a direct consequence of Tenant's holding over at the Premises beyond the one hundred thirty-fifth (135th) day after the expiration or earlier termination of the Term; ***then***, in the event each of the foregoing criteria are met, Tenant shall be liable to Landlord for liquidated damages in an amount equal to the "base rent" payable by Replacement Tenant to Landlord for the first six (6) months (without taking into account any free rent or other tenant concessions) of the lease that was terminated by Replacement Tenant due to Tenant's holding over at the Leased Premises beyond such 135-day period. Tenant acknowledges that (x) Landlord shall suffer an adverse impact on its business if a Replacement Tenant terminates a lease for some or all of the Premises as a result of Tenant's holding over in excess of such 135-day period, and (y) the resulting damages to Landlord may not be susceptible of precise determination (in particular, as the period of time that the Premises may remain vacant after a Replacement Tenant terminates its lease, and the eventual rent to be received by Landlord in a future lease for some or all of the Premises, are unable to be ascertained with certainty). Tenant therefore acknowledges that the liquidated damages described above is a reasonable approximation of Landlord's damages for such holding over, and such liquidated damages shall not be deemed to be a penalty. No such holding over shall be deemed to constitute a renewal or extension of the Lease Term.

24. CONDEMNATION

If the whole or any part of the Premises shall be taken under the power of eminent domain, then the Lease shall terminate as to the part taken on the day when Tenant is required to yield possession thereof, and Landlord, to the extent of the condemnation award, shall, using its best efforts to minimize the interference with Tenant's business operations, make such repairs and alterations as may be necessary in order to restore the part not taken to useful condition. The Base Rent shall be reduced proportionately as to the part of the Premises taken, the reduction to be effective on the date that Tenant is required to yield possession. If the amount of the Premises so taken is such as to impair substantially the usefulness of the Premises for the purposes for which the same are hereby leased, then either party shall have the option to terminate this Lease as of the date when Tenant is required to yield possession. All compensation awarded for such taking of the fee and the leasehold shall belong to and be the property of Landlord; *provided*, *however*, that Tenant shall be entitled to such award as may be allowed for moving expenses, fixtures and other equipment installed by it (specifically excluding fixtures, alterations, additions and other components of the Leased Premises which under this Lease or by law are or at the expiration or earlier termination of the Lease Term will become the property of Landlord) and any other compensation allowed under the laws of the Commonwealth of Pennsylvania, but only if such award or other compensation shall be in addition to the award otherwise available to or for the benefit of Landlord.

25. TENANT'S LIMITED PURCHASE OPTION

(a) So long as a Tenant Default does not then exist, Tenant (or an affiliate of Tenant) shall have the option ("***Purchase Option***") to purchase the Building and the Improvements and take a corresponding assignment of Landlord's rights under the Landlord Ground Lease ("***Option Property***") for $[**] which Purchase Option may be exercised by Tenant at any time prior to the date that is [**] ([**]) days after the Initial Delivery Date (the "***Outside Exercise Date***") by delivering written notice of Tenant's exercise of the Purchase Option ("***Purchase Notice***") to Landlord. In the event Tenant does not provide a written Purchase Notice on or before the Outside Exercise Date, it shall be deemed that Tenant has waived its Purchase Option and Landlord shall then have the right to market and sell or transfer any or all of the Option Property at its sole discretion; *provided*, *however*, that Landlord's right to then market and sell or transfer any or all of the Option Property is subject in all respects to Tenant's ROFO described in Section 26 below.

(b) If Tenant provides Landlord with the Purchase Notice in accordance with Section 25(a) above, Landlord and Tenant shall, within [**] ([**]) days after Tenant's delivery of the Purchase Notice, enter into a commercially reasonable purchase and sale agreement containing typical representations and warranties for the sale of commercial property to be prepared by Tenant or its counsel and which shall reflect, among other things:

(i) the purchase price set forth in Section 25(a) above;

(ii) that Tenant's Security Deposit and the dollar value of any Rent abatements rights accrued under the second paragraph of Section 1.9 above shall be applied toward the purchase price for the Option Property;

(iii) that Landlord shall convey title to the Option Property via commercially reasonable assignment and sale documents, free and clear of all objectionable title encumbrances as reasonably determined by Tenant and its title insurer (*provided*, *however*, that the Landlord Ground Lease shall not be considered an objectionable title encumbrance);

(iv) Tenant shall have thirty (30) days after execution of the purchase agreement for the Option Property to perform due diligence on the Option Property;

(v) that the closing on Tenant's acquisition of the Option Property shall occur on the later to occur of (1) the date that is [**] ([**]) days after the conclusion of Tenant's due diligence period review period set forth in such purchase and sale agreement and (2) the date upon which Landlord achieves Substantial Completion of the Landlord's Work (subject to the completion of any Punch List Items, which may be completed after such closing in accordance with the terms set forth in the Work Letter);

(vi) that Landlord and Tenant shall each be responsible for one half of any and all transfer taxes incurred in connection with the closing on Tenant's acquisition of the Option Property;

(vii) that Landlord and Tenant shall pro rate all Taxes related to the Option Property and other items customarily pro-rated at the closing of similar real estate transactions in Allegheny County, Pennsylvania; and

(viii) upon the closing of this sale transaction, this Lease shall terminate and the parties shall have no further rights, duties or responsibilities hereunder, except as otherwise expressly provided herein.

(c) If Landlord either fails to keep, observe, and perform any terms, covenants, conditions or provisions of this Section 25, such failure could irreparably harm Tenant's business interests and shall be deemed to be a "Landlord Default" under this Lease. Upon the occurrence of a Landlord Default under this Section 25(c) then, in addition to the remedies set forth in Section 20.2 above, Tenant shall be entitled to seek specific performance of Landlord's obligations set forth in this Section 25, and Landlord shall reimburse Tenant for all costs and expenses incurred in connection with Tenant's pursuit of specific performance hereunder.

26. TENANT'S RIGHT OF FIRST OFFER TO PURCHASE

Beginning after the expiration of the [**] ([**]) complete calendar month of the Lease Term and continuing until the expiration of the Lease Term ("***ROFO Period***"), so long as a Tenant Default does not then exist, Tenant, together with its successors, assigns and affiliates, shall have the ongoing right of first offer to assume the Landlord Ground Lease and purchase the Option Property ("***ROFO***") on the following terms and conditions:

(a) If, during the ROFO Period, Landlord decides to offer to sell (or is otherwise in the process of offering or selling) the Option Property or any portion thereof to a third party (excluding the Landlord Transferees defined herein, a "***Third Party Buyer***") or receives an unsolicited bona fide offer to purchase the Option Property from a Third Party Buyer, including by means of a sale directly or indirectly of the partnership interests, membership interests, stock, or other equity interests of Landlord or by means of a merger of Landlord, Landlord shall send written notice to Tenant ("***Offer***"), which Offer shall set forth the terms on which Landlord would be willing to consummate the sale of the Option Property, including all material economic terms and conditions thereof ("***Material Terms***"), and which Material Terms shall include, without limitation, the proposed sale price, the proposed timing for sale and the property which will be offered for sale (as applicable, "***Offer Property***"). Landlord agrees to bargain in good faith on any terms not stated in the Offer.

(b) Within [**] ([**]) days after receipt of the Offer, Tenant shall reply by written notice to Landlord either accepting to purchase the Offer Property on the Material Terms set forth in the Offer or rejecting the Offer. Tenant's failure to respond within such [**]-day period shall be deemed a rejection of the Offer. If Tenant timely accepts the Offer for the Offer Property, then Landlord and Tenant shall endeavor to promptly, but in any case within [**] ([**]) days after Tenant's notice of acceptance of the Material Terms set forth in the Offer, execute a commercially reasonable purchase and sale contract incorporating the Material Terms set forth in the Offer. If Tenant rejects, or is deemed to have rejected, such Offer, Landlord shall have the right to consummate a sale with a Third Party Buyer for the Offer Property within the [**]-day period commencing on the date that Tenant rejects (or is deemed to have rejected) the Offer, upon the Material Terms set forth in the Offer and for a purchase price not less than [**] ([**]) of the purchase price stated in the Offer, free and clear of Tenant's ROFO set forth in this Section 26; *provided*, *however*, that any such transfer shall be subject to this Lease. If, however, a sale of the Offer Property is not consummated with a Third Party Buyer within the [**]-day period commencing on the date that Tenant rejects (or is deemed to have rejected) the Offer, Landlord shall provide written notice to Tenant of such fact and Tenant's ROFO set forth in this Section 26 shall automatically be revived and thereafter continue in full force and effect, and Landlord shall thereafter re-offer the applicable Offer Property to Tenant upon any subsequent decision by Landlord to offer to sell the Option Property or any portion thereof to a Third Party Buyer. Furthermore, if, during any such [**]-day period, Landlord offers the Offer Property to a Third Party Buyer (i) for a sales price that is less than [**] ([**]) of the purchase price stated in the Offer, or (ii) upon terms or conditions that are more favorable to a Third Party Buyer than the Material Terms set forth in the Offer as determined by Tenant in its reasonable discretion, then in either event Landlord shall re-offer the Offer Property to Tenant on the terms offered to such Third Party Buyer and said re-offering shall constitute a new "Offer" and trigger the procedures and timelines set forth above as if said re-offer was a new Offer for purposes of this Section 26.

(c) In the event Tenant rejects or is deemed to have rejected any Offer provided to Tenant in accordance with Section 26(b) above, in no event shall such rejection or deemed rejection constitute a waiver with respect to (i) Tenant's right to receive written notices from Landlord with respect to a sale not consummated within the [**]-day period described above or with respect to a re-offering required pursuant to the terms set forth above, or (ii) Tenant's ongoing ROFO to purchase all or any portion of the Option Property in accordance with the terms set forth in this Section 26.

(d) Notwithstanding anything to the contrary in this Section, nothing in this Section shall restrict Landlord from transferring the Landlord Ground Lease or transferring or selling the entire Option Property at any time to a wholly owned subsidiary of Landlord or the parent of Landlord, or for purposes of placing a mortgage or deed of trust on the Premises in connection with financing or refinancing of the Premises by Landlord (any of which is a "***Landlord Transferee***").

(e) If Landlord either fails to keep, observe, and perform any terms, covenants, conditions, or provisions of this Section 26, such failure could irreparably harm Tenant's business interests and shall be deemed to be a "Landlord Default" under this Lease. Upon the occurrence of a Landlord Default under this Section 26(e) then, in addition to the remedies set forth in Section 20.2 above, Tenant shall be entitled to seek specific performance of Landlord's obligations set forth in this Section 26, and Landlord shall reimburse Tenant for all costs and expenses incurred in connection with Tenant's pursuit of specific performance hereunder.

27. NOTICES

Whenever in this Lease it shall be required or permitted that notice, approval, advice, consent or demand be given or served by either party to this Lease to or on the other, such notice or demand shall not be deemed to have been duly given or served unless in writing and forwarded by certified or registered mail, or by a nationally recognized overnight or locally recognized same-day delivery service to the Landlord's and Tenant's addresses set forth in Sections 1.2, and 1.4, respectively, of this Lease (or such other address as may be given by one party to the other pursuant to this Section), or upon the receipt of an email during normal business hours, addressed in all cases to the party at his or its address set forth in Section 1.2 and Section 1.4 above.

28. RIGHTS RESERVED BY LANDLORD / FORCE MAJEURE

Subject in all respects to the other terms set forth in this Lease (including, without limitation, in Section 9 above), Landlord reserves the following rights, each of which Landlord may exercise with notice to Tenant and without liability to Tenant, and the exercise of any such rights shall not be deemed to constitute an eviction or disturbance of Tenant's use or possession of the Premises and shall not give rise to any claim for set-off or abatement of Rent or any other claim: (a) to retain at all times, and to use in appropriate instances, keys to the main entry doors within and into the Premises; (b) to inspect the Premises at reasonable times and upon reasonable notice; (c) to install, use and maintain in and through the Premises, pipes, conduits, wires and ducts serving the Building, provided that such installation, use and maintenance does not unreasonably interfere with Tenant's use of the Premises; and (d) to take any other reasonable action in connection with the Landlord's performance of its obligations set forth in this Lease.

The term "***Force Majeure***" as used in this Lease means and refers to acts of God, riots, labor strikes (other than strikes of workers, contractors, and suppliers), acts of a public enemy, governmental embargo restrictions, or other events or delays that are beyond Landlord's or Tenant's (as the case may be) reasonable control, including, but not limited to, actions or inactions on the part of public utilities or local, state or federal governmental authorities, provided that Landlord or Tenant (as the case may be) has timely made appropriate applications or requests of and to such authorities and has diligently pursued the same. The term Force Majeure will not, however, include any lack of available funds that may otherwise be required for performance of any obligation hereunder.

29. MISCELLANEOUS PROVISIONS

29.1. Term "Landlord"

The term "***Landlord***" as used in this Lease so far as covenants or obligations on the part of Landlord are concerned shall be limited to mean and include only landlord at the time in question of the Premises and in the event of any transfer or transfers of the title to the Premises, upon Tenant's receipt of documentation signed by any such new landlord, evidencing that any such new landlord has assumed, in writing, all of Landlord's obligations and liabilities under this Lease, Landlord herein named (and in case of any subsequent transfers or conveyances, the then Landlord) shall be automatically freed and relieved from and after the date of such transfer or conveyance of all liability as respect to the performance of any covenants or obligations on the part of Landlord contained in this Lease thereafter to be performed.

29.2. Captions of Paragraphs

The captions of the paragraphs in this Lease are for convenience only and shall not be considered or referred to in resolving questions of interpretation or construction.

29.3. Terms "Landlord" and "Tenant"

The terms "***Landlord***" and "***Tenant***" wherever used herein shall be applicable to one or more persons, as the case may be, and the singular shall include the plural, and the neuter shall include the masculine and feminine, and if there be more than one, the obligations hereof shall be joint and several.

29.4. Words "person" and "persons"

Both the word "***person***" and the word "***persons***" wherever used in this Lease shall include individuals, partnerships, firms, associations and corporations or any other form of business entity. In the event that two or more individuals, corporations, partnerships or other business associations (or any combination of two or more thereof) shall sign this Lease as Tenant, the liability of each such individual, corporation, partnership or other business association to pay Rent and perform all other obligations hereunder shall be deemed to be joint and several. In like manner, in the event that Tenant named in this Lease shall be a partnership or other business association the members of which are, by virtue of statute or general law, subject to personal liability, then in the event, the liability of each such member shall be deemed to be joint and several.

29.5. Rights, Options, Election, Powers and Remedies

The various rights, options, elections, powers and remedies contained in this Lease shall be construed as cumulative and no one of them shall be exclusive of any of the others, or of any other legal or equitable remedy which either party might otherwise have in the event of breach or default in the terms hereof, and the exercise of one right or remedy by such party shall not impair its right to any other right or remedy until all obligations upon the other party have been fully performed.

29.6. Financial Statements

Tenant hereby acknowledges that it has provided Landlord with the ability to publicly access Tenant's financial statement(s) prior to the date hereof as a primary inducement to Landlord's agreement to lease the Premises to Tenant, and that Landlord has relied on the accuracy of said financial statement(s) in entering into this Lease. Tenant represents to the best of its knowledge and belief that the information contained in said financial statement(s) is true, complete and correct in all material aspects. Only in the event Tenant is no longer a publicly traded company or Tenant's financial statements are not publicly available to Landlord at no cost, during the Lease Term, within ten (10) business days of receipt by Tenant of Landlord written request therefor, Tenant shall furnish to Landlord a balance sheet of Tenant as of the end of the most current fiscal period and a statement of income and expense for that same period, along with a certificate of the chief financial officer, owner or partner of Tenant to the effect that to the best of their knowledge and belief the financial statements have been prepared in conformity with generally accepted accounting principles consistently applied and fairly present the financial condition and results of operations of Tenant as of and for the period covered. Landlord agrees to keep confidential and not disclose to any person or entity any financial information furnished by Tenant, except that Landlord may disclose such information to its attorneys, lenders, potential purchasers, partners and financial advisors.

29.7. Time

Time is of the essence with respect to the performance of each of the covenants and agreements under this Lease.

29.8. Provisions Binding

Each and all the provisions of this Lease shall be binding upon and inure to the benefit of the parties hereto and, except as otherwise specifically provided elsewhere in this Lease, their respective heirs, executors, administrators, successors and assigns, subject at all times, nevertheless, to all agreements and restrictions contained elsewhere in this Lease with respect to the assignment, transfer, encumbering or subletting of all or any part of Tenant's interest in this Lease.

29.9. State Law

This Lease shall be interpreted in accordance with the laws of the Commonwealth of Pennsylvania.

29.10. Covenants and Agreements

This Lease contains all covenants and agreements between Landlord and Tenant relating in any manner to the rental, use and occupancy of the Premises and the other matters set forth in this Lease. No prior agreement or understanding pertaining to the same shall be valid or of any force or effect, and the covenants and agreements of this Lease cannot be altered, changed, modified or added to except in writing signed by Landlord and Tenant. No representation, inducement, understanding or anything of any nature whatsoever made, stated or represented on Landlord's behalf, either orally or in writing (except as expressly set forth in this Lease), has induced Tenant to enter into this Lease.

29.11. Invalid or Illegal Provisions

Any provision or provisions of this Lease which shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision hereof, and the remaining provisions hereof shall nevertheless remain in full force and effect.

29.12. Effective Date of Conditions, Covenants and Agreements

Except with respect to those conditions, covenants and agreements of this Lease which by their nature could only be applicable after the commencement of, during or throughout the Lease Term, all of the other conditions, covenants and agreements of this Lease shall be deemed to be effective as of the Effective Date.

29.13. Lease Commissions

Tenant and Landlord each represents and warrants for the benefit of the other that they have not engaged any broker, finder or other person, other than CBRE, Inc. ("***CBRE***") representing both Landlord and Tenant as a dual agent. Landlord shall be responsible for the payment of any commission or fee to CBRE in respect of the negotiation, execution of delivery of this Lease, and Landlord and Tenant shall each indemnify the other against loss, cost, liability or expense incurred by either party as a result of any claim asserted by any broker, finder or other person on the basis of any arrangement or agreement made or alleged to have been made by or on behalf of the other party.

29.14. Relationship of Landlord and Tenant

Nothing contained herein will be deemed or construed by the parties hereto, nor by any third party, as creating the relationship of principal and agent or of partnership or of joint venture between the parties hereto, it being understood and agreed that neither the method of computation of Rent, nor any other provision contained herein nor any acts of the parties herein, shall be deemed to create any relationship between the parties hereto other than the relationship of Landlord and Tenant.

29.15. Recording of Memorandum of Lease

Landlord and Tenant each hereby agrees that it will not record this Lease; *however*, a Memorandum of Lease in the form attached hereto as Exhibit H ("***MOL***") shall be executed by Landlord and Tenant simultaneously with this Lease and Landlord will, at its expense, thereafter promptly cause the MOL to be recorded in the Allegheny County Department of Real Estate (in any case within seven (7) days of the Effective Date). Failure by Landlord to timely record such MOL shall be Landlord Default hereunder, without application of any cure period in respect thereof.

29.16. Submission of Lease

The submission of this Lease, whether in blank form or with all or some of the blanks herein completed, shall not vest in Tenant any rights with respect to the Premises or the Building or be deemed, in any respect, to be binding upon Landlord. Until both Landlord and Tenant have executed this Lease, Tenant shall not be deemed to have acquired any rights with respect to the Premises or the Building.

29.17. Counterparts

This Lease may be executed and delivered in counterparts, each of which shall be deemed an original and all of which, when taken together, shall constitute one and the same instrument. Furthermore, the undersigned agree that electronic transmission of this Lease by e-mail, facsimile or telecopy shall be deemed transmission of the original Lease for all purposes.

29.18. Representations on Authority of Parties/Signatories

Each person signing this Lease represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Lease. Each party represents and warrants to the other that the execution and delivery of the Lease and the performance of such party's obligations hereunder have been duly authorized and that the Lease is a valid and legal agreement binding on such party and enforceable in accordance with its terms.

29.19. Personal Liability

Landlord, and any person, firm, or corporation comprising Landlord shall not have any personal liability with respect to any of the provisions of this Lease. Tenant's sole recourse shall be against the Building, and the real and personal property comprising the same for the satisfaction of any of the Tenant's claims and remedies. No partner, member or shareholder of Tenant, nor any director, officer, employee or other party with interests in Tenant or any such partner, member or shareholder of Tenant shall be subject to personal liability hereunder.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease to be effective as of the above date, but actually on the dates set forth below.

LANDLORD:

NORTHFIELD I, LLC,
an Ohio limited liability company

By: Al. Neyer, LLC
an Ohio limited liability company,
its Manager

By: _____
Stephanie P. Gaither,
Sr. Vice President & CFO

STATE OF OHIO)
)
COUNTY OF HAMILTON)

SS:

The foregoing instrument was acknowledged before me this ___ day of December, 2019, by Stephanie P. Gaither, Sr. Vice President & CFO, of Al. Neyer, LLC, an Ohio limited liability company, the Manager of Northfield I, LLC, an Ohio limited liability company, on behalf of such company.

_____
Notary Public

[TENANT'S SIGNATURE PAGE FOLLOWS]

TENANT:

KRYSTAL BIOTECH, INC.,
a Delaware corporation

By: _____
Krish S. Krishnan,
President and Chief Executive Officer

STATE OF _____ **)**
) SS:
COUNTY OF _____ **)**

The foregoing instrument was acknowledged before me this ____ day of December, 2019, by Krish S. Krishnan, President and Chief Executive Officer of Krystal Biotech, Inc., a Delaware corporation, on behalf of such corporation.

_____
Notary Public

EXHIBIT A

Site Plan of Premises

[See attached.]

EXHIBIT A-1

Property Legal Description

All that certain lease area being a part of lands now or formerly of The Allegheny County Airport Authority, situate in the Township of Findlay, County of Allegheny and Commonwealth of Pennsylvania, being more particularly bounded and described as follows:

Beginning at a point on the southerly line of Halverson Road, a sixty-eight (68) foot road, said point being the northerly corner of the parcel herein conveyed and intersection with lands now or formerly of The Allegheny County Airport Authority; thence from beginning through lands now or formerly The Allegheny County Airport Authority the following four (4) courses and distances:

1. S 84°13’31” E a distance of 76.33 feet to a point;

2. S 03°26’54” E a distance of 921.81 feet to a point;

3. N 86°26’37” W a distance of 558.89’ feet to a point;

4. N 03°26’54” E a distance of 723.36 feet to a point on the southerly line of Halverson Road;

thence along Halverson Road S 86°33’46” E a distance of 192.68 feet to a point; thence by same with an arc having a curve to the left, having a radius of 309.00 feet, an arc length of 375.10 feet to a point the northerly corner of the parcel, at the point of beginning.

Containing an area of 10 acres.

EXHIBIT B

WORK LETTER

The terms, definitions, and other provisions of the Lease are hereby incorporated into this Work Letter by reference as if set forth in full. In the event of any inconsistencies between this Work Letter and the provisions of the Lease, the provisions of this Work Letter shall control. Capitalized terms used herein but not otherwise defined herein shall have the meanings ascribed to such terms in the Lease.

IN CONSIDERATION OF the execution of the Lease and the mutual covenants and conditions hereinafter set forth, the parties agree that this Work Letter and the terms hereof shall apply to the completion of Landlord's Work.

1. **CONSTRUCTION OF THE BUILDING**

Landlord, by and through Al. Neyer, LLC, an Ohio limited liability company ("***Contractor***"), shall promptly construct the Building in an effort to achieve Substantial Completion on or before the Estimated Lease Commencement Date.

2. **LANDLORD'S WORK**

Landlord's Work shall include the planning, designing and construction of the Landlord's Work, including the Building, in accordance with the Plans and Specifications attached hereto as Exhibit B-1 and in accordance with all Applicable Laws including, but not limited to, all applicable building codes. In addition, Landlord's Work shall include the (i) procurement of all permits and approvals necessary for the development and construction of the Landlord's Work required by any governmental agency having jurisdiction over the development and construction of the Landlord's Work; (ii) coordination of architectural and engineering services necessary for the construction of the Building; (iii) site preparation, construction and providing labor, supplies, materials and equipment and such other services required to be furnished and performed in accordance with the Plans and Specifications necessary to complete the Landlord's Work; and (iv) if not precluded by the scope of Tenant's Work remaining to be completed as of the time Landlord has achieved Substantial Completion of Landlord's Work, procurement of a certificate of occupancy from the applicable governmental authorities permitting Tenant to occupy the Premises upon Substantial Completion of the Landlord's Work.

3. **COST OF LANDLORD'S WORK**

Landlord's Work shall be completed at Landlord's sole cost and expense, except that Tenant shall fund Tenant's Cash Contribution (as defined below) in accordance with the following:

a. On or before the date Landlord closes on its construction loan with respect to the Premises, and in any case upon no less than ten (10) days' prior written notice from Landlord to Tenant, Tenant shall deposit with TriState Capital Bank (the "***Escrow Agent***") the sum of Two Million Four Hundred Thousand Dollars ($2,400,000.00) ("***Tenant's Cash Contribution***"), which amount shall be applied against the first $2,400,000.00 of hard costs associated with Landlord's Work.

b. Landlord and Tenant agree that, on or before the date Landlord closes on its construction loan with respect to the Premises, Landlord, Tenant and the Escrow Agent shall enter into a commercially reasonable escrow agreement (the "***Escrow Agreement***") pursuant to which an escrow account shall be established with the Escrow Agent, for the collection of Tenant's Cash Contribution and disbursement thereof for the first $2,400,000.00 of hard costs associated with Landlord's Work. In no event shall Tenant be obligated to make Tenant's Cash Contribution until the Escrow Agreement has been fully executed by Landlord, Tenant and the Escrow Agent, and a fully executed copy thereof has been provided to Tenant. The Escrow Agreement shall provide, among other things, the manner in which draws may be made from the escrow account established thereby.

c. Landlord and Tenant hereby acknowledge and agree that Tenant's Cash Contribution shall not cover the entire cost of Landlord's Work, but rather is intended to reduce the amount of Landlord's equity and debt required in order to accomplish the construction of Landlord's Work hereunder.

4. **PLANS; CHANGES TO PLANS**

a. Construction Plans: Landlord's Work shall be constructed in accordance with the Plans and Specifications.

b. Changes to Plans and Specifications:

i. No material change to the Plans and Specifications shall be made by Landlord or Tenant unless such change is first approved in writing by both parties, which approval shall not be unreasonably withheld, conditioned or delayed ("***Change Order***"). Provided a Change Order is reasonably acceptable to Landlord, Landlord shall prepare and submit promptly to Tenant a memorandum setting forth the impact on cost and the Schedule resulting from said Change Order ("***Change Order Memorandum***"). Tenant shall, within three (3) days following Tenant's receipt of a Change Order Memorandum, either (a) execute and return the Change Order Memorandum to Landlord, (b) retract its request for the Change Order, or (c) revise the original request for the Change Order.

ii. At Landlord's option, Tenant shall pay to Landlord (or Landlord's designee), within thirty (30) days following Landlord's request, any increase in the cost of Landlord's Work resulting from a Change Order, as set forth in the applicable Change Order Memorandum.

iii. In the event of any decrease in the cost of Landlord's Work resulting from a Change Order, as set forth in the applicable Change Order Memorandum, Base Rent will proportionately adjust to account for any such decreases, which adjustment shall be equal to the product of (x) a rent constant equal to Eight and 25/100 Percent (8.25%) *multiplied by* (y) the amount of the actual decrease to the cost to perform Landlord's Work due to any such Change Order. All adjustments to Base Rent resulting from Change Orders that decrease the cost of Landlord's Work – as well as the corresponding adjustment to the Purchase Price for Tenant's exercise of the Purchase Option – shall be memorialized in the Lease Commencement Date Memorandum attached to the Lease as Exhibit C.

iv. Landlord shall not be obligated to commence any work set forth in a Change Order until such time as Tenant has delivered to Landlord the executed Change Order Memorandum associated with such Change Order and Tenant has paid Landlord in full, at Landlord's discretion, for said Change Order.

v. Upon receipt of a request from Tenant to Landlord to make a material change to the Plans and Specifications ("***Proposed Tenant Change***"), Landlord shall cause the Contractor, within fourteen (14) days of receipt of same, to promptly estimate the effect on cost and schedule in completing the Proposed Tenant Change, if any, and to report such estimate to Landlord who is responsible for in turn reporting the estimate to Tenant. Prior to Landlord implementing a Change Order for the purpose of effectuating a Proposed Tenant Change, Tenant must agree, in writing, within three (3) business days after delivery of the estimated cost and delay from Landlord, to pay any increased costs of Landlord's Work associated with such Proposed Tenant Change. Contractor shall proceed with Landlord's Work, excluding any Proposed Tenant Change, pending the consideration of said Proposed Tenant Change. Any actual delay in Landlord's Work caused by a Proposed Tenant Change shall constitute a Tenant Delay. No Proposed Tenant Change shall be deemed approved until Tenant notifies Landlord in writing of Tenant's willingness to accept responsibility for a Tenant Delay, if any, which arises from such Proposed Tenant Change as specifically delineated by Landlord. Tenant shall have the right to withdraw any requested Proposed Tenant Change if Tenant is unwilling to pay any increased costs or accept responsibility for a Tenant Delay associated with the Proposed Tenant Change.

vi. If a Change Order is necessitated by Landlord's failure to complete the Landlord's Work in accordance with the Plans and Specifications or any other act or omission of Landlord or Contractor, Landlord shall be responsible for all of the reasonable costs associated with such Change Order and the delay resulting from such Change Order, if applicable.

4. **PUNCHLIST**

The term "***Punch List Items***" shall mean details of construction, decoration, and mechanical adjustment which, in the aggregate, are minor in character and do not interfere with the Tenant's use or enjoyment of the Premises. Punch List Items shall be identified by Tenant within a reasonable time after Substantial Completion and completed by Landlord as soon as reasonably practical and no later than thirty (30) days after Tenant identifies the Punch List Items. Landlord shall be granted reasonable rights of access to the Premises after Substantial Completion for the purposes of completing such Punch List Items provided that Landlord shall use its reasonable efforts to cause as little interference with Tenant's Work, and otherwise with Tenant's use and occupancy of the Premises, as reasonably possible. All Punch List Items shall be completed by Landlord (or Contractor, at Landlord's direction) to the reasonable satisfaction of Tenant, irrespective of whether said Punch List Items have been completed as of the date upon which Tenant closes on its acquisition of the Option Property in accordance with Section 25 of the Lease, if applicable.

5. **COOPERATION**

Throughout the entire process of completing the construction of the Building, Landlord and Tenant shall cooperate with the other to promptly provide any additional information and details and to respond promptly to any requests reasonably requested by the other party regarding such construction. Each party shall consider reasonable alternatives and solutions to any disputed elements in the construction and act in a timely manner with reasonable cooperation to provide maximum flexibility in completing the construction.

6. **DRAWINGS AND AUTOCAD FILES**

Landlord shall provide Tenant with electronic files of all architectural, construction and subcontractor drawings of the leased Premises within Sixty (60) days following the Commencement Date. These files may be used solely in connection with the Building and the Premises. Landlord shall provide Tenant with a complete set of the Plans and Specifications and as-built drawings (including space planning, architectural, mechanical, engineering, electrical and plumbing) with respect to the Premises within thirty (30) day of the Lease Commencement Date.

EXHIBIT B-1

Plans and Specifications for Landlord's Work

Items defined below as specific scope items relative to the Base Building are considered scope that is included in Base Building cost and not part of the $60/SF TI Office Allowance. Any unused portion of allowance could be used to offset other Tenant related FFE.

Included in this project are the following:

1. Complete plans and specifications.
   a. Architectural (for Base Building – TI Design will be part of TI Allowance)
   b. Structural engineering
   c. Civil engineering
   d. Design build mechanical and electrical engineering (for Base Building – TI Design will be part of TI Allowance)

2. Building permit and tap fees for potable and sanitary service. Additional Electrical and Gas related fees (if any) associated with Utility Company evaluation/installation of enhanced Gas or Electric Service are not included.

3. General condition items:
   a. Field and office supervision
   b. Temporary facilities and controls
   c. Progress and final clean up
   d. Liability insurance including Builder's Risk
   e. Layout

4. Excavation & Site Utilities
   a. Al. Neyer will perform all cut/fill soil operations and fine grading to bring grades from existing condition to proposed grades.
   b. On site utilities
      1) Storm piping and structures piped to existing storm detention system.
      2) Water (for fire protection and domestic) shall enter the building at a point to be determined by the engineer.
      3) Sanitary sewer shall enter the building from existing sanitary manhole on site. Invert Elevation for Sanitary will allow for Sanitary to be run approximately midway through the building at 1% slope. More remote sanitary can be accommodated with 8 inch line run at 0.5% slope. Final design to be coordinated with Tenant.
      4) Gas piping to be extended by the service provider into the building. People's Gas – See note above on fees.
      5) Electric and phone/data shall enter the building on the dock side.

5. Asphalt paving
   a. Heavy duty for main drive and entire paved dock area. Heavy duty design is made of 8" of limestone subbase + 4" asphalt binder course + 1.5" asphalt wearing course.
   b. Light duty is included for the parking lot and road connecting to main drive. Light duty design is made of 6" of limestone subbase + 2.5" asphalt binder course + 1.5" asphalt wearing course.

6. Landscaping per Township requirements.

7. Concrete building foundations shall consist of conventional perimeter strip footings, and isolated column pads using 3,000psi concrete.

8. Exterior concrete.
   a. 7” unreinforced concrete over 4” of compacted gravel base extending 60’ from the dock wall of the building.
   b. 4” concrete sidewalk with turn down curb as shown.
   c. Asphalt wedge curb at car parking lot only. There are no curbs around perimeter of concrete paving.
   d. Concrete Equipment Pad 52’ x 52’, including concrete drive aisle as well as a 12’ tall privacy fence and access via two-man gates and two large equipment swing gates – Design of Slab will support 23,000 lb storage tank.

9. The building slab-on-grade at the office space includes 7” concrete reinforced with poly fibers at a rate of 1.5 #/cy on a 6” compacted limestone base. The SOG will receive an Ashford Sealer or equal 10 mil vapor barrier at the office areas. 13,985 sf of concrete is included for the office area. The rest of the slab on grade will be left out for future installation by tenant. The cement stabilized subbase will be prepared at 13 inches below finished floor to allow for Tenant utility rough in work followed by 6” of stone and 7’ inches of concrete by Tenant

10. Load bearing nominal 8” precast concrete wall panels per elevations finished with a textured paint system on exterior face. Interior face of concrete walls to remain unpainted. All exposed exterior wall joints shall be caulked. Exterior precast walls to have R-13 insulation and Building envelope will be designed to meet current Energy Code (Fabcon verscore + green panels).

11. Conventional steel framing system consisting of steel columns, girders, joists and deck; using approximately 50’-0” x 50’-0” bay spacing or as shown on floor plans:
   a. Single slope roof draining to dock side.
   b. Tube columns.
   c. Bar joists and joist girders.
   d. Metal roof deck (underside) to be prime painted white.
   e. 40’ clear height in warehouse area (40 ft clear height will begin 61 ft in from dock wall – or 39’-0” clear from dock wall to, one-foot past speed bay column line).
   f. Joists are designed as KCS for allowance of up to 30psf worth of hanging loads. The 30PSF collateral can be applied up to a 2,000-pound point from bottom chord of joist. The quantity of points loads on an individual joist can exceed the uniform 30 PSF load. 30 PSF design applied to entire building with exception of current and future office area location and at dock bay.
   g. Four (4) roof frames for HVAC rooftop units.
   h. One (1) roof ladder with cage to be coordinated with Tenant at an interior location.
   i. Bollards to protect drive-in doors.
   j. (2) two galvanized dock stairs.
   k. (3) three dock pit frames.

12. The roof shall be a mechanically fastened .060” mechanically attached EPDM roof membrane system with a manufacturer’s 15-year material and labor warranty over R-30 (or, as required by code) 3.8” polyiso insulation. Roofing shall include prefinished gutters and downspouts draining at rear dock elevations as indicated on drawings.

13. Exterior insulated hollow metal egress doors and frames with medium duty hardware as shown on plans. Doors requiring vision lights to be coordinated with Tenant.

14. Aluminum framed storefront system as shown on elevations consisting of anodized aluminum finish, medium stile, and 1” tempered clear glass. Approximately 2,300 SF of glass is included.

15. Painting includes:

a. Exterior of precast wall panels to include one (1) coat of LOXON primer + one (1) coat of textured medium Sherwin Williams finish paint.

b. Paint all HM doors and frames.

16. Overhead doors and equipment include:

a. Five (5) 9’ x 10’ insulated manual overhead dock door capable of air curtain in the future.

b. Two (2) 12’ x 14’ insulated automatic overhead drive in doors.

c. Three (3) dock seals.

d. Three (3) 40” double arm incandescent dock lights.

e. Three (3) 6’ x 8’, 30,000 lb mechanical dock levelers.

f. Three (3) dock locks.

17. Plumbing system includes:

a. Approximately 600 lineal feet of 8” sanitary piping run underground along 1st interior column bay with clean outs every 50 feet. Final configuration TBD.

b. Approximately 660 lineal feet 4” insulated water line run overhead from a point 1’-0” AFF in the meter room located on the south side and then extended up to the underside of the roof deck above. Includes two hose bibs. Final configuration TBD.

c. Gas piping, 3 “ (3 psig) run from the meter inside the building, up to the roof.

18. Fire protection system shall be installed in the new warehouse as an ESFR K-17 system with a fire pump. A fire hydrant is included on the office side of the building and a wall hydrant is included for the dock side of the building. Fire protection for Office space will be part of TI Allowance

a. Water storage tank for increased water pressure is not included.

19. Warehouse Heating and Ventilation:

a. Provide unit heaters (Reznor type or equivalent) adequate to maintain 50 deg F indoor air temperature with 0 deg F outside air temperature.

b. Includes gas piping to heaters.

20. Electric consists of the following:

a. Electric service to be 5,000 amp, 480/277V, 3 phase, 4-wire service with copper conductors from the utility in the street to the main electrical distribution panel located in the building. Ground bar to be provided. Provide a separate panel for exterior lighting.

b. Primary and secondary conduit to consist of (2) 5” conduit for electric, and (3) 5” for data/phone.

c. Warehouse interior lighting shall consist of one hi bay fixture per bay based on an open floor plan.

d. Power for unit heaters.

e. Power for two (2) overhead door operators.

f. Exterior lighting consisting of wall packs to meet zoning requirements and will be controlled by photocell. Light poles are included on the parking side of the building as required by code and controlled by Photocell and/or timer.

g. Emergency and exit lighting as required by code.

h. Fire alarm and/or sprinkler monitoring system as required by code.

<u>Tenant Specifications for Krystal Biotech included:</u>

a. 100,000 SF Warehouse which includes 13,985 sf interior office fit-out.

b. 200 car parking spots.

c. Office finish allowance of $839,100 included.

d. Pipe bollard protection included at overhead doors.

e. Levelers, bumpers, seals included on dock doors.

f. 5,000 amps at 277/480 volt - 3 phase power to be provided.

g. Clear height of 40 feet
h. LED Lighting included in warehouse, at 1 fixture per bay.
i. Unit heaters included in warehouse sufficient to heat entire building including above office space.

Clarifications

1. No interior tenant improvements other than outlined above.
2. Auxiliary Power Systems (UPS and Generator) are not included.
3. No special process related items are included.
4. Phone and data wiring are considered part of TI costs – Landlord provided TI will include Phone/data conduit rough in to be coordinated with Tenant.


KRYSTAL BIOTECH
PRELIMINARY DESIGN | FINDLAY TOWNSHIP, PA | 04 DEC 2019
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EXHIBIT B-2

Schedule for Landlord's Work

[*See attached.*]

EXHIBIT B-3

Description of Tenant's Work

Tenant's work in the Building shall generally include (but not be limited to) the construction or installation of the following items:

1. Approximately 15,000 – 20,000 square feet of structural steel mechanical mezzanine with walkable ceiling system.
2. Approximately 300 lineal feet of internal demising walls separating Tenant's Phase I build out area from the future planned Phase II expansion area.
3. Secondary employee entrance with access control system.
4. Production employee locker rooms, gowning area, and break room; and three restrooms for each such area.
5. Production team offices as needed.
6. Clean room structures.
7. Dry fire suppression system in process areas.
8. Air handling equipment and air filtration systems.
9. Water purification and distribution system.
10. Potable and sanitary water system.
11. Effluent purification system.
12. UPS and backup generator systems.
13. Process gas and LN2 tanks and piping.
14. Air compressor and air line systems.
15. Boiler system.
16. Trash compactor.
17. Concrete floor slab in areas of the Building other than the office area being constructed by Landlord.

EXHIBIT B-4

Initial Delivery Conditions

Each of the following aspects of Landlord's Work shall be completed in accordance with the Plans and Specifications:

1. Building shell complete, including all exterior walls, roof and roof membrane fully installed and in working condition sufficient to allow Tenant to commence (or cause the commencement of) Tenant's Work.

2. Landlord shall have completed the portion of interior slab on grade related to the office portion of the Premises as described in Exhibit B-1; Landlord shall have completed the remainder of the Premises with subbase prepared in accordance with Exhibit B-1.

3. All exterior doors and aluminum façade of the Building installed so the Building is capable of being secured.

EXHIBIT C

Commencement Date Memorandum

THIS COMMENCEMENT DATE MEMORANDUM is entered into on _____, 202__ between NORTHFIELD I, LLC, an Ohio limited liability company ("***Landlord***") and KRYSTAL BIOTECH, INC., a Delaware corporation ("***Tenant***").

On December ___, 2019 Landlord and Tenant entered into a lease ("***Lease***") covering certain Premises described in the Lease.

In accordance with Sections 3.1 and 3.4 of the Lease, Landlord and Tenant are executing, acknowledging and delivering this Agreement for the purposes of specifying (a) the dates of the commencement and termination of the Lease Term**[and][,]** (b) the final rentable square footage of the Building**[, (c) an updated Base Rent table, and (d) an updated Purchase Price for the Option Property, relative to Tenant's Purchase Option]**. Any terms capitalized herein, but no defined herein shall have the meanings ascribed to them in the Lease.

1. The Lease Term commenced on _____, 202__ ("***Lease Commencement Date***"), and shall terminate on _____.

2. The approximate number of square feet of the Building is _____ rentable square feet.

3. Tenant's Base Rent obligation under the Lease shall commence on the Lease Commencement Date.

4. [The Base Rent table set forth in Section 1.11 of the Lease is hereby amended and restated as follows:]

TIME PERIOD (Months)	**ANNUAL BASE RENT**	**MONTHLY BASE RENT**
1 – 12	$ [_____]	$ [_____]
13 – 24	$ [_____]	$ [_____]
25 – 36	$ [_____]	$ [_____]
37 – 48	$ [_____]	$ [_____]
49 – 60	$ [_____]	$ [_____]
61 – 72	$ [_____]	$ [_____]
73 – 84	$ [_____]	$ [_____]
85 – 96	$ [_____]	$ [_____]
97 – 108	$ [_____]	$ [_____]
109 – 120	$ [_____]	$ [_____]
121 – 132	$ [_____]	$ [_____]
133 – 144	$ [_____]	$ [_____]
145 – 156	$ [_____]	$ [_____]
157 – 168	$ [_____]	$ [_____]
169 – 180	$ [_____]	$ [_____]

5. [The Purchase Price set forth in Section 25(a) of the Lease is hereby amended and restated to be $[_____].]

6. Payment of Additional Rent shall commence on the Lease Commencement Date.

7. The Landlord has Substantially Completed all of Landlord's Work in accordance with the Work Letter, and has fulfilled all other items designated as Landlord's obligation under the Lease which were to be completed prior to the Lease Commencement Date (excluding punch list items as agreed upon by Landlord and Tenant), and Tenant has accepted the Premises as of the Lease Commencement Date.

8. The execution of this memorandum shall not constitute the exercise by Tenant of any option it may have to extend the Lease Term.

9. The Lease is in full force and effect and is hereby ratified and confirmed.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Landlord and Tenant have executed two (2) originals hereof on the above date.

LANDLORD:

NORTHFIELD I, LLC,
an Ohio limited liability company

By: Al. Neyer, LLC
an Ohio limited liability company,
its Manager

By: _____
Name: _____
Title: _____
Date: _____

TENANT:

KRYSTAL BIOTECH, INC.,
a Delaware corporation

By: _____
Name: _____
Title: _____
Date: _____

EXHIBIT D

RULES AND REGULATIONS

Tenant covenants and agrees to comply with the following rules and regulations as they may be modified or amended during the Lease Term.

1. The sidewalks, entrances and passages of the Park Common Areas shall not be obstructed by Tenant or used for any purpose other than ingress and egress to and from the Premises.
2. Tenant shall be responsible for maintaining ADA compliance within the Premises.
3. Tenant shall not use handbills for advertising at the Property.
4. Landlord agrees that at any time during Tenant's occupancy, Tenant shall have the right to install & maintain an antenna or communications device or similar equipment on the roof of the Premises or at any other location at the Property; in-building wireless antennas; an uninterruptible power supply (UPS) in the Premises; and any generator and generator pad necessary for Tenant's operations in the Premises so long as such installation and maintenance does not in any way void, in whole or in part, the roof warranty or any other warranty for the Premises. Prior to vacating the Premises, Tenant must remove Tenant's equipment which has been installed on the roof and make repairs to the roof as necessary to bring it back to its original condition in accordance with Section 3.3 of the Lease.
5. Tenant shall not suffer, allow, or permit any vibration, light, or other effect to emanate from the Premises, or from any machine or other installation therein, or otherwise suffer, allow, or permit the same to constitute a nuisance or otherwise interfere with the safety, comfort, or convenience of other tenants at the Park. Upon notice by Landlord to Tenant that any of the aforesaid is occurring, Tenant agrees to forthwith remove or take reasonable steps to control the same.
6. Canvassing, soliciting and peddling in the Park Common Areas are prohibited and Tenant shall cooperate to prevent the same.
7. Tenant shall, at Tenant's cost, use such pest extermination contractor as Landlord may direct at such intervals as Landlord may reasonably require, provided the cost thereof is competitive to any similar service available to Tenant.
8. Tenant, upon termination of its tenancy, shall deliver to the Landlord all keys of offices, rooms and toilet rooms which have been furnished to Tenant or which Tenant shall have had made, or in the event of loss of any such keys so furnished, shall pay Landlord therefor. Tenant shall provide Landlord with a key to access the main entrance of the Premises in accordance with Section 9 of the Lease.
9. Smoking is prohibited anywhere inside the Building. Smoking shall be permitted only in the exterior "designated smoking" areas, where refuse receptacles have been made available for the proper disposal of all discarded tobacco products. Tenant and its authorized representatives or invitees shall not throw litter of any kind in or about the Building, except in receptacles placed in it for that purpose.
10. No animals or birds may be brought in or kept in or about the Building or Premises, except for bona fide service animals.
11. Disposal of trash and other materials shall be done in compliance with all governmental requirements.
12. No foreign substances shall be disposed of in toilets, urinals, or wash bowls. Any expense incurred by Landlord resulting from violation of this rule shall be borne by Tenant.
13. In order to maintain an environment that is safe and free of violence, except for professionally licensed security personnel hired by Landlord or Tenant, Landlord prohibits the wearing, transporting, storage, presence or use of weapons on any part of the Property, regardless of whether the person is licensed to carry the weapon. Tenant shall at all times observe this policy and take all actions necessary or appropriate to enforce this policy with respect to its employees, agents, contractors, subcontractors, invitees, licensees and customers. Tenant must further ensure that: (i) any agent, employee, contractor or subcontractor who violates this policy will be subject to disciplinary action, up to and including dismissal, and (ii) any of Tenant's agents, employees,

contractors, subcontractors, invitees, licensees or customers who violate this policy will be immediately removed from the Property and reported to the police authorities. Landlord shall have no obligation to ensure, and Tenant shall be solely responsible for ensuring, that said Tenant and its respective agents, employees, contractors, subcontractors, invitees, licensees and customers comply with this policy and any further rules and regulations with respect to the presence of a weapon on the Property. The terms and provisions of this section shall be in accordance with 18 PA C.S.A. sec.6102 et seq.

14. Landlord may waive any one or more of these rules and regulations, but no waiver by Landlord will be construed as a waiver of those rules and regulations as a whole, nor prevent Landlord from enforcing any rules and regulations.

15. Landlord may, at Landlord's option, amend or add new rules and regulations for the use and care of the Premises, but only to the extent that Landlord has provided a written copy of same to Tenant at least thirty (30) days in advance.

EXHIBIT E

Landlord Ground Lease

[See attached.]

EXHIBIT F

Form of SNDA

[*To be provided*.]

EXHIBIT G

Form of Landlord Ground Lease NDA

GROUND LANDLORD'S NON-DISTURBANCE AGREEMENT

The undersigned, Allegheny County Airport Authority, a body politic, organized under the Municipal Authorities Act of 1945 ("***Ground Landlord***"), for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound hereby, represents, warrants, covenants and agrees to and with KRYSTAL BIOTECH, INC., a Delaware corporation ("***Tenant***") as follows with respect to that certain Lease Agreement between Tenant and NORTHFIELD I, LLC, an Ohio limited liability company ("***Landlord***"), dated December 26, 2019 ("***Lease***") pertaining to the lease of certain real property consisting of approximately 10 acres located on that certain land in Findlay Township, Pennsylvania described on Exhibit A attached hereto, together with all rights, privileges and easements appurtenant thereto and a building to be constructed thereon, as more particularly described in the Lease (collectively, "***Premises***"):

1. Ground Landlord and Landlord are parties to that certain Ground Lease Agreement, dated December 26, 2019 ("***Ground Lease***"), of which the Lease is subject and subordinate.

2. Tenant shall not be disturbed in its possession of the Premises by Ground Landlord, or any person acting by, through or under Ground Landlord, for so long as Tenant is not in default under the Lease.

3. In the event that the Ground Lease is repudiated, disclaimed, or terminated at any time prior to the expiration or earlier termination of the term of the Lease, including without limitation as a result of Landlord's default, bankruptcy, insolvency or dissolution, and Tenant is not then in default of its obligations under the Lease, then Ground Landlord agrees that the Lease shall automatically continue in full force and effect, and Ground Landlord shall continue to honor the terms of the Ground Lease and Lease, as modified by, and with respect to, this Landlord's Consent, as though Tenant were the direct tenant of Ground Landlord, and Tenant's interest in the Premises shall continue without interruption.

4. Landlord forever waives (i) any right provided by law or otherwise to obtain, foreclose upon, execute upon or otherwise benefit from a lien or other encumbrance against the Personal Property (as defined in the Lease) located at the Premises for rent or other sums due Ground Landlord, whether under the Ground Lease or Lease, or any other obligation of Tenant to Ground Landlord, and (ii) any right provided by law or otherwise to distraint or distress the Personal Property of Tenant located on the Premises.

5. With respect to the Lease, Ground Landlord represents, warrants and covenants to Tenant as follows:

(A) Tenant's intended use of the Premises for industrial manufacturing, warehouse, distribution, storage, office and ancillary uses related to the foregoing uses is permitted under the Ground Lease.

(B) The term of the Ground Lease expires on _____.

(C) The Ground Lease is presently in full force and effect.

(D) Landlord is in possession and full occupancy of all of the Premises.

(E) To Ground Landlord's knowledge, Landlord has not subleased or licensed to any other person or entity any of the Premises.

(F) As of the Effective Date, no "Lessor" or "Lessee" default is continuing under the terms of the Ground Lease, and no event has occurred which with notice or the passage of time or both would constitute a "Lessor" or "Lessee" default under the terms of the Lease.

(G) All obligations on the part of Landlord as "Lessee" under the terms of the Ground Lease through the Effective Date have been fully performed to the satisfaction of Ground Landlord.

6. Ground Landlord represents and warrants to Tenant that it has full power and authority to enter into and grant this Non-Disturbance Agreement. This Non-Disturbance Agreement shall be binding upon and shall inure to the benefit of Tenant and Tenant's successors and assigns.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Ground Landlord has signed this Non-Disturbance Agreement this ____ day of December, 2019.

ATTEST/WITNESS:

By: _____
Name: _____
Title: _____
Date: December ___, 2019

GROUND LANDLORD:
THE ALLEGHENY COUNTY AIRPORT AUTHORITY

By: _____
Name: _____
Title: _____
Date: December ___, 2019

APPROVED AS TO FORM:

_____
Jeffrey W. Letwin, Esquire, Solicitor

COMMONWEALTH OF PENNSYLVANIA)
) SS:
COUNTY OF _____)

The foregoing instrument was acknowledged before me this ___ day of December, 2019, by _____, the _____ of The Allegheny County Airport Authority, a body politic under the Municipal Authorities Act of 1945.

_____
Notary Public

EXHIBIT A
TO
GROUND LANDLORD'S NON-DISTURBANCE AGREEMENT

Legal Description of the Property

All that certain lease area being a part of lands now or formerly of The Allegheny County Airport Authority, situate in the Township of Findlay, County of Allegheny and Commonwealth of Pennsylvania, being more particularly bounded and described as follows:

Beginning at a point on the southerly line of Halverson Road, a sixty-eight (68) foot road, said point being the northerly corner of the parcel herein conveyed and intersection with lands now or formerly of The Allegheny County Airport Authority; thence from beginning through lands now or formerly The Allegheny County Airport Authority the following four (4) courses and distances:

1. S 84°13’31” E a distance of 76.33 feet to a point;

2. S 03°26’54” E a distance of 921.81 feet to a point;

3. N 86°26’37” W a distance of 558.89’ feet to a point;

4. N 03°26’54” E a distance of 723.36 feet to a point on the southerly line of Halverson Road;

thence along Halverson Road S 86°33’46” E a distance of 192.68 feet to a point; thence by same with an arc having a curve to the left, having a radius of 309.00 feet, an arc length of 375.10 feet to a point the northerly corner of the parcel, at the point of beginning.

Containing an area of 10 acres.

EXHIBIT H

Form of Memorandum of Lease

MEMORANDUM OF LEASE

THIS MEMORANDUM OF LEASE is made and entered into as of the ____ day of December 2019, between NORTHFIELD I, LLC, an Ohio limited liability company (the "***Landlord***"), and KRYSTAL BIOTECH, INC., a Delaware corporation (the "***Tenant***").

RECITALS

A. Pursuant to that certain Lease Agreement dated as of December ___, 2019 between Landlord and Tenant (the "***Lease***"), Landlord leased and demised to Tenant, and Tenant leased from Landlord, the Premises (as hereinafter defined).

B. Landlord and Tenant desire to enter into this Memorandum of Ground Lease pursuant to the provisions of the Act of June 2, 1959, P.L. 454 (21 P.S. §404 *et seq*.).

C. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Lease.

NOW, THEREFORE, intending to be legally bound, Landlord and Tenant hereby set forth the following information with respect to the Lease and the Premises:

1. The name of the Landlord is NORTHFIELD I, LLC, an Ohio limited liability company.

2. The name of the Tenant is KRYSTAL BIOTECH, INC., a Delaware corporation.

3. The addresses set forth in the Lease as addresses of the parties are as follows:

Landlord's Address:	c/o Al. Neyer, LLC 302 West Third Street, Suite 800 Cincinnati, OH 45202 Attn: Legal Services Email: lkoth@neyer.com
with copy to:	c/o Al. Neyer, LLC 302 West Third Street, Suite 800 Cincinnati, OH 45202 Attn: Asset Management Email: jcheung@neyer.com
Tenant's Address:	2100 Wharton Street, Suite 701 Pittsburgh, PA 15203 Attn: Tony Riley Email: triley@krystalbio.com and 2100 Wharton Street, Suite 701 Pittsburgh, PA 15203 Attn: Josh Suskin Email: jsuskin@krystalbio.com
with copy to:	Jonathan P. Altman, Esq. Sherrard, German & Kelly, P.C. 535 Smithfield Street, Suite 300 Pittsburgh, PA 15222 Email: jpa@sgkpc.com

4. The Lease is dated as of December ___, 2019.

5. The description of the "Premises" leased from Landlord to Tenant under the Lease is (a) the Property described on Exhibit A attached hereto, together with (b) all improvements located on the Property (including, without limitation, a Building to be constructed containing approximately 100,000 rentable square feet of space, and all utility systems located within or otherwise serving the Building, and a parking lot containing at least 200 parking spaces), and (c) all appurtenances thereto, including but not limited to, rights of ingress, egress and regress to the Property and the Building.

6. The initial Term of the Lease shall commence upon Substantial Completion of the Landlord's Work (the "***Lease Commencement Date***") and shall expire on the last day of the one hundred eightieth (180th) complete calendar month thereafter.

7. The Tenant shall have three (3) consecutive renewal options, the first two of which shall be for a period of five (5) years each, and the third of which shall be for a period of up to a maximum of four (4) years and eleven (11) months.

8. As more particularly set forth in the Lease, the Tenant has an option to purchase the Building and Improvements and take a corresponding assignment of Landlord's rights under the Landlord Ground Lease, to be exercised at any time prior to the date that is thirty (30) days after the Initial Delivery Date (as defined in the Lease).

9. As more particularly set forth in the Lease, commencing after the expiration of the twenty-fourth (24th) complete calendar month after the Lease Commencement Date, and continuing until the expiration of the Lease Term, Tenant shall have an ongoing right of first offer to purchase the Building and Improvements and take a corresponding assignment of Landlord's rights under the Landlord Ground Lease; *provided*, *however*, that Tenant's right of first offer shall not apply to any sale of the Premises to an Affiliate of Landlord, but Tenant's right of first offer shall continue in full force and effect for any subsequent sale by any and all such Affiliates of Landlord.

10. It is the intention of this instrument to give notice of the existence of the Lease and certain terms and conditions thereof, and is not intended to supersede, diminish, add to or change any of the terms or conditions of the Lease. All of the terms and conditions of the Lease are incorporated herein by this reference to the same extent as if set forth herein at length, and the failure to include any such terms or conditions shall not prejudice the rights of the Landlord or Tenant with respect thereto.

11. This Memorandum may be executed in counterparts or with counterpart signature pages, all of which taken together shall constitute one integrated agreement.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have executed this Memorandum of Lease as of the day and year first above written.

LANDLORD:

NORTHFIELD I, LLC,
an Ohio limited liability company

By: Al. Neyer, LLC
an Ohio limited liability company,
its Manager

By: _____
Stephanie P. Gaither,
Sr. Vice President & CFO

STATE OF OHIO **)**
) **SS:**
COUNTY OF HAMILTON **)**

The foregoing instrument was acknowledged before me this ___ day of December, 2019, by Stephanie P. Gaither, Sr. Vice President & CFO, of Al. Neyer, LLC, an Ohio limited liability company, the Manager of Northfield I, LLC, an Ohio limited liability company, on behalf of such company.

_____
Notary Public

[*LANDLORD'S SIGNATURE PAGE TO MEMORANDUM OF LEASE*]

IN WITNESS WHEREOF, the parties hereto have executed this Memorandum of Lease as of the day and year first above written.

TENANT:

KRYSTAL BIOTECH, INC.,
a Delaware corporation

By: _____
Krish S. Krishnan,
President and Chief Executive Officer

STATE OF _____ **)**
) SS:
COUNTY OF _____ **)**

The foregoing instrument was acknowledged before me this ___ day of December, 2019, by Krish S. Krishnan, President and Chief Executive Officer of Krystal Biotech, Inc., a Delaware corporation, on behalf of such corporation.

_____
Notary Public

[*TENANT'S SIGNATURE PAGE TO MEMORANDUM OF LEASE*]

EXHIBIT A
TO
MEMORANDUM OF LEASE

Legal Description of the Property

All that certain lease area being a part of lands now or formerly of The Allegheny County Airport Authority, situate in the Township of Findlay, County of Allegheny and Commonwealth of Pennsylvania, being more particularly bounded and described as follows:

Beginning at a point on the southerly line of Halverson Road, a sixty-eight (68) foot road, said point being the northerly corner of the parcel herein conveyed and intersection with lands now or formerly of The Allegheny County Airport Authority; thence from beginning through lands now or formerly The Allegheny County Airport Authority the following four (4) courses and distances:

1. S 84°13’31” E a distance of 76.33 feet to a point;

2. S 03°26’54” E a distance of 921.81 feet to a point;

3. N 86°26’37” W a distance of 558.89’ feet to a point;

4. N 03°26’54” E a distance of 723.36 feet to a point on the southerly line of Halverson Road;

thence along Halverson Road S 86°33’46” E a distance of 192.68 feet to a point; thence by same with an arc having a curve to the left, having a radius of 309.00 feet, an arc length of 375.10 feet to a point the northerly corner of the parcel, at the point of beginning.

Containing an area of 10 acres.

Exhibit 21.1

SUBSIDIARIES OF KRYSTAL BIOTECH, INC. AS OF DECEMBER 31, 2019

Name	Direct Parent	Ownership	Jurisdiction of Incorporation
Krystal Australia Pty Ltd	Krystal Biotech, Inc.	100%	Australia
Jeune, Inc.	Krystal Biotech, Inc.	100%	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statements:

(1) Registration Statement (Form S-8 No. 333-220589) of Krystal Biotech, Inc.; and

(2) Registration Statement (Form S-3 No. 333-227632) of Krystal Biotech, Inc.;

of our report dated March 10, 2020, relating to the financial statements of Krystal Biotech, Inc. included in this Annual Report (Form 10-K) as of December 31, 2019 and 2018 and for the two years then ended.

/s/ Mayer Hoffman McCann P.C.

San Diego, California

March 10, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Krish S. Krishnan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Krystal Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the small business issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 10, 2020

By: /s/ Krish S. Krishnan
Krish S. Krishnan
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kathryn A. Romano, certify that:

1. I have reviewed this Annual Report on Form 10-K of Krystal Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the small business issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 10, 2020

By: /s/ Kathryn A. Romano
Kathryn A. Romano
Chief Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Krystal Biotech, Inc. (the "Company") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 10, 2020

By: /s/ Krish S. Krishnan
Krish S. Krishnan
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Krystal Biotech, Inc. (the "Company") on Form 10-K for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 10, 2020

By: /s/ Kathryn A. Romano
Kathryn A. Romano
Chief Accounting Officer
(Principal Financial and Accounting Officer)