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, 2020

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: 001-36694

PROTARA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-4580525**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

345 Park Avenue South
3rd Floor
New York, NY
(Address of Principal Executive Offices)
10010
(Zip Code)
(646) 844-0337
(Registrant's telephone number, including area code)

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, par value $0.001 per share	**TARA**	**The Nasdaq Capital Market**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes o 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 o

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 o

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 definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934:

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

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. o

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes o No ☒

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $76.9 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market on June 30, 2020 of $29.32 per share.

As of March 9, 2021, 11,228,606 shares of the registrant's common stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission by April 30, 2021 are incorporated by reference into Part III of this report.

PROTARA THERAPEUTICS, INC.

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For the Year Ended December 31, 2020

PART I

FORWARD-LOOKING STATEMENTS

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

The forward-looking statements are contained principally in the sections entitled "*Business*," "*Risk Factors*," and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*." All statements, other than statements of historical facts, contained in this document, including statements regarding our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "potential," "should," "target," "will," "would," or the negative of those terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, but are not limited to, statements about:

- the impact of the novel coronavirus disease ("COVID-19") pandemic on our business and operations as well as the business or operations of our manufacturers, research partners, and other third parties with whom we conduct business or regulatory agencies;
- estimates regarding our financial performance, including future revenue, expenses and capital requirements;
- our expected cash position and ability to obtain financing in the future on satisfactory terms or at all;
- expectations regarding our plans to research, develop and commercialize our current and future product candidates, including TARA-002, and Intravenous (IV) Choline Chloride;
- expectations regarding the safety and efficacy of our product candidates;
- expectations regarding the timing, costs and outcomes of our planned clinical trials;
- expectations regarding potential market size;
- expectations regarding the timing of the availability of data from our clinical trials;
- expectations regarding the clinical utility, potential benefits and market acceptance of our product candidates;
- expectations regarding our commercialization, marketing and manufacturing capabilities and strategy;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- expectations regarding our ability to identify additional products or product candidates with significant commercial potential;
- developments and projections relating to our competitors and industry;
- our ability to remain listed on the Nasdaq Capital Market;
- the impact of government laws and regulations;

- the timing or likelihood of regulatory filings and approvals; and

- our ability to protect our intellectual property position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this document, particularly in the "***Risk Factors***" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

SUMMARY OF RISKS AFFECTING OUR BUSINESS

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, and other risks and uncertainties that we face, are set forth in Part I, Item 1A, Risk Factors, and should be carefully considered, together with other information in this Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our securities.

- We have a very limited operating history and have never generated any revenues.

- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

- The COVID-19 coronavirus could adversely impact our business, including our clinical development plans.

- We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

- Our business depends on the successful clinical development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride.

- We have never made an IND, BLA or NDA submission or conducted a clinical trial and may be unable to successfully do so for TARA-002 or IV Choline Chloride.

- TARA-002 is an immunopotentiator, and the indications for which we plan to pursue are the treatment of lymphatic malformations and non-muscle invasive bladder cancer. There are no FDA-approved therapies for the treatment of lymphatic malformations. It is difficult to predict the timing and costs of clinical development for TARA-002 with respect to lymphatic malformations as well as the corresponding regulatory approval path.

- Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

- Our product candidates, if approved, will face significant competition, and may face competition sooner than anticipated, and their failure to compete effectively may prevent them from achieving significant market penetration.

- We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

- We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

- Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval.

Item 1. ***Business.***

Overview

We are a New York City based clinical-stage biopharmaceutical company committed to identifying and advancing transformative therapies for the treatment of cancer and rare diseases with significant unmet needs. We prioritize creativity, diverse perspectives, integrity and tenacity to expedite our goal of bringing life-changing therapies to people with limited treatment options.

Our portfolio includes two development programs utilizing TARA-002, an investigational cell therapy based on the broad immunopotentiator, OK-432, which was originally granted marketing approval by the Japanese Ministry of Health and Welfare as an immunopotentiating cancer therapeutic agent. This cell therapy is currently approved in Japan for lymphatic malformations, or LMs, and multiple oncologic indications. It has never been approved outside Japan and we have secured worldwide rights to the asset excluding Japan and Taiwan and have begun to explore its use in rare and oncology indications. We are developing TARA-002 in non-muscle invasive bladder cancer, or NMIBC, and in LMs.

TARA-002's lead oncology program is in NMIBC, which is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle. Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses. Approximately 65,000 patients are diagnosed with NMIBC in the United States each year. Very few new therapeutics have been approved in NMIBC since the 1990s and the current standard of care for NMIBC includes intravesical Bacillus Calmette-Guerin, or BCG,. The mechanism of TARA-002 is similar to BCG. Both TARA-002 and BCG are intravesically administered and elicit a type Th1 type immune response and locally activated generally similar array of cytokines and immune cells.

In August of 2020, we announced constructive feedback following a pre-Investigational New Drug (pre-IND) interaction with the Office of Tissues and Advanced Therapies division of the Center for Biologics Evaluation and Research, or CBER, at the FDA on a development plan for TARA-002 in NMIBC. Building on existing data from OK-432, and subject to the completion of non-clinical studies as well as acceptance of the IND application, we plan to commence a Phase 1 clinical trial in late 2021 to assess the safety and tolerability of TARA-002 in patients with high grade NMIBC.

Our most advanced clinical program is for LMs, which are rare, non-malignant cysts of the lymphatic vascular system that primarily form in the head and neck region of children before the age of two. In July 2020, the U.S. Food and Drug Administration, or FDA, granted Rare Pediatric Disease designation for TARA-002 for the treatment of LMs. OK-432, the originator compound to TARA-002, has been the standard of care in LMs in Japan for over 20 years. In addition to the clinical experience in Japan, we have secured the rights to a dataset from one of the largest ever conducted Phase 2 studies in lymphatic malformations, in which OK-432 was administered via a compassionate use program led by the University of Iowa to over 400 pediatric and adult patients. We have updated the initial IND that was submitted by the University of Iowa and submitted the update and accompanying clarifying questions to the FDA Division of Vaccines and Related Products Applications, or the Division, in connection with the IND for TARA-002 in LMs. We plan to utilize the robust dataset for OK-432 in LMs to support the potential filing of a Biological License Application (BLA) for TARA-002 in lymphatic LMs. We are encouraged by the progress to date and, at the FDA's request, have submitted the full Clinical Study Report (CSR) of the randomized Phase 2 study of OK-432 in LMs led by the University of Iowa. We continue to prepare for a potential BLA filing in the second half of 2021, or to initiate additional clinical work as required by FDA.

TARA-002 was developed from the same master cell bank of genetically distinct group A *Streptococcus pyogenes* as OK-432 (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd., or Chugai Pharmaceutical). Following a pre-IND interaction with the Office of Tissues and Advanced Therapies Division of the Center for Biologics Evaluation and Research, or CBER, the FDA agreed that we have successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432. This initial comparability will be confirmed by GMP scale batches, which are currently underway using the same release tests that have already been approved by the FDA.

The third development program in our portfolio is intravenous, or IV, Choline Chloride, an investigational phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition, or PN, who have intestinal failure associated liver disease, or IFALD. IV Choline Chloride has been granted Orphan Drug Designation by the FDA for this indication and has also been granted Fast Track Designation for the treatment of IFALD. Following a positive end of Phase 2 meeting with the FDA, we received feedback on the design of the studies necessary to complete the registration package for IV Choline Chloride for the treatment of IFALD, including a Phase 1 pharmacokinetic study followed by Phase 3 trial. Prior to initiating these clinical studies, we are currently undertaking a prevalence study in partnership with a large home health organization in the United States to enhance understanding of the PN patient population and we plan to use this information to determine the next steps for the development program. The goal of the study is to understand the presence/incidence of liver disease in this patient population.

Our fourth program, vonapanitase, is a recombinant human elastase. We are reviewing the research and preclinical and clinical data of vonapanitase and have not yet determined whether to pursue further development of this product candidate in the future.

We have devoted substantial efforts to the development of these programs and do not have any approved products and have not generated any revenue from product sales. TARA-002 is in later stage development for LMs and has not yet been approved for use for treatment of LMs, NMIBC or any other indications. We do not expect to generate revenues prior to 2022, if ever. To finance our current strategic plans, including the conduct of ongoing and future clinical trials and further research and development costs, we will need to raise additional capital.

Our Product Candidate Pipeline

The following chart summarizes the current status of our product candidate pipeline:

* TARA-002 Granted Rare Pediatric Disease Designation for the treatment of LMs. OK-432 Granted Orphan Drug Designation by the U.S. FDA for the treatment of LMs, which we believe is applicable under established comparability.
** Granted Orphan Drug and Fast Track Designations by the U.S. FDA
† Phase 1 PK study to be conducted prior to commencing Phase 3

Our Corporate Strategy:

We are an oncology and rare disease company focused on identifying and acquiring or licensing de-risked assets and optimizing and/or accelerating their development. Leveraging the drug development and commercialization experience of our management team, our goal is to build a leading biopharmaceutical company focused on bringing life-saving therapies to patients with significant unmet needs.

1. Establish comparability of OK-432 and TARA-002

Utilizing the same genetically distinct *Streptococcus pyogenes* strain and proprietary manufacturing process used by Chugai Pharmaceutical to manufacture OK-432 (marketed as Picibanil® in Japan and Taiwan), we have produced development batches of TARA-002 and conducted comparability studies using commercial OK-432 manufactured in Japan as a reference. Following a pre-IND interaction with the Office of Tissues and Advanced Therapies division of the Center for Biologics Evaluation and Research, or CBER, the FDA agreed that we had successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432. This initial comparability will be confirmed by GMP scale batches, which are currently underway using the same release tests that have already been accepted by the FDA.

2. Seek FDA approval for the use of TARA-002 in Lymphatic Malformations

We plan to utilize the robust dataset for OK-432 in LMs to support the potential filing of a Biological License Application (BLA) for TARA-002 in lymphatic LMs. We are encouraged by the progress to date and, at the FDA's request, have submitted the full Clinical Study Report (CSR) of the randomized Phase 2 study of OK-432 in LMs led by the University of Iowa. We continue to prepare for a potential BLA filing in the second half of 2021, or to initiate additional clinical work as required by FDA.

3. Pursue development of TARA-002 for the treatment of non-muscle invasive bladder cancer (NMIBC). Complete toxicology and MOA characterization & immunogenicity studies in order to file an IND and initiate P1 study

We are developing TARA-002 for the treatment of non-muscle invasive bladder cancer, or NMIBC. Building on existing safety and efficacy data from OK-432, and subject to the completion of non-clinical studies, including toxicology and MOA characterization & immunogenicity studies, which are currently underway, as well as acceptance of an Investigational New Drug, or IND, application, we plan to commence a Phase 1 clinical trial in 2021 to assess the safety and tolerability of TARA-002 in patients with high grade NMIBC.

4. Further characterize the patient population of IFALD to determine the appropriate strategy/path for IV Choline Chloride as a potential treatment option

Following a positive end of Phase 2 meeting with the FDA, we received feedback on the design of the studies necessary to complete the registration package for IV Choline Chloride for the treatment of IFALD, including a Phase 1 pharmacokinetic study followed by Phase 3 trial. Prior to initiating these clinical studies, we are currently undertaking a prevalence study in partnership with a very large home health organization in the United States to enhance understanding of the PN patient population and plan to use this information to inform the next steps for the development program.

5. Explore opportunities to expand our pipeline

The immunological activity of TARA-002's reference product, OK-432, has been effectively interrogated in patients in a long list of indications. We plan to carefully evaluate the case reports and the literature and perform initial *in vitro* characterization studies to better understand the mechanism of action of TARA-002 and its potential activity in indications beyond LMs and NMIBC. We also plan to engage with regulatory authorities outside of the US to explore the potential opportunities to bring TARA-002 to other geographies.

In addition, our leadership team has a strong track record of licensing, acquiring and optimizing product candidates and we intend to leverage this skill to identify opportunities for potential combination opportunities for TARA-002, particularly in NMIBC

Our Pipeline

TARA-002 / OK-432

TARA-002, our lead program, is an investigational cell therapy developed from the master cell line of the same genetically distinct *Streptococcus pyogenes* (group A, type 3) Su strain as OK-432, a the broad immunopotentiator (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd. (Chugai Pharmaceutical)). We expect to utilize the same regulatory starting materials as OK-432 and manufacture TARA-002 using an updated version of the same proprietary processes used to manufacture OK-432. Functionally, our lead product is OK-432. We have designated this product as TARA-002 in order to differentiate the regulatory path in the U.S. and other geographies from that of OK-432 in Japan.

We entered into an agreement with Chugai Pharmaceutical in June 2019 to support our development of TARA-002. The agreement provides us with exclusive access to certain materials and documents relating to OK-432 including the master cell bank of *Streptococcus pyogenes* used in the manufacture of OK-432. Additionally, the agreement provides technical support during a certain period. We have utilized the materials, proprietary manufacturing process and technical support provided by Chugai Pharmaceutical to produce TARA-002 at a GMP-compliant facility in the United States. Under the agreement with Chugai Pharmaceutical, we will have sole responsibility for the development and commercialization of TARA-002 worldwide, excluding Japan and Taiwan. On July 14, 2020, we entered into an amendment with Chugai to the Chugai Pharmaceutical agreement. This agreement is exclusive through June 17, 2030 or following any termination of the agreement by either party.

In Japan, OK-432 is indicated for: the treatment of lymphangiomas (lymphatic malformations); the prolongation of survival time in patients with gastric cancer (postoperative cases) or primary lung cancer in combination with chemotherapy; and the reduction of cancerous pleural effusion or ascites in patients with lung cancer or gastrointestinal cancer respectively, head and neck cancer (maxillary cancer, laryngeal cancer, pharyngeal cancer, and tongue cancer) and thyroid cancer that are resistant to other drugs.

We plan to pursue development of TARA-002 for the treatment of lymphatic malformations (LMs) and non-muscle invasive bladder cancer (NMIBC) initially in the U.S. and plan to also seek approval in Europe and other regions in the future, and may also explore additional indications where its utility as an immunostimulant has been hypothesized to be of therapeutic benefit.

TARA-002 in NMIBC

Disease Overview:

Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses. NMIBC is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle. There are 3 subtypes of NMIBC: Ta (non-invasive papillary carcinoma), Tis (carcinoma in situ or CIS), and T1 (carcinoma invading the lamina propria). Among the types of NMIBC, Ta accounts for most NMIBC cases (70%), whereas T1 and CIS account for 20% and 10%, respectively.

Based on currently available treatment data, we believe that there are approximately 30,000 incident cases of High-Grade NMIBC per year that would be appropriate for treatment with TARA-002 in the U.S. There are 65,000 incident cases of NMIBC in the U.S. every year, of these, approximately 45% (~30,000) are made up of High-Grade tumor types that are considered higher risk, and therefore candidates for immunotherapies, such as TARA-002). In addition, NMIBC has one of the highest rates of recurrence with 3-year rate estimated at up to 80%.

Treatment:

Treatment for NMIBC is typically targeted to reduce unresectable persistence, recurrence after resection, and to prevent disease progression to muscle-invasive bladder cancer. The initial treatment for NMIBC includes cystoscopy and complete transurethral resection of the bladder tumor (TURBT) for papillary Ta or T1, or biopsy for CIS. A single postoperative instillation of intravesical chemotherapy is recommended in patients with low risk of progression, and for patients with intermediate and high-risk disease, a longer course of intravesical therapy is administered. The most efficacious intravesical agent is Bacillus Calmette-Guerin (BCG), a live attenuated form of *Mycobacterium bovis*. BCG has been the subject of multiple supply shortages in the past decade due to the inability to meet demand to treat the large population of patients with NMIBC resulting in strategies to conserve the use of the therapy. There has been a significant increase in bladder cancer recurrence and progression and an escalated number of patients who needed to be treated by cystectomy have been reported. As such, with the current BCG shortage and limited effective alternate therapies or dosing strategies, there continues to be a significant unmet need for treatment options for patients with NMIBC.

Manufacturing:

TARA-002 will be manufactured using an equivalent, but modernized, proprietary manufacturing process as is used to produce OK-432 by Chugai Pharmaceutical, starting with a master cell line propagated by us but utilizing the same genetically distinct strain of *Streptococcus pyogenes* (A group, type 3) Su strain as OK-432. We have contracted a contract development and manufacturing organization (CDMO), to manufacture TARA-002. TARA-002 has received initial comparability to OK-432 from the FDA. We are currently conducting confirmatory large scale GMP manufacturing comparability, which are scheduled to be completed in 2021.

TARA-002 for the Treatment of Lymphatic Malformations

Disease Overview:

We are pursuing regulatory approval for TARA-002 for the treatment of lymphatic malformations. Lymphatic malformations are rare, non-malignant cystic masses that primarily form in the head and neck region of children before the age of two. The International Society for the Study of Vascular Anomalies classifies LMs as either macrocystic, microcystic, or mixed. Macrocystic and microcystic LMs are differentiated by the size of the fluid-containing portion of the malformation. Macrocystic LMs are characteristically large, fluid-filled cysts with a thin endothelial lining. Macrocystic LMs are composed of cysts greater than 2 cm3 in size and present as a soft, fluid-filled swelling beneath normal or slightly discolored skin. Macrocystic LMs are usually located in the antero-lateral cervical region of the neck; however, it is possible for this type of LM to originate in other areas of the body. In contrast, microcystic LMs have very limited internal space with a thick irregular endothelial lining. Microcystic LMs are comprised of cysts less than 2 cm3 in size and are often composed of micro-lymphatic channels that integrate and infiltrate normal soft tissue. Microcystic LMs can involve both superficial and deep aspects including muscle and bone. Microcystic LMs can thicken or swell causing enlargement of surrounding soft tissue and bones and can be found on any area of the skin or mucous membrane. Mixed LMs are comprised of varying degrees of both macrocystic and microcystic LMs.

While the exact prevalence of LMs is not known, in the United States, the condition is thought to be present in approximately one in every 4,000 live births and we believe there are approximately 1,400-1,800 LM cases per year.

Treatment:

Outside of Japan and Taiwan, the standard of care is surgical excision, which is associated with high rates of recurrence and complications. There are no approved pharmacotherapies for LMs, except in Japan and Taiwan where OK-432 is approved. In these countries, OK-432 has been the standard of care for LMs for over 25 years.

Treatment of LMs varies depending on the symptoms and complications that present themselves. The standard of care outside Japan and Taiwan for the treatment of LMs is either a partial or complete surgical excision of the cysts. While surgery is the standard approach to the treatment of LMs in the head and neck, the region is a difficult area to operate in because of the large number of important anatomical structures in the area. Major venous and arterial trunks travel through the neck, as do important nerves. Surgery on such malformations frequently results in high rates of recurrence and complications including life-long chronic conditions, such as damage to nerves and other important structures of the head and neck.

Clinical Development

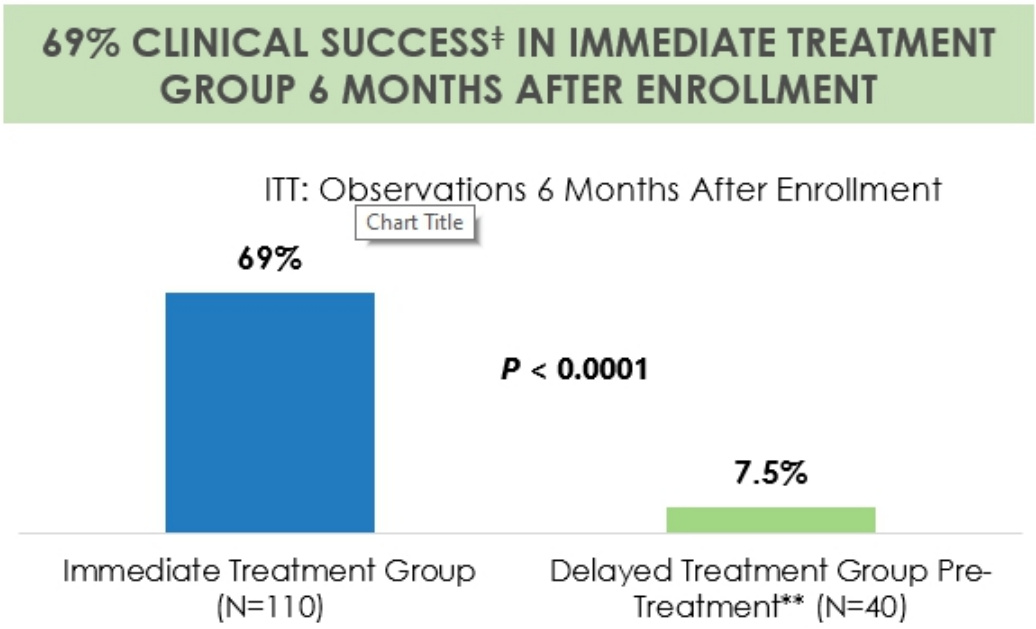
When OK-432 is administered locally for LMs, it is hypothesized that innate immune cells within the cyst are activated and produce a strong immune cascade. Neutrophils and monocytes infiltrate the cyst and various cytokines, including interleukins IL-6, IL-8, IL-12, interferon (IFN)-gamma, tumor necrosis factor (TNF)-alpha, and vascular endothelial growth factor (VEGF) are secreted by immune cells within the cyst in response to the presence of OK-432. In concert, these immune activities induce a strong local inflammatory reaction in the cyst wall, resulting in fluid drainage, shrinkage and fibrotic adhesion of the cyst.

A randomized, phase 2 clinical trial led by the University of Iowa studied the use of OK-432 in patients with LM from 1998 to 2005. Most eligible subjects were between 6 months and 18 years of age with macrocystic or mixed macrocystic-microcystic LMs (with ≥ 50% macrocytic disease) of the head and/or neck. There were three treatment groups: immediate treatment (ITG), delayed treatment (DTG), and open label treatment group. The immediate treatment group received treatment with OK-432 upon diagnosis. The delayed treatment group received OK-432 treatment following a six-month observation period; the cross-over design was intended to investigate spontaneous resolution. The open-label treatment group included infants younger than six months of age, adults older than 18 years of age, patients with LMs involving sites other than the head and neck (such as the axilla, thorax, and extremities), and patients treated on an emergent basis. The open label treatment group were treated immediately with OK-432. Response to therapy was measured by quantitating change in lesion size. Clinical success was defined as a complete (90% to 100%) or substantial (60% to 89%) response to treatment based on radiographically confirmed shrinkage in lesions.

Results presented in this report were based on a retrospective analysis of source verified data that included the full dataset of subjects enrolled in the P2 randomized study between January 1998 and August 2005, including data in the published study (Smith et al. 2009) which included subjects enrolled between January 1998 and November 2004.

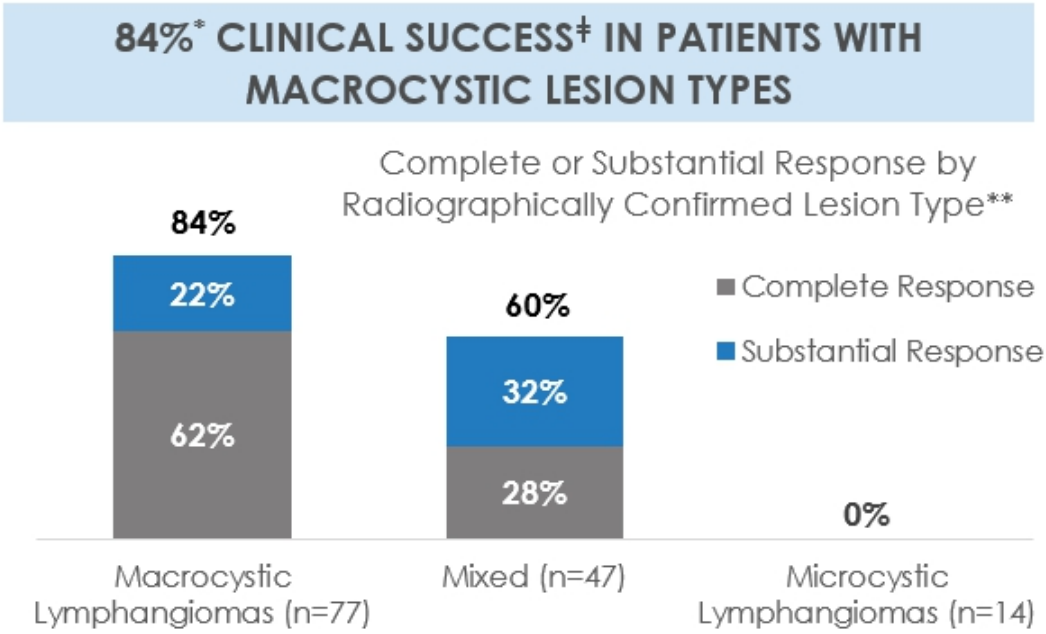
Overall, 310 subjects were enrolled with intent to treat: 246 subjects were randomized to the immediate (ITG, N=171) and delayed (DTG, N=75) treatment groups; 64 subjects were nonrandomized and assigned to the open-label group. Analysis of the primary efficacy endpoint (N=150) demonstrated clinical success (complete and/or substantial response) in 69% of patients in the ITG 6 months after enrollment, while 7.5% of patients in the DTG experienced spontaneous regression of a LM during this time interval ($p < 0.0001$)). When the results were analyzed by lesion type across all treatment groups, a successful outcome was observed in 84% and 60% of patients with macrocystic and mixed macrocystic-microcystic LM, respectively. None of the patients with microcystic LM demonstrated clinical success to OK-432 therapy. The results of the retrospective analysis were consistent with the results observed in the original analysis (Smith et al. 2009).

Figure 1: demonstrates that the primary endpoint was met showing that 69% of patients in the immediate treatment group had a complete or substantial response to OK-432 while 7.5% of patients in the delayed treatment group had a complete or substantial response after six months of observation and before treatment.



‡ Clinical Success was defined as complete or substantial response
** Results were analyzed by lesion type across all treatment groups

Figure 2: illustrates that patients with radiographically confirmed macrocystic lesions had the greatest likelihood of clinical success and in those patients with mixed legions, clinical success was also achieved.



‡ Clinical Success was defined as complete or substantial response
* Reflects data prior to dosing with OK-432. After dosing, the clinical success rate was 66%, which was not statistically different from the Immediate Treatment Group
** Results were analyzed by lesion type across all treatment groups

Safety Profile

The most common adverse events with treatment were local injection site reactions, fever, fatigue, decreased appetite, with resolution within a few days. Treatment emergent serious adverse events (defined as any SAE occurring or worsening on or after the first dose of study drug and within 35 days after the last dose of study drug) associated with OK-432 treatment were reported in 4.1% of patients, with the most severe events being airway obstruction and facial paralysis due to massive swelling post-injection that required tracheostomy and hospitalization. Both of these events were reported as resolved

The safety findings from the Sponsor-conducted retrospective analysis are consistent with the original analysis reported in Smith et al. 2009, and with safety data in published studies in approximately 865 patients with LMs after treatment with OK-432.

Preclinical Development:

A comprehensive preclinical development program for OK-432, including *in vitro* and *in vivo* pharmacology and toxicology studies, was conducted by Chugai Pharmaceutical to support the filing of a new drug application with the Japan Pharmaceuticals and Medical Devices Agency. We plan to discuss with the FDA the ability to rely on these studies for the submission of a BLA for TARA-002.

Regulatory Interactions:

In July 2020, the U.S. Food and Drug Administration, or FDA, granted Rare Pediatric Disease designation for TARA-002 for the treatment of LMs. The FDA grants Rare Pediatric Disease designation for serious diseases that primarily affect children ages 18 years or younger and fewer than 200,000 persons in the United States. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application or biologics license application for a product for the prevention or treatment of a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application or may be sold or transferred.

We plan to utilize the robust dataset for OK-432 in LMs to support the potential filing of a Biological License Application (BLA) for TARA-002 in lymphatic LMs. We are encouraged by the progress to date and, at the FDA's request, have submitted the full Clinical Study Report (CSR) of the randomized Phase 2 study of OK-432 in LMs led by the University of Iowa. We continue to prepare for a potential BLA filing in the second half of 2021, or to initiate additional clinical work as required by FDA.

Manufacturing Plans:

TARA-002 will be manufactured using an equivalent, but modernized, proprietary manufacturing process as is used to produce OK-432 by Chugai Pharmaceutical. Starting with a master cell line propagated by us but utilizing the same genetically distinct strain of *Streptococcus pyogenes* (A group, type 3) Su strain as OK-432. We have contracted a contract development and manufacturing organization (CDMO), to manufacture TARA-002. TARA-002 has received initial comparability to OK-432 from the FDA. We are currently conducting confirmatory large scale GMP manufacturing comparability, which are scheduled to be completed in 2021.

IV Choline Chloride for the treatment of Intestinal Failure Associated Liver Disease

Background:

IV Choline Chloride is an intravenous (IV) substrate replacement therapy initially in development for patients receiving parenteral (typically intravenous) nutrition (PN) who have intestinal failure associated liver disease (IFALD).

Choline is a known important substrate for phospholipids that are critical for healthy liver function. Because patients receiving PN cannot sufficiently absorb adequate levels of choline and no available PN components contain sufficient amounts of choline to correct this deficit, they often experience a prolonged progression to hepatic failure and death, with the only known intervention being a dual small bowel / liver transplant. If approved, IV Choline Chloride would be the first approved therapy for IFALD. It has been granted Orphan Drug Designations (ODDs) by the FDA for the treatment of IFALD and the prevention of choline deficiency in PN patients. We are currently undertaking a prevalence study in partnership with a very large home health organization in the United States to enhance understanding of the PN patient population.

We have entered into a license agreement with Dr. Alan Buchman for exclusive rights to the IND, ODDs and other regulatory assets related to IV Choline Chloride, as well as exclusive rights to the data from previously conducted phase 1 and phase 2 clinical trials led by Dr. Buchman.

The results of a randomized, controlled, phase 2 clinical trial demonstrated that treatment with IV Choline Chloride resulted in normalization of plasma-free choline concentrations, improvement of hepatic steatosis, and a clinically meaningful and statistically significant improvement in cholestasis in patients dependent on PN.

We had an end of phase 2 meeting with the FDA in November 2018 and received the FDA's support for the design of studies necessary to complete the registration package for IV Choline Chloride for the treatment of IFALD, including a Phase 1 pharmacokinetic study followed by Phase 3 trial.

Disease Overview:

Intestinal Failure Associated Liver Disease or IFALD is a rare hepatic/metabolic disease. IFALD, which occurs in patients dependent upon PN, is characterized by choline deficiency, hepatic steatosis, cholestasis, and rapid progression of liver disease through to hepatic failure and death, in the absence of intestine-liver transplant. IFALD carries a relatively poor prognosis, with a 15-34% death rate within one to four years. When IFALD presents in children, mortality is even higher, with studies reporting death rates of 23-40% within 18 months. A patient is considered to have IFALD if she/he:

- is dependent on PN for more than six months (e.g., has chronic intestinal failure);
- has evidence of steatosis, determined by imaging techniques or histologic assessments;
- has evidence of cholestasis (e.g., elevated alkaline phosphatase (ALP), elevated bilirubin and/or histology); and
- may have evidence of ongoing, progressive liver injury on the basis of multiple abnormal liver function tests, in conjunction with findings of fibrosis, cirrhosis, and/or end-stage liver disease (ESLD).

According to recent Medicare diagnosis data, we estimate that there are about 5,000 IFALD patients in the U.S.

Many patients receiving PN are entirely dependent on PN for their nutritional needs. PN delivers nearly all the macro and micro-nutrients necessary for survival in their patients, with the notable exception of choline. Consequently, patients dependent on PN support have been shown to be choline deficient. Patients dependent upon PN are unable to synthesize sufficient levels of choline and malabsorption limits the bioavailability of choline chloride from the PN diet. The American Society for Parenteral and Enteral Nutrition and the Academy of Nutrition and Dietetics' Dietitians in Nutrition Support both recommend that choline be required in PN products; however, there are currently no FDA-approved choline chloride PN products.

Dependence on PN and resulting choline deficiency often leads to IFALD, which is the most common adverse outcome in chronic PN adult patients that is associated with death. Low free choline plasma concentrations are associated with alanine aminotransferase ("ALT"), aspartate aminotransferase ("AST"), and alkaline phosphatase ("ALP") elevations as well as steatosis (fatty liver) and Cholestasis (when bile from the liver stops or slows), all indicators of ongoing liver damage.

Clinical History:

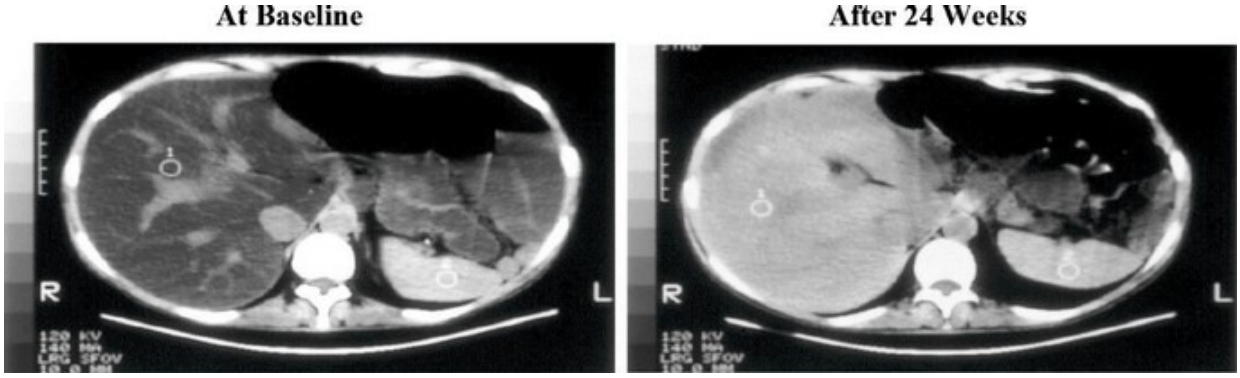
In a Phase 2 randomized, double-blind, controlled 24-week clinical trial, patients (n=15) receiving nightly PN for > 85% of their nutritional needs (for at least 12 weeks prior to entry) were randomized to receive via IV infusion (10-12 hours) their usual PN with placebo (n = 8), or PN to which 2g IV Choline Chloride was added (n = 7).

In the IV Choline Chloride group, mean choline levels were within or greater than the estimated normal range (i.e., 6.7 to 26.9 nmol/mL) throughout the 24-week trial and quickly returned to baseline levels when treatment was discontinued.

Steatosis:

Upon conversion of the quantification of computed tomography (CT) values to magnetic resonance imaging proton density fat fraction (MRI-PDFF), significant differences in the least square (LS) mean change from baseline in estimated MRI-PDFF were observed in the IV Choline Chloride group in comparison to placebo group at Week 4 through Week 24, demonstrating a clinically meaningful and statistically significant reduction in steatosis. When LS mean percent changes from baseline in MRI-PDFF were compared between treatment groups, significant differences in LS mean changes (range, 31.7% to 53.6%) were observed from Weeks 4 to 24 with p-values of 0.0009 to 0.0297 favoring the IV Choline Chloride group.

Figure 3. Liver CT Images: Before and After Treatment with IV Choline Chloride

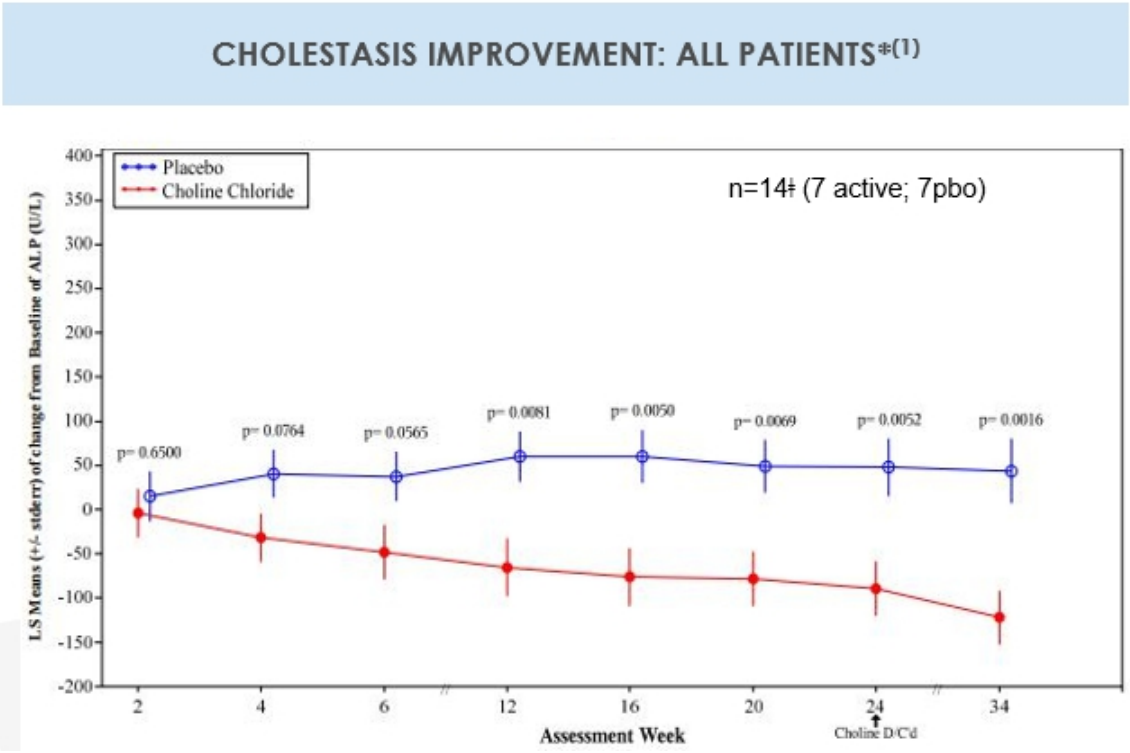


Alkaline Phosphatase:

At baseline, LS mean ALP concentration was 239.3 ± 118.93 in the IV Choline Chloride group and 148.1 ± 100.2 in the placebo group. The MMRM analyses demonstrated statistically significant decreases in ALP concentrations at Week 12 (p = 0.008), Week 16 (p = 0.005), Week 20 (p = 0.007), and Week 24 (p = 0.005) for the IV Choline Chloride group, demonstrating a reduction in cholestasis. A trend towards significance was observed at Week 4 (p = 0.076) and Week 6 (p = 0.056). At Week 34, 10 weeks after discontinuation of IV Choline Chloride treatment, LS mean change from baseline in ALP concentrations still demonstrated statistically significant decreases (p = 0.002), demonstrating a significant improvement in cholestasis with treatment with IV Choline Chloride (Figure 4).

In the subgroup of subjects with ALP concentration > 1.5x upper limit of normal (ULN) at baseline, (n=7), mean values at baseline were comparable between the IV Choline Chloride and placebo groups (294.20 ± 87.947 versus 277.00 ± 128.693, respectively). In the sub-group analysis, improvement in ALP was consistent and substantial, with 20-30% improvement over 12-24 weeks of treatment.

Figure 4. Improvement in Cholestasis[1]: All Patients



1 Protara Therapeutics re-analysis of patient CRF's, data on file

* mixed model for repeated measurement ("MMRM") method used for imputation

‡ A placebo subject was excluded from all analyses due to likely IV contrast-induced imaging abnormalities, confirmed by independent radiologist in subsequent re-analysis.

Preclinical Development:

Table 1. Preclinical Studies Conducted by us for IV Choline Chloride

Study Type	Brief Description
In vitro protein binding	Evaluation of Protein Binding by Choline Chloride in Plasma Using Rapid Equilibrium Dialysis
In vitro cardiac ion channel study	In Vitro Assessment of the Effect of Choline on Currents Mediated by hERG, Cav1.2, and Peak and Late Nav1.5 Channels Expressed in Human Embryonic Kidney (HEK) Cells
In vitro drug-drug interaction	Evaluation of Transporter Inhibition by Choline Chloride in Transporter-Transfected HEK293 Cells Evaluation of OCT2, MATE1 and MATE2-K Inhibition by Choline Chloride in Transporter-Transfected HEK293 Cells Evaluation of Transporter Inhibition by Choline Chloride in Caco-2 Cells Evaluation of Time Dependent Cytochrome P450 Inhibition (IC50 Shift) by Choline Chloride in Human Liver Microsomes Evaluation of Direct Cytochrome P450 Inhibition by Choline Chloride in Human Liver Microsomes Evaluation of Cytochrome P450 Induction by Choline Chloride in Human Hepatocytes Evaluation of Transporter Inhibition by Choline Chloride in Caco-2 Cells Evaluating of Cytochrome P450 2C8, 2C9, and 2C19 mRNA Induction by Choline Chloride in Human Hepatocytes
In vitro BSEP inhibition	Assessment of Choline as an Inhibitor of Human BSEP Mediated Transport Assessment of Choline as a Substrate of Human BSEP Mediated Transport
Nonclinical pharmacology studies	Non-GLP Pilot Single Dose, Escalating Dose Tolerance Study of Choline by Intravenous Infusion in Male Beagle Dogs GLP Single-dose IV Cardiovascular Study in Surgically Instrumented Male Dogs Monitored by Telemetry GLP Combined Single-dose IV Neurobehavioral and Respiratory Study

Clinical Development Plan:

We have reached agreement with FDA on a number of key aspects of the overall clinical program necessary for registration, including a Phase 1 pharmacokinetic study and a Phase 3 study. We are currently undertaking a prevalence study in partnership with a large home health organization in the United States to enhance understanding of the PN patient population, and plans to use this information to determine the appropriate next steps for the development program.

Manufacturing Plans:

We have manufactured sufficient amounts of GMP drug substance and drug product to initiate the planned clinical trials. Scale up for commercial demand is ready and will commence when appropriate. Our end-to-end manufacturing of IV Choline Chloride is conducted in the United States by a GMP-compliant CDMO.

Vonapanitase

As a result of the Merger, we acquired the product candidate, vonapanitase, a recombinant human elastase that we previously pursued development for the improvement of vascular access outcomes in patients with chronic kidney disease, undergoing or preparing for hemodialysis, and as a treatment for patients with symptomatic peripheral artery disease. We are reviewing the research, preclinical and clinical data of vonapanitase and has not yet determined whether to pursue any further development of this product candidate in the future.

Collaborations and License Agreements

Chugai Agreement

On June 17, 2019, we entered into an agreement (the "Chugai Agreement") with Chugai Pharmaceutical, a company organized and existing under the laws of Japan. Chugai Pharmaceutical has developed and commercialized a therapeutic product, OK-432 (Existing Product), in Japan and Taiwan (the "Chugai Territory"), and owns and controls certain materials and documents related to the Existing Product (the "Chugai Materials"). Pursuant to the Chugai Agreement, Chugai Pharmaceutical will provide us with certain materials and documents relating to the Existing Product and will provide certain technical services to us for our development and commercialization in territories other than the Chugai Territory (the "Protara Territory") of a new therapeutic product (the "New Product" or "TARA-002") comparable to the Existing Product beginning on the effective date of the Chugai Agreement and ending on June 30, 2020, or any other date to be agreed to by the parties (the "Chugai Service Period"), Chugai Pharmaceutical will exclusively provide the Existing Product and Chugai Materials to us and will not provide the Existing Product or Chugai Materials to any third parties during the Chugai Service Period, other than for medical, compassionate use and/or non-commercial research purposes. Additionally, beginning on the effective date of the Chugai Agreement and ending on the fifth anniversary of such date or upon the termination of the Chugai Agreement, whichever comes earlier, Chugai Pharmaceutical shall not provide Chugai Materials or technical support to any third party for the purpose of development and commercialization in the Protara Territory of a therapeutic product comparable to the Existing Product. We are responsible, at our sole cost and expense, for the development and commercialization of the New Product in the Protara Territory.

On July 14, 2020, we entered into an amended agreement with Chugai Pharmaceutical (the "Amended Chugai Agreement") with an effective date as of June 30, 2020. The Chugai Amendment extended the date through which Chugai will exclusively provide the Existing Product and materials to us from June 30, 2020 to June 30, 2021, extended the date through which Chugai will not provide materials or technical support to any third party for the purpose of development and commercialization in a given area from the fifth anniversary to the eleventh anniversary of the original effective date (extended to June 17, 2030) and provides that, in addition to the designated fee provided upon the initial indication approval in the Chugai Pharmaceutical Agreement, we will pay Chugai a designated fee for each additional indication approval.

As consideration for Chugai Pharmaceutical's performance under the Chugai Agreement, we agreed to pay Chugai Pharmaceutical a payment in the low, single-digit millions, which payments shall be made in two installments with an initial payment in July 2020, and the remaining majority of the payment payable upon FDA approval of the New Product.

We granted Chugai Pharmaceutical a right of first refusal on terms to be negotiated between the parties for a license related to the New Product-relevant information, data and documentation and inventions to develop and commercialize the New Product in the Chugai Territory. We will be responsible for manufacturing and supplying or causing our CDMO to manufacture and supply the New Product to Chugai Pharmaceutical.

The Chugai Agreement shall remain in full force and effect until the first anniversary of the date of FDA approval of the New Product, unless terminated sooner (the "Chugai Term"). Following the Chugai Service Period and during the Chugai Term, Chugai Pharmaceutical may terminate the Chugai Agreement, in whole or in part, without cause, by providing us 90 days prior written notice. Following such termination, we would maintain exclusive access to Chugai Materials, subject to the termination clauses outlined below. We may terminate the Chugai Agreement, in whole only, by providing Chugai Pharmaceutical 90 days prior written notice if (i) we decide to discontinue the New Product development; (ii) we decide that the FDA's requirements for the New Product are not likely to be met; or (iii) the FDA identifies a safety issue regarding the New Product.

In addition, either party may terminate the Chugai Agreement, in whole or in part, in the event that the other party materially breaches the Chugai Agreement and fails to cure the breach within 30 days of written notice. Either party may terminate the Chugai Agreement in its entirety immediately upon notice to the other party if such other party: (i) is dissolved or liquidated or takes any corporate action for such purpose; (ii) becomes insolvent or is generally unable to pay, or fails to pay, its debts as they become due; (iii) files or has filed against it a petition for voluntary or involuntary bankruptcy or otherwise becomes subject to any proceeding under any domestic or foreign bankruptcy or insolvency laws; (iv) makes or seeks to make a general assignment for the benefit of creditors; or (v) applies for or has a receiver, trustee, custodian or similar agent appointed by order of any court to take charge of or sell any material portion of its property or business.

In the event that we undergo a change of control, Chugai Pharmaceutical may terminate the Chugai Agreement upon 90 days written notice to us, absent a written pledge by the new controlling party of its agreement to fulfill and undertake all obligations of ours and to be bound by the Chugai Agreement.

Sponsored Research and License Agreement

On November 28, 2018, we entered into a sponsored research and license agreement (the "Research Agreement") with The University of Iowa (the "University"), pursuant to which the University will provide access to certain program data related to Chugai Pharmaceutical's OK-432 and will assist us in conducting certain clinical studies. As consideration for the University's performance under the Research Agreement, we will pay the University $30,000 per year in funding for the project, taking into consideration the time spent by University employees required for the Project. The parties also agree to discuss in good faith potential additional funding required for completion of the project pursuant to the Research Agreement as applicable and necessary. In addition, within 45 days of approval of the TARA-002 BLA by the FDA, we will pay a one-time approval milestone to the University, the amount of which depends on the usefulness of the program data in TARA-002's BLA filing, and the milestone amount will range from $0 to $1 million. We will also be responsible for certain tiered royalties on annual net sales of products for the indication, which royalty rates are in the low single digit percentages. These royalty rates are also subject to a reduction in the event that regulatory authorities determine that the program data is not sufficient for regulatory approval on its own and additional pediatric efficacy and safety clinical studies are required. In the event that the annual net sales surpass certain dollar amount thresholds, we will need to make certain additional milestone payments following the close of the calendar quarter in which each milestone is reached, with the payments ranging from $62,500 to $125,000.

We may terminate the Research Agreement upon 30 days prior written notice to the University. Either party may terminate the project under the Research Agreement and all commitments and obligations with respect thereto upon 30 days prior written notice to the other party. In the event of any termination of the project under the Research Agreement by the University, (a) the University agrees to complete certain phases of the project and (b) we will continue to provide annual funding until the completion of the second phase of the project. Upon termination of the project by us, the Agreement will terminate and we will reassign to the University the IND.

Choline License Agreement

On September 27, 2017, we entered into a choline license agreement (the "Choline Agreement") with Alan L. Buchman, M.D., pursuant to which Dr. Buchman granted us an exclusive, worldwide, non-transferable license in and to certain licensed orphan designations, certain licensed IND, certain existing study data and to certain licensed know-how to develop, make, use, sell, offer for sale and import the licensed product during the term of the Choline Agreement. We are solely responsible for all fees and expenses related to the undertaking of the Choline Agreement, including all due diligence obligations, regulatory authority fees, attorney fees and consulting fees. During the term of the Choline Agreement, Dr. Buchman may not work with any third parties on any product competing with the licensed product. In consideration for the rights and licenses granted under the Agreement, we made an initial upfront payment of $50,000 payable to Dr. Buchman.

We will also owe Dr. Buchman certain milestone and royalty payments. Pursuant to the Choline Agreement, we paid Dr. Buchman $50,000 in October 2019 because we had not received at least $5 million in working capital from any source or in any manner as of October 15, 2019. Also, we paid Dr. Buchman an additional $550,000 upon the closing of the Private Placements following the consummation of the Merger because we received at least $5 million in working capital.

Regardless of whether development or commercialization is undertaken by us under the Choline Agreement, commencing on November 21, 2022 and during the term of the Choline Agreement, we shall pay Dr. Buchman a minimum annual royalty that ranges between $25,000 and $75,000.

We owe Dr. Buchman sales royalties based on aggregate net sales of IV Choline Chloride in each calendar quarter, with the royalty rates ranging from 5.0% to 10.5% based on the amount of net sales. In the event of development or commercialization activity by any sublicensees, we also agreed to pay Dr. Buchman a royalty in the mid-single digit percentage of (i) net cash receipts after payment of taxes received by us from sublicensees for their sales of licensed products and (ii) any other consideration received by us from such sublicensees; in each case, including a fair monetary value for any transaction that is not a bona fide arms-length transaction or that is for consideration other than monetary. Further, in the event of a sale or transfer of a priority review voucher regarding the license product, regardless of whether any development or commercialization activity is undertaken by us or our sublicensees, we agreed to pay Dr. Buchman a milestone payment representing the mid-single digit percentage of (i) net cash receipts after payment of taxes and (ii) any other consideration; in each case, received by us, our affiliates, or our sublicensees, including a fair monetary value for any transaction that is not a bona fide arms-length transaction or that is for consideration other than monetary.

We shall also pay Dr. Buchman up to an aggregate of up to $775,000 in additional milestone payments upon the achievement of various regulatory approval milestones.

The Choline Agreement will remain in full force and effect until the last sale of the licensed product under the Choline Agreement. After we received the FDA's written minutes regarding its initial FDA meeting concerning the development of the first licensed product for one or more of the licensed indications, we paid an additional payment of $100,000 to Dr. Buchman and elected not terminate the Choline Agreement. The Choline Agreement may be terminated by Dr. Buchman if, following regulatory approval of a licensed product, we have not made our first sale of a licensed product within such country within a specified time period. We may terminate the Choline Agreement for convenience upon 90 days prior written notice to Dr. Buchman. Dr. Buchman may terminate the Choline Agreement effective immediately for non-payment of any payment due that has not been cured. Either party may terminate the Choline Agreement effective immediately if the other party is in material breach and has not cured such breach within 60 days' notice. In addition, Dr. Buchman may terminate the Choline Agreement effective immediately upon 60 days prior written notice if (a) we cease or threaten to cease to carry on its business; (b) a petition or resolution for the making of an administration order or for the bankruptcy, winding-up or dissolution of us is presented or passed; (c) we file a voluntary petition in bankruptcy or insolvency; (d) a receiver or administrator takes possession of our assets or (e) any similar procedure is commenced against us in the United States.

License Agreement

On December 22, 2017, we entered into a license agreement (the "License Agreement") with The Feinstein Institute for Medical Research, a not-for-profit corporation organized and existing under the laws of New York (the "Institute"). The Institute owns, by assignment, a U.S. patent related to the treatment of fatty liver disease in humans. Pursuant to the License Agreement, the Institute granted us an exclusive, worldwide license, with the right to grant sublicenses to non-affiliate third parties, to develop, make, have made, use, sell, offer for sale and import certain products for use in the field of fatty liver disease in humans receiving total parenteral nutrition, by administering, as monotherapy, a pharmaceutical composition comprising intravenous choline, wherein the fatty liver disease is selected from IFALD, non-alcoholic fatty liver, non-alcoholic steatohepatitis ("NASH"), NASH-associated liver fibrosis, or non-alcoholic cirrhosis. Notwithstanding the exclusive rights granted to us, the Institute shall retain the right to make, use and practice such patents in its own laboratories solely for non-commercial scientific purposes and for continued non-commercial research.

As consideration for the license grant, we agreed to pay the Institute tiered royalties of between 1.0% and 1.5% of all net sales. In addition, we agreed to pay the Institute a low double digit percentage of net proceeds resulting from agreements entered into within two years from the effective date of the License Agreement and a mid-single digit percentage of net proceeds resulting from agreements entered into thereafter. We also agreed to make certain license maintenance payments of $15,000 beginning on the second anniversary of the effective date of the License Agreement and continuing upon every anniversary thereafter until the first commercial sale of a licensed product. Beginning on the first anniversary of the effective date of the License Agreement after the first commercial sale of a licensed product and every anniversary of the effective date of the License Agreement thereafter, we shall pay the Institute $30,000 as a license maintenance fee. Such license maintenance fees are non-refundable but are creditable against future royalty payments due to the Institute during the 12-month period following each such anniversary.

We agreed to make certain one-time milestone payments in the aggregate amount of $375,000 upon the achievement of certain regulatory approval milestones, of which $100,000 was paid on January 28, 2020 upon us having consummated the Private Placements.

Unless terminated earlier, the License Agreement will expire upon the expiration of the last to expire patent under the License Agreement. We may terminate the License Agreement by giving the Institute 60 days prior notice. Either party may terminate the License Agreement in the event of a default or breach by the other party that has not been cured within 60 days of such notice. If we (i) make an assignment for the benefit of creditors or if proceedings for a voluntary bankruptcy are instituted on behalf of us; (ii) is declared bankrupt or insolvent or (iii) is convicted of a felony relating to the manufacture, use or sale of the licensed products or a felony relating to moral turpitude, the Institute may terminate the License Agreement.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the U.S. and internationally for our product candidates, novel biological discoveries, epitopes, new therapeutic approaches and potential indications, and other inventions that are important to our business. Throughout the development of our product candidates, we will seek to identify additional means of obtaining patent protection that would potentially enhance commercial success.

The patent positions of biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual questions. We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that it may require to develop or commercialize our future technology may have a material adverse impact on it. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office (the "USPTO") to determine priority of invention. For a more comprehensive discussion of the risks related to our intellectual property, please see "*Risk Factors—Risks Related to Our Intellectual Property.*"

TARA-002:

TARA-002 is a genetically distinct Su strain of *Streptococcus pyogenes* (group A, type 3). TARA-002 is produced through a proprietary manufacturing process. We believe a significant barrier to entry exists, as it believes only Chugai Pharmaceutical and us have the specific strain and possess the know-how to manufacture the product. We anticipate that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity.

IV Choline Chloride:

With respect to IV Choline Chloride, we have acquired an exclusive, worldwide license to U.S. Patent 8,865,641 B2 from the Feinstein Institute for Medical Research providing protection in the United States until 2035. The patent applies to a method of treating a fatty liver disease in a subject. In particular, the method comprises administering to the subject an effective amount of a cholinergic pathway stimulating agent, wherein the fatty liver disease is selected from non-alcoholic fatty liver (NAFL), alcoholic fatty liver (AFL), non-alcoholic steatohepatitis (NASH), alcoholic steatohepatitis (ASH), NASH-associated liver fibrosis, ASH-associated liver fibrosis, non-alcoholic cirrhosis and alcoholic cirrhosis.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we may file, the patent term is 20 years from the earliest date of filing a non-provisional patent application related to the patent. A U.S. patent also may be accorded a patent term adjustment under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a patent term adjustment may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering certain of those products, when applicable.

We also rely on trade secrets relating to product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, including through breaches of such agreements with our employees and consultants. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Manufacturing

We rely on contract development and manufacturing organizations ("CDMOs") to produce our drug candidates in accordance with current Good Manufacturing Practices ("cGMP"), regulations for use in clinical trials and commercial product. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

The CDMOs that we partner with have the capability to produce clinical supply required for clinical trials, as well as support commercial scale up activities for both products.

Both TARA-002 and Choline Chloride will be produced in the United States. The starting materials for TARA-002 were provided to us pursuant to an agreement with Chugai Pharmaceutical. The regulatory starting materials for Choline Chloride are available commercially.

Sales and Marketing

We plan to become a fully integrated biopharmaceutical company pursuing our mission of supporting and improving the lives of patients suffering from cancer and rare diseases.

If approved by the FDA, we plan to commercialize both of our current product candidates in the U.S. first and then move to other geographies. As we advance TARA-002 and IV Choline Chloride through our respective clinical development programs, we plan to grow our commercial organization in support of anticipated product launches.

Competition

The process for commercialization of new drugs is very competitive, and we could potentially face worldwide competition from other pharmaceutical companies, biotechnology companies and ultimately generic products. Our potential competitors may develop or market therapies that are more clinically effective, safer or less expensive than any therapeutic products we develop.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drugs and biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and biologics additionally under the Public Health Services Act ("PHSA") as well as their respective implementing regulations. The process required by the FDA before biopharmaceutical product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of a drug product candidate and the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of an NDA or BLA after completion of all pivotal clinical trials that includes substantial evidence of safety, purity and potency or efficacy from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and of selected clinical investigation sites to assess compliance with Good Clinical Practices ("GCP"); and
- FDA review and approval, or licensure, of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so- called Phase 4 trials may be made a condition to approval of the NDA or BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Application Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of an NDA or BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once an NDA or BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews the application to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the NDA or BLA. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may impose a Risk Evaluation and Mitigation Strategy (REMS), to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing trials.

Orphan Drug Designation

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

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

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

The FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects 200,000 or more in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program until September 30, 2024, with the potential for PRVs to be granted until September 30, 2026.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Biopharmaceutical manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon sponsors and their third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon sponsor and third-party manufacturers. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biopharmaceuticals. A company can make only those claims relating to safety and efficacy, purity and potency of a biopharmaceutical that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (ACA), signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare &Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS") (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs will need to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act ("HIPAA"), and similar state laws, each as amended, as applicable.

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

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "Affordable Care Act") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act 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 federal False Claims Act (the "FCA") (discussed below).

The federal false claims, including the FCA, and civil monetary penalty laws, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

We may be subject to data privacy and security regulations by both the federal government and the states in which it conducts business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, imposes requirements on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act"), within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

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

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

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic 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.

We cannot be sure that reimbursement will be available for any product that it commercializes and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that it successfully develops.

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

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

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

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

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

There remain legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the Trump administration signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the tax reform bill, the remaining provisions of the Affordable Care Act are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2030 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation has suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. Several final rules have been recently promulgated that seek to implement several of the Trump administration's proposals. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical 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. Further, it is possible that additional government action is taken in response to the COVID-19 pandemic.

The Foreign Corrupt Practices Act

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

Additional Regulation

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

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of March 11, 2021, we had twenty-nine employees, twenty-seven of whom were full-time employees and two of whom were contract employees. As of March 11, 2021, twelve of our employees were engaged in research and development activities and seventeen of our employees were engaged in business development, finance, commercial, information systems, facilities, human resources or administrative support. As of March 11, 2021, all of our employees were located in the U.S. None of our U.S. employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees.

COVID-19

The ultimate impact of the current COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We have experienced delays, but may experience additional future delays that impact our business, our research and development activities, healthcare systems and the global economy as a whole. However, we will continue to monitor the COVID-19 situation closely should the effects have a material impact on our operations, liquidity and capital resources.

In response to public health directives and orders, we have implemented work-from-home policies for our employees and temporarily modified our operations to comply with applicable social distancing recommendations. Similar health directives and orders are affecting third parties with whom we do business, including the third parties that we have contracted with to conduct studies for TARA-002. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems around the globe will negatively impact our ability to conduct clinical trials in the near term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in the trials. We also anticipate that the global impact of COVID-19 will negatively impact our ability to conduct nonclinical studies due primarily to laboratory closures and limited availability of personnel. In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Corporate Information

On January 9, 2020, Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc. the “Company” or “Protara”), and privately-held ArTara Subsidiary, Inc. (“Private ArTara”), completed the merger and reorganization, or the Merger, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 23, 2019, or the Merger Agreement, by and among the Company, Private ArTara and REM 1 Acquisition, Inc., a wholly owned subsidiary of the Company (“Merger Sub”), whereby Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of the Company. The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors.

Refer to Note 3, Reverse Merger with Protara and Recapitalization, to our financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information.

We were originally incorporated in Delaware in March 2006, and at that time, acquired Proteon Therapeutics, LLC, the predecessor of Protara, which was formed in June 2001.

Our principal executive offices are located at 345 Park Avenue South, 3rd Floor, New York, New York 10010, our telephone number is (646) 844-0337 and our website address is www.protaratx.com.

Unless the context requires otherwise, references in this Annual Report to “Protara”, “TARA”, “we”, “us”, the “Company” and “our” refer to Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc.) and our subsidiaries.

Available Information

Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. The contents of our website are not incorporated into this Annual Report and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this document.

Item 1A. ***Risk Factors.***

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Financial Condition

We have a very limited operating history and have never generated any revenues.

We are an early-stage biopharmaceutical company with a very limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations, with respect to the entity that operationally survived the Merger, have been limited to organizing and staffing the company, business planning, raising capital, developing our pipeline assets (TARA-002 and IV Choline Chloride), identifying product candidates, and other research and development. Although our employees have made regulatory submissions and conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, we have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, nor have we ever generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and cannot estimate with precision the extent of our future losses. We expect to incur increasing levels of operating losses for the foreseeable future as we execute on the plan to continue research and development activities, including the ongoing and planned clinical development of our product candidates, potentially acquire new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur the additional costs of operating as a public company. We expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

To become and remain profitable, we must develop or acquire and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval, manufacturing, marketing and selling any product candidate for which we obtain marketing approval, and satisfying post-marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval for and commercializing one or more products, we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical product 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 achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of us and could impair our ability to raise capital, maintain our research and development efforts, expand the business or continue operations. A decline in the value of us could also cause you to lose all or part of your investment.

The COVID-19 coronavirus could adversely impact our business, including our clinical development plans.

In December 2019, a novel coronavirus disease ("COVID-19") was reported and in January 2020, the World Health Organization (the "WHO") declared it a Public Health Emergency of International Concern. On February 28, 2020, the WHO raised its assessment of the COVID-19 threat from high to very high at a global level due to the continued increase in the number of cases and affected countries, and on March 11, 2020, the WHO characterized COVID-19 as a pandemic. As COVID-19 continues to spread in the United States and around the world, we may experience disruptions that could severely impact our business, including:

- interruption of key manufacturing, research and clinical development activities, due to limitations on work and travel imposed or recommended by federal or state governments, employers and others;

- delays or difficulties in clinical trial site operations, including difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling patients;

- interruption of key business activities, due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third party service providers;

- delays in research and clinical trial sites receiving the supplies and materials needed to conduct preclinical studies and clinical trials, due to work stoppages, travel and shipping interruptions or restrictions or other reasons;

- delays or difficulties conducting nonclinical studies due to limitations in employee resources or laboratory closures;

- difficulties in raising additional capital needed to pursue the development of our programs due to the slowing of our economy and near term and/or long term negative effects of the pandemic on the financial, banking and capital markets;

- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which research, including clinical development, is conducted, which may result in unexpected costs; and

- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources, travel restrictions or forced furlough of government employees.

The global outbreak of COVID- continues to evolve. The extent to which the COVID-19 coronavirus may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. The duration and extent of the impact from the COVID-19 pandemic depend on future developments that cannot be accurately predicted at this time, such as the severity and transmission rate of the virus, the extent and effectiveness of containment actions and the impact of these and other factors on our operations, employees, partners and vendors. If we are not able to respond to and manage the impact of such events effectively, our business will be harmed.

In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access additional capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this “Risk Factors” section.

We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

We will require substantial additional funds to conduct the costly and time-consuming clinical efficacy trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of TARA-002 and IV Choline Chloride in new indications or uses. Our future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders’ ownership interests or inhibit our ability to achieve our business objectives. As a result of economic conditions, general global economic uncertainty, political change, and other factors, including uncertainty associated with the COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity.

If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interests of our common stockholders will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Clinical drug development is very expensive, time-consuming and uncertain.

Clinical development for our product candidates is very expensive, time-consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved many do not cover their costs of development. In addition, we, any partner with which we may in the future collaborate, the FDA, an institutional review board (IRB), or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time.

Risks Related to Drug/Biologics Development

Our business depends on the successful clinical development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride.

The success of our business, including our ability to finance our self and generate revenue in the future, primarily depends on the successful development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride. The clinical and commercial success of TARA-002 and IV Choline Chloride depends on a number of factors, including the following:

- timely and successful completion of required clinical trials not yet initiated, which may be significantly slower or costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional studies beyond those planned to support the approval and commercialization of TARA-002 and IV Choline Chloride;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with their contractual obligations and with all regulatory requirements applicable to TARA-002 and IV Choline Chloride;
- ability to confirm the comparability of TARA-002 and OK-432;
- ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of TARA-002 and IV Choline Chloride, to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (“cGMP”);
- a continued acceptable safety profile during clinical development and following approval of TARA-002 and IV Choline Chloride;
- ability to obtain favorable labeling for TARA-002 and IV Choline Chloride through regulators that allows for successful commercialization, given the drugs may be marketed only to the extent approved by these regulatory authorities (unlike with most other industries);
- ability to successfully commercialize TARA-002 and IV Choline Chloride in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety and efficacy of TARA-002 and IV Choline Chloride, if either is approved, including relative to alternative and competing treatments;
- existence of a regulatory environment conducive to the success of TARA-002 and IV Choline Chloride;
- ability to price TARA-002 and IV Choline Chloride to recover our development costs and generate a satisfactory profit margin; and
- our ability and our partners’ ability to establish and enforce intellectual property rights in and to TARA-002 and IV Choline Chloride.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize TARA-002 and IV Choline Chloride. Even if regulatory approvals are obtained, we may never be able to successfully commercialize TARA-002 and IV Choline Chloride. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of TARA-002 and IV Choline Chloride to continue our business.

The COVID-19 pandemic is impacting our business and the business of the third-parties with which we contract for key services related to our clinical development plans. If the crisis persists, it is likely to have a significant delay in our development timelines and result in additional and unexpected costs. Presently, we anticipate that the stress of COVID-19 on healthcare systems around the globe will negatively impact our ability to conduct clinical trials in the near term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in these trials. In addition, it is possible that the stress of the COVID-19 pandemic on regulatory agencies may make it more difficult to collaborate with, and receive guidance from, such agencies, which could delay our development timelines and negatively impact our business.

We have never made an IND, BLA or NDA submission or conducted a clinical trial and may be unable to successfully do so for TARA-002 or IV Choline Chloride.

The conduct of a clinical trials is a long, expensive, complicated and highly regulated process. Although our employees have made regulatory submissions and conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, we, as a company, have not submitted an investigational new drug application (IND), conducted any clinical trials, or submitted a BLA or new drug application (NDA), and as a result may require more time and incur greater costs than we anticipate. Failure to commence or complete, or delays in, our planned regulatory submissions or clinical trials would prevent us from, or delay us, in obtaining regulatory approval of and commercializing TARA-002 and IV Choline Chloride, which would adversely impact our financial performance, as well as subject us to significant contract liabilities.

TARA-002 is an immunopotentiator, and one indication for which we plan to pursue is the treatment of lymphatic malformations. There are no FDA-approved therapies for the treatment of lymphatic malformations. It is difficult to predict the timing and costs of clinical development for TARA-002 with respect to lymphatic malformations as well as the corresponding regulatory approval path.

To date, there are no FDA-approved therapies for the treatment of lymphatic malformations. The regulatory approval process for novel product candidates such as TARA-002 can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. In addition, the previous clinical trials conducted on OK-432 for LMs in the United States included a control arm in which treatment was initially delayed. It is unclear whether this trial design could support FDA approval or whether a placebo-control or other randomization will be required by the FDA. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring TARA-002 to market could decrease our ability to generate sufficient revenue to maintain our business.

The regulatory path to approval of TARA-002 is dependent on FDA acceptance of prior clinical data from OK-432.

The proposed regulatory strategy for the TARA-002 program is a combination of demonstrating comparability to a product that is not FDA approved and relying upon existing data. By demonstrating that TARA-002 is, in fact, OK-432, we believe that the large volume of data published on OK-432 including the data generated by the University of Iowa led study in LMs will then apply to TARA-002. We have been granted initial comparability by FDA and if comparability is fully demonstrated and accepted by regulatory authorities, we will attempt to rely on existing OK-432 safety and efficacy data to submit the BLA. There is no example to date of a biologic product that was approved utilizing this regulatory approach that we are aware of.

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from TARA-002 or IV Choline Chloride could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining U.S. or foreign regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process for IV Choline Chloride for the treatment of IFALD.

The FDA has granted fast track designation to IV Choline Chloride for the treatment of IFALD. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. Even though we have received fast track designation for IV Choline Chloride for the treatment of IFALD, we may not experience a faster development process, review or approval. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Although the FDA has granted Rare Pediatric Disease Designation for TARA-002 for the treatment of LMs, a BLA for TARA-002, if approved, may not meet the eligibility criteria for a priority review voucher.

Rare Pediatric Disease Designation has been granted for TARA-002 for the treatment of LMs. In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this 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. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30,2024. However, if a drug candidate received Rare Pediatric Disease Designation before September 30,2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

However, TARA-002 for the treatment of LMs may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that a BLA will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease Designation does not lead to faster development or regulatory review of the product, or increase the likelihood that it will receive marketing approval. We may or may not realize any benefit from receiving a voucher.

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of both TARA-002 and IV Choline Chloride, if approved, will depend significantly on the broad adoption and use of them by physicians and patients for approved indications, and neither may be commercially successful even though the product is shown to be safe and effective. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which a product is approved;
- the effectiveness of the product compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- in the case of TARA-002, overcoming physician or patient biases toward surgery for the treatment of lymphatic malformations;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration;
- patient satisfaction with the results, administration and overall treatment experience;

- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final FDA-approved labeling for the applicable product;
- any FDA requirement to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If either TARA-002 or IV Choline Chloride is approved for use but fails to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Any adverse developments that occur in patients undergoing treatment with OK-432 / Picibanil or in patients participating in clinical trials conducted by third parties may affect our ability to obtain regulatory approval or commercialize TARA-002.

Chugai Pharmaceutical Co., Ltd., over which we have no control, has the rights to commercialize TARA-002 and it is currently marketed in Japan and Taiwan, under the name Picibanil, for various indications. In addition, clinical trials using Picibanil are currently ongoing in various countries around the world. If serious adverse events occur with patients using Picibanil or during any clinical trials of Picibanil conducted by third parties, the FDA may delay, limit or deny approval of TARA-002 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for TARA-002 and a new and serious safety issue is identified in connection with use of Picibanil or in clinical trials of Picibanil conducted by third parties, the FDA may withdraw the approval of the product or otherwise restrict our ability to market and sell TARA-002. In addition, treating physicians may be less willing to administer TARA-002 due to concerns over such adverse events, which would limit our ability to commercialize TARA-002.

We may in the future conduct clinical trials for our product candidates outside the United States, and the FDA and applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside of the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate the potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. For example, we are reviewing the research and preclinical and clinical data of vonapanitase and have not yet determined whether to pursue further development of this product candidate in the future.

If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

Our or our third party's clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during their development, which could prevent or delay marketing approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of the product candidate.

Before obtaining marketing approvals for the commercial sale of any product candidate, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in the applicable indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and are associated with side effects or have characteristics that are unexpected. Based on the safety profile seen in clinical testing, we may need to abandon development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more tolerable from a risk-benefit perspective. The FDA or an IRB may also require that we suspend, discontinue, or limit clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for the product candidate. Many pharmaceutical candidates that initially showed promise in early stage testing and which were efficacious have later been found to cause side effects that prevented further development of the drug candidate and, in extreme cases, the side effects were not seen until after the drug was marketed, causing regulators to remove the drug from the market post-approval.

Our regulatory strategy for TARA-002 requires that we demonstrate that TARA-002 is the same biologic substance as OK-432, which is currently manufactured in Japan and marketed in Japan and Taiwan by Chugai. The FDA has agreed that we have successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432; we are on track to conduct three large-scale batch runs to confirm comparability. Good Manufacturing Practice (GMP) scale up is currently in process and we have initiated GMP comparability runs. There can be no assurances that our contract manufacturer will be able to produce a sufficiently comparable product or that the FDA will find such substances comparable or permit us to use any of the data from prior clinical trials as part of the BLA filing for TARA-002.

Other Risks Related to Our Business

Our product candidates, if approved, will face significant competition and their failure to compete effectively may prevent them from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, less effective patent terms, and a strong emphasis on developing newer, fast-to-market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing, including TARA-002 and IV Choline Chloride. We will face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, more international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than we have. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts.

With respect to our lead product candidate, TARA-002, for the treatment of LMs and NMIBC, the active ingredient in TARA-002 is a genetically distinct strain of *Streptococcus pyogenes* (group A, type 3) Su strain. TARA-002 is produced through a proprietary manufacturing process. We anticipate that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity. In addition, TARA-002 is likely to have seven years of concurrent Orphan Drug Designation exclusivity for the treatment of LMs if deemed comparable to OK-432 by the FDA based on the prevalence of the disease. There are no approved pharmacotherapies currently available for the treatment of LMs and the current standard of care is a high-risk surgical procedure. There are a number of drug development companies and academic researchers exploring oral formulations of various agents including macrolides, phosphodiesterase inhibitors, and calcineurin/ mTOR inhibitors. These are in early development. TARA-002, if approved for the treatment of NMIBC, would be subject to competition from existing treatment methods of surgery, chemotherapy and immunomodulatory therapy.

There are no treatments currently available for IFALD. With respect to IV Choline Chloride for the treatment of IFALD, IV Choline Chloride is the only sterile injectable form of choline chloride that can be combined with parenteral nutrition. Further, if approved, IV Choline Chloride will be protected by Orphan Drug Designation exclusivity for seven years.

TARA-002 and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes are intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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

We rely on third-party CROs and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.

We rely on third-party contract research organizations (CROs) to conduct and oversee our TARA-002 and IV Choline Chloride clinical trials and other aspects of product development. We also rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practice (GCP) requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties will play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We will rely heavily on these parties for the execution of our clinical trials and preclinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and good laboratory practice (GLP) requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials comply with applicable GCP and GLP requirements. In addition, our clinical trials generally must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union, Latin America and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, we, as a company, have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

We have only received the exclusive rights to the materials required to commercialize TARA-002 in territories other than Japan and Taiwan until June 17, 2030, or an earlier date if Chugai terminates the agreement with us for any number of reasons, following which such rights become nonexclusive.

Pursuant to an agreement with Chugai Pharmaceutical Co., Ltd. dated June 17, 2019, as amended on July 14, 2020 (effective June 30, 2020), Chugai agreed to provide us with exclusive access to the starting material necessary to manufacture TARA-002 as well as technical support necessary for us to develop and commercialize TARA-002 anywhere in the world other than Japan and Taiwan. However, this agreement does not prevent Chugai from providing such materials and support to any third party for medical, compassionate use and/or non-commercial research purposes and this agreement is exclusive through June 17, 2030 or following any termination of the agreement by either party. Once our rights to the materials and technology necessary to manufacture, develop and commercialize TARA-002 are not exclusive, third parties, including those with greater expertise and greater resources, could obtain such materials and technology and develop a competing therapy, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our product candidates.

The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our biopharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country and frequently are revised.

Even after we achieve U.S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates.

These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with cGMP requirements and with the FDA's GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that it conducts post-approval, as well as continued compliance with the FDA's laws governing commercialization of the approved product, including but not limited to the FDA's Office of Prescription Drug Promotion (OPDP) regulation of promotional activities, fraud and abuse, product sampling, scientific speaker engagements and activities, formulary interactions as well as interactions with healthcare practitioners. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar or more onerous (i.e., prohibition on direct-to-consumer advertising that does not exist in the United States) restrictions and requirements imposed by laws and government regulators in those countries.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the sale, marketing or manufacturing of the product, amend, suspend or withdraw product approvals or revoke necessary licenses;

- mandate modifications to promotional and other product-specific materials or require us to provide corrective information to healthcare practitioners or in our advertising;

- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for noncompliance and, in extreme cases, require an independent compliance monitor to oversee our activities;
- issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- place restrictions on the kind of promotional activities that can be done;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change, and new or additional statutes or government regulations may be enacted, including at the state and local levels, which can differ by geography and could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulations that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to commercialize our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability or similar causes of action as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or potentially even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend our self against product liability or similar claims, we will incur substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;

- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- significant delay in product launch;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

We intend to obtain product liability insurance coverage for our clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive and narrow, and, in the future, we may not be able to maintain adequate insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability or other similar legal actions. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which we wish to launch. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and future prospects.

Our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with whom we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti-kickback and Medicare/Medicaid rules, or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against us and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarments, contractual damages, imprisonment, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could adversely affect our ability to operate our business and our operating results.

We may be subject to risks related to off-label use of our product candidates.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities.

Even if we obtain regulatory approval for our product candidates, the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In the United States, engaging in impermissible promotion of our product candidates for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil, criminal and/or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which we promote or distribute our product candidates. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect on our business, financial condition and operating results and even result in having an independent compliance monitor assigned to audit our ongoing operations for a lengthy period of time.

If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for TARA-002 or IV Choline Chloride following regulatory approval, their commercial success may be hindered severely.

If TARA-002 and IV Choline Chloride only becomes available by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse most or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and private third-party payors is often critical to new product acceptance. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available, or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use TARA-002 and IV Choline Chloride. Even if we obtain coverage for our products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use a product unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies and there may be time limitations on when a new drug may even apply for formulary inclusion. Also, third-party payors may refuse to include products in their formularies or otherwise restrict patient access to such products when a less costly generic equivalent or other treatment alternative is available in the discretion of the formulary.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical and health economics support for the use of our products compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

Healthcare reform measures could hinder or prevent the commercial success of our product candidates.

The Trump administration and certain members of the U.S. Congress sought to repeal all or part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "Affordable Care Act"), and implement a replacement program. For example, the so-called "individual mandate" was repealed as part of tax reform legislation adopted in December 2017, informally titled the Tax Cuts and Jobs Act (the "Tax Act"), such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code was eliminated beginning in 2019. In addition, litigation may result in the repeal or replacement of prevent some or all of the Affordable Care Act legislation from taking effect. For example, on December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. Although the United States Supreme Court has yet ruled on the constitutionality of the Affordable Care Act on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform efforts of the Biden administration will impact the Affordable Care Act and our business.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers, and the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Several final rules have been recently promulgated that seek to implement several of the Trump administration's proposals. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new Presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

There are also calls to place additional restrictions on or to ban all direct-to-consumer advertising of pharmaceuticals, which would limit our ability to market our product candidates. The United States is in a minority of jurisdictions that allow this kind of advertising and its removal could limit the potential reach of a marketing campaign. Further, it is possible that additional government action is taken in response to the COVID-19 pandemic.

We may also be subject to stricter healthcare laws, regulation and enforcement, and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct business. The healthcare laws and regulations that may affect our ability to operate include but are not limited to: the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the Prescription Drug Marketing Act (for sampling of drug product among other things); the federal physician sunshine requirements under the Affordable Care Act; the Foreign Corrupt Practices Act as it applies to activities outside of the United States; the new federal Right-to-Try legislation; and state law equivalents of many of the above federal laws.

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. In addition, recent healthcare reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert 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 federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, 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 management's attention from the operation of our business and result in reputational damage. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, imprisonment, additional oversight and reporting obligations, or the curtailment or restructuring of our operations, and injunctions, any of which could adversely affect our ability to operate our business and financial results.

We intend to in-license and acquire product candidates and may engage in other strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management.

Our strategy is to in-license and acquire product candidates and we may engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects. We have no current plan, commitment or obligation to enter into any transaction described above, and we are not engaged in discussions related to additional partnerships.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We intend to in-license, acquire, develop and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.

We expect to rely upon the efforts of third parties for the successful development and commercialization of our current and future product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third-party partners which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;
- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of our current or future product candidates; and
- other risks in potentially meeting our current and future product commercialization schedule or satisfying the requirements of our end-users.

We cannot assure you that we will be able to establish or maintain third-party relationships in order to successfully develop and commercialize our product candidates.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, and our ability to supply our products commercially will depend, in part, on our ability to obtain the APIs and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates.

We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying us with API and finished products or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMPs for production of both APIs and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and we may be held liable for injuries sustained as a result.

In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities, more cost-effectively and, in certain cases, at higher yields than they currently achieve. If our third-party contractors are unable to scale up the manufacture of any of our product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturer's or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries.

In addition, we cannot be certain that any prolonged, intensified or worsened effect from the COVID-19 pandemic would not impact our supply chain.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If our CDMO encounters such difficulties, the ability to provide supply of TARA-002 for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of TARA-002, if approved, could be delayed or stopped.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on CDMOs to fulfill our clinical and commercial supply of TARA-002. The process of manufacturing biologics is complex, highly regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for TARA-002 or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Scaling up a biologic manufacturing process is a difficult and uncertain task, and any CDMO we contract may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely meet product demand.

We expect our stock price to be highly volatile.

The market price of our shares could be subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to:

- our ability to obtain timely regulatory approvals for TARA-002, IV Choline Chloride or future product candidates, and delays or failures to obtain such approvals;
- failure of TARA-002 or IV Choline Chloride, if approved, to achieve commercial success;
- issues in manufacturing TARA-002, IV Choline Chloride or future product candidates;
- the results of current and any future clinical trials of TARA-002 or IV Choline Chloride;
- failure of other of our product candidates, if approved, to achieve commercial success;
- the entry into, or termination of, or breach by partners of key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and
- the loss of key employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares.

In the past, following periods of volatility in the market price of a company’s securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity. Such litigation if brought could impact negatively our business.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that ArTara Subsidiary Inc. did not incur as a private company, including costs associated with public company reporting and other SEC requirements. We have also incurred, and will continue to incur, costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq.

We expect the rules and regulations applicable to public companies will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. Our executive officers and other personnel will need to continue to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it expensive for us to operate our business.

We are able to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

We have a public float of less than $250 million and therefore qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for our investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive due to our reliance on these exemptions. 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 be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $100 million and we have a public float of less than $700 million.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Under the Tax Act, as modified by the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020. It is uncertain if and to what extent various states and localities will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

We may be adversely affected by natural disasters, pandemics and other catastrophic events and by man-made problems such as terrorism that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate office is located in New York, New York. If a disaster, power outage, computer hacking, or other event occurred that prevented us from using all or a significant portion of an office, that damaged critical infrastructure, such as enterprise financial systems, IT systems, manufacturing resource planning or enterprise quality systems, 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. As an example, New York City has been significantly impacted by the COVID-19 pandemic and, due to safety considerations for our employees and government restrictions, we do not know when we will be able to use our office facilities located there. Our contract manufacturer's and suppliers' facilities are located in multiple locations where there are similar stay-at-home orders in place for the current crisis and where other natural disasters or similar events, such as tornadoes, fires, explosions or large-scale accidents or power outages, or IT threats, pandemic, acts of terrorism and other geo-political unrest, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of TARA-002 or IV Choline Chloride, our business, financial condition, operating results and prospects would suffer.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding voting stock from merging or combining with us. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

The certificate of incorporation of ours provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

The certificate of incorporation of ours provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval.

Certain stockholders have consent rights over certain significant matters of our business. These include decisions to effect a merger or other similar transaction, changes to the principal business of ours, and the sale or other transfer of TARA-002 or other assets with an aggregate value of more than $2,500,000. As a result, these stockholders, have significant influence over certain matters that require approval by our stockholders.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Risks Related to Intellectual Property Rights

We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target.

Competitors in the field of immunology and oncology therapeutics have created a substantial amount of prior art, including scientific publications, posters, presentations, patents and patent applications and other public disclosures including on the Internet. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the United States, and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting, or are otherwise precluded from effectively protecting, our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use and if we and our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, we may not be allowed to retrieve this and maintain the exclusivity we previously enjoyed.

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

Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and even in launching an identical version of our product notwithstanding we have a valid patent in that country. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement on infringing activities is inadequate or where we have no patents. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, and the judicial and government systems are often corrupt, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our global patents at risk of being invalidated or interpreted narrowly and our global patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate or infringement actions brought against us, and the damages or other remedies awarded, if any, may not be commercially meaningful when we are the plaintiff. When we are the defendant we may be required to post large bonds to stay in the market while we defend ourselves from an infringement action.

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patent holder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby disaffecting the patent holder's business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the Unites States. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals For example, in Brazil, pharmaceutical patents require initial approval of the Brazilian health agency (ANVISA). Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay a prosecution fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We have entered into in-license arrangements with respect to certain of our product candidates. These license agreements impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot assure that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding patents we may possess. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or the like. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act or other countries' laws similar to the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us is ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party significant damages for having violated the other party's patents.

Because we rely on certain third-party licensors and partners and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results.

We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

General Risk Factors

We do not anticipate paying any dividends in the foreseeable future.

The current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of your shares of us will be your sole source of gain, if any, for the foreseeable future.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. 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. In the first quarter of 2020, our email server was compromised in a cyber-attack. We quickly isolated the incident and have, since, implemented additional risk prevention measures. In addition, since we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in us to recruit for future clinical trials. 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 and the further development and commercialization of our products and product candidates could be delayed.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Item 1B. ***Unresolved Staff Comments.***

This item is not applicable.

Item 2. ***Properties.***

As of December 31, 2020, we lease approximately 10,252 square feet of space for our headquarters in New York, New York under an agreement that expires in March 2028, with monthly rent of $93,122. This lease has been entered into but the Company will not have access to the premises until the second quarter of 2021. Our previous headquarters for approximately 700 square feet of space with monthly rent of $15,300 expires in March 2021 and we do not intend to extend this lease. In addition, we entered into a quarter-to-quarter lease agreement for a development lab, a manufacturing space and an additional manufacturing space, all located in North Carolina for quarterly rent of $1,309, $19,173 and $10,625, respectively. The development lab space has been occupied as of May 2019, the manufacturing space has been occupied as of March 2020 and the additional manufacturing space has been occupied as of December 2020. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. ***Legal Proceedings.***

From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. ***Mine Safety Disclosures.***

This item is not applicable.

PART II

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

Our common stock is traded on the Nasdaq Capital Market under the symbol "***TARA***".

Holders of Our Common Stock

As of March 11, 2021, there were 11,228,606 shares of common stock outstanding held by approximately 25 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid cash dividends on our Common Stock, and we do not expect to pay any cash dividends on our Common Stock in the foreseeable future. Payment of future dividends, if any, on our Common Stock will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs, and plans for expansion.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

Recent Sales of Unregistered Securities

Other than as previously disclosed in our past Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we did not have any sales of unregistered securities for the period covered by this Annual Report on Form 10-K.

Item 6. ***Selected Financial Data.***

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this document, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a New York City based clinical-stage biopharmaceutical company committed to identifying and advancing transformative therapies for the treatment of cancer and rare diseases with significant unmet needs. We prioritize creativity, diverse perspectives, integrity and tenacity to expedite our goal of bringing life-changing therapies to people with limited treatment options.

Our portfolio includes two development programs utilizing TARA-002, an investigational cell therapy based on the broad immunopotentiator, OK-432, which was originally granted marketing approval by the Japanese Ministry of Health and Welfare as an immunopotentiating cancer therapeutic agent. This cell therapy is currently approved in Japan for lymphatic malformations, or LMs, and multiple oncologic indications. It has never been approved outside Japan and we have secured worldwide rights to the asset excluding Japan and Taiwan and have begun to explore its use in rare and oncology indications. We are developing TARA-002 in non-muscle invasive bladder cancer, or NMIBC, and in LMs.

TARA-002's lead oncology program is in non-muscle invasive bladder cancer or NMIBC, which is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle. Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses. Approximately 65,000 patients are diagnosed with NMIBC in the United States each year. Very few new therapeutics have been approved in NMIBC since the 1990s and the current standard of care for NMIBC includes intravesical Bacillus Calmette-Guerin, or BCG. The mechanism of TARA-002 is similar to BCG. Both TARA-002 and BCG are intravesically administered and elicit a type Th1 type immune response and locally activated generally similar array of cytokines and immune cells.

In August of 2020, we announced constructive feedback following a pre-Investigational New Drug (pre-IND) interaction with the Office of Tissues and Advanced Therapies division of the Center for Biologics Evaluation and Research, or CBER, at the FDA on a development plan for TARA-002 in NMIBC. Building on existing data from OK-432, and subject to the completion of non-clinical studies as well as acceptance of the IND application, we plan to commence a Phase 1 clinical trial in late 2021 to assess the safety and tolerability of TARA-002 in patients with high grade NMIBC.

The most advanced clinical program is for LMs, which are rare, non-malignant cysts of the lymphatic vascular system that primarily form in the head and neck region of children before the age of two. In July 2020, the U.S. Food and Drug Administration, or FDA, granted Rare Pediatric Disease designation for TARA-002 for the treatment of LMs. OK-432, the originator compound to TARA-002, has been the standard of care in LMs in Japan for over 20 years. In addition to the clinical experience in Japan, we have secured the rights to a dataset from one of the largest ever conducted Phase 2 studies in lymphatic malformations, in which OK-432 was administered via a compassionate use program led by the University of Iowa to over 400 pediatric and adult patients. We have updated the initial IND that was submitted by the University of Iowa and submitted the update and accompanying clarifying questions to the FDA Division of Vaccines and Related Products Applications, or the Division, in connection with the IND for TARA-002 in LMs. We plan to utilize the robust dataset for OK-432 in LMs to support the potential filing of a Biological License Application (BLA) for TARA-002 in lymphatic LMs. We are encouraged by the progress to date and, at the FDA's request, have submitted the full Clinical Study Report (CSR) of the randomized Phase 2 study of OK-432 in LMs led by the University of Iowa. We continue to prepare for a potential BLA filing in the second half of 2021, or to initiate additional clinical work as required by FDA.

TARA-002 was developed from the same master cell bank of genetically distinct group A Streptococcus pyogenes as OK-432 (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd., or Chugai Pharmaceutical). Following a pre-IND interaction with the Office of Tissues and Advanced Therapies Division of the Center for Biologics Evaluation and Research, or CBER, the FDA agreed that we have successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432. This initial comparability will be confirmed by GMP scale batches, which are currently underway using the same release tests that have already been approved by the FDA.

The third development program in our portfolio is intravenous, or IV, Choline Chloride, an investigational phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition, or PN, who have intestinal failure associated liver disease, or IFALD. IV Choline Chloride has been granted Orphan Drug Designation by the FDA for this indication and has also been granted Fast Track Designation for the treatment of IFALD. Following a positive end of Phase 2 meeting with the FDA, we received feedback on the design of the studies necessary to complete the registration package for IV Choline Chloride for the treatment of IFALD, including a Phase 1 pharmacokinetic study followed by Phase 3 trial. Prior to initiating these clinical studies, we are currently undertaking a prevalence study in partnership with a large home health organization in the United States to enhance understanding of the PN patient population and we plan to use this information to determine the next steps for the development program. The goal of the study is to understand the presence/incidence of liver disease in this patient population.

Our fourth program, vonapanitase, is a recombinant human elastase. We are reviewing the research and preclinical and clinical data of vonapanitase and have not yet determined whether to pursue further development of this product candidate in the future.

We have devoted substantial efforts to the development of these programs and do not have any approved products and have not generated any revenue from product sales. TARA-002 is in later stage development for LMs and has not yet been approved for use for treatment of LMs, NMIBC or any other indications. We do not expect to generate revenues prior to 2022, if ever. To finance our current strategic plans, including the conduct of ongoing and future clinical trials and further research and development costs, we will need to raise additional capital.

Since inception, we have incurred significant operating losses. As of December 31, 2020, we had an accumulated deficit of approximately $46.8 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next few years as we continue our development of, and seek marketing approvals for, our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States.

As a clinical-stage company, our expenses and results of operations are likely to fluctuate significantly from quarter to quarter and year to year. We believe that our period-to-period comparisons of our results of operations should not be relied upon as indicative of our future performance.

As of December 31, 2020, we had approximately $168.6 million in cash and cash equivalents.

Merger

On January 9, 2020, Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc., the “Company”), completed its previously announced merger transaction with ArTara Subsidiary, Inc. (formerly ArTara Therapeutics, Inc., “Private ArTara”) in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of September 23, 2019, by and among the Company, REM 1 Acquisition, Inc. (“Merger Sub”), and Private ArTara (as amended on November, 19, 2019, the “Merger Agreement”), pursuant to which Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of the Company (the “Merger”).The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors. Following the completion of the Merger, the Company is focused on advancing Private ArTara’s drug development programs.

On January 9, 2020, in connection with, and prior to the completion of, the Merger, the Company effected a 1-for-40 reverse stock split of its common stock (the “Reverse Stock Split”), Private ArTara changed its name from “ArTara Therapeutics, Inc.” to “ArTara Subsidiary, Inc.”, and the Company changed its name from “Proteon Therapeutics, Inc.” to “ArTara Therapeutics, Inc.”. On May 11, 2020, the Company changed its name to Protara Therapeutics, Inc. In addition, immediately following the closing of the Private Placement (defined below), all of the outstanding shares of the Company’s Series A Preferred Stock were converted into shares of the Company’s common stock.

Under the terms of the Merger Agreement, the Company issued shares of its common stock (“Common Stock”) to Private ArTara’s stockholders, at an exchange ratio of 0.190756 shares of Common Stock, after taking into account the Reverse Stock Split, for each share of Private ArTara common stock outstanding immediately prior to the Merger. The Company assumed all of the outstanding and unexercised stock options of Private ArTara, with such stock options now representing the right to purchase a number of shares of Common Stock equal to 0.190756 multiplied by the number of shares of Private ArTara common stock previously represented by such Private ArTara stock options. The Company also assumed all of the unvested Private ArTara restricted stock awards, which were exchanged for a number of shares of Common Stock equal to 0.190756 multiplied by the number of shares of Private ArTara common stock previously represented by such Private ArTara restricted stock awards and unvested to the same extent as such Private ArTara restricted stock awards and subject to the same restrictions as such Private ArTara restricted stock awards.

The shares of Common Stock issued to the former stockholders of Private ArTara were registered with the U.S. Securities and Exchange Commission (the "SEC") on a Registration Statement on Form S-4 (Reg. No. 333-234549) (the "Registration Statement").

The shares of Common Stock listed on The Nasdaq Capital Market, previously trading through the close of business on Thursday, January 9, 2020 under the ticker symbol "PRTO," commenced trading on The Nasdaq Capital Market, on a post-Reverse Stock Split adjusted basis, under the ticker symbol "TARA," on Friday, January 10, 2020.

COVID-19

The ultimate impact of the current COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We have experienced delays, but may experience additional future delays that impact our business, our research and development activities, healthcare systems and the global economy as a whole. However, we will continue to monitor the COVID-19 situation closely should the effects have a material impact on our operations, liquidity and capital resources.

In response to public health directives and orders, we have implemented work-from-home policies for our employees and temporarily modified our operations to comply with applicable social distancing recommendations. Similar health directives and orders are affecting third parties with whom we do business, including the third parties that we have contracted with to conduct studies for TARA-002. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems around the globe will negatively impact our ability to conduct clinical trials in the near term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in the trials. We also anticipate that the global impact of COVID-19 will negatively impact our ability to conduct nonclinical studies due primarily to laboratory closures and limited availability of personnel. In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Financial Overview

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of TARA-002 and IV Choline Chloride, which include employee-related expenses, including salaries, benefits, travel and stock-based compensation expense, expenses incurred under agreements with clinical research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs"), the cost of acquiring, developing and manufacturing clinical trial materials, clinical and non-clinical related costs, costs associated with regulatory operations and facilities, depreciation and other expenses, which include expenses for rent and maintenance of facilities and other supplies.

General and Administrative Expenses

General and administrative expenses consist principally of employee-related expenses, including salaries, benefits, travel and stock-based compensation expense, in executive and other administrative functions. Other general and administrative expenses also include professional fees for legal, patent review, consulting and accounting services as well as facility related costs, as well as expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with our NASDAQ listing and SEC requirements, director and officer liability insurance premiums and investor relations costs associated with being a public company.

Interest Income, Net

Interest income, net, consists of interest income earned on our cash, cash equivalents and restricted cash, net of interest expense related to our short-term debt.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial position and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, 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 estimates related to clinical trial accruals, valuation of deferred tax assets, fair value of business combinations, fair value of goodwill and evaluation of impairment, stock stock-based compensation expense, and reported amounts of revenues and expenses during the reported 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 consolidated financial statements and related notes appearing elsewhere in this Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Goodwill

Goodwill represents the excess of purchase price over the fair value of identifiable net assets acquired in a business combination. Goodwill and other intangible assets acquired in a business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually. An entity has the option to first assess qualitative factors to determine whether events or circumstances lead to a conclusion that is more likely than not that the fair value of a reporting unit is greater than its carrying amount. If an entity determines that qualitative factors indicate that it is more likely than not that the fair value of the entity exceeds the carrying amount, the quantitative evaluation is not necessary. Under the quantitative impairment test, the evaluation of impairment involves comparing the current fair value of each reporting unit to its carrying value, including goodwill.

In the event the estimated fair value of our company is less than the carrying value, we would recognize a goodwill impairment equal to the difference between the carrying value and its fair value, not to exceed the carrying value of goodwill.

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. The measurement of net deferred tax assets is reduced by the amount of any tax benefit that, based on available evidence, is not expected to be realized, and a corresponding valuation allowance is established.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in our tax returns that do not meet these recognition and measurement standards. As of December 31, 2020 and 2019, no liability for unrecognized tax benefits was required to be recorded. The guidance also discusses the classification of related interest and penalties on income taxes. Our policy is to record interest and penalties on uncertain tax positions as a component of income tax expense. No interest or penalties were recorded during the years ended December 31, 2020 and 2019.

Business Combinations

For a business combination, the assets acquired and the liabilities assumed are recognized at the acquisition date, measured at their fair values as of that date. In a business combination achieved in stages, the identifiable assets and liabilities are recognized at their fair values. In a bargain purchase in which the total acquisition-date fair value of the identifiable net assets acquired exceeds the fair value of the consideration transferred plus any non-controlling interest in the acquiree, that excess in fair value is recognized as a gain.

Deferred tax liabilities and assets are recognized for the deferred tax consequences of differences between the tax bases and the recognized values of assets acquired and liabilities assumed in a business combination in accordance with ASC Topic 740-10 "Income Taxes".

Stock-Based Compensation

We issue stock-based awards to employees and non-employees. We account for our stock-based 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 modifications to existing stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values. We account for stock-based awards to non-employees in accordance with ASC 718, which requires the fair value of the award to be remeasured at fair value as the award vests.

Our stock-based awards are subject to service-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions 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. Compensation expense related to awards to non-employees with service-based vesting conditions is recognized on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term, using the accelerated attribution method.

Described below is the methodology we have utilized in measuring stock-based compensation expense. Following the consummation of the Merger, stock option values have been determined based on the quoted market price of our common stock.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (i) the expected volatility of our stock, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. We calculate the expected volatility using the historical volatility for a pool of peer companies over the most recent period equal to the expected term and evaluate the extent to which available information indicate that future volatility may differ from historical volatility. For these analyses, we select companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We account for forfeitures as they occur. We estimate the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option were based on the U.S. Treasury yield curve in effect during the period the options were granted.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		Period-to-Period Change
	2020	2019	
Operating expenses:			
Research and development	$ 11,982	$ 3,878	$ 8,104
General and administrative	22,462	3,952	18,510
Total operating expenses	34,444	7,830	26,614
Loss from operations	(34,444)	(7,830)	(26,614)
Other income, net:			
Interest income, net	(466)	–	(466)
Total other income, net	(466)	–	(466)
Net Loss	$ (33,978)	$ (7,830)	$ (26,148)

Research and Development Expenses. During the year ended December 31, 2020, our research and development expenses were approximately $12.0 million which represented an increase of approximately $8.1 million as compared to the year ended December 31, 2019. This increase was primarily due to an increase of approximately $3.2 million of non-clinical, clinical, regulatory expenses and outside services associated with TARA-002, an increase of approximately $2.5 million for manufacturing activities associated with TARA-002, an increase of approximately $1.5 million in headcount cost due to bonuses earned upon the merger and the hiring of additional employees and an increase of approximately $0.5 million in stock-based compensation.

General and Administrative Expenses. During the year ended December 31, 2020, our general and administrative expenses were approximately $22.5 million which represented an increase of approximately $18.5 million as compared to the year ended December 31, 2019. The increase, principally on account of becoming a public company on January 9, 2020, was primarily due to an increase of approximately $8.8 million in stock-based compensation, an increase of approximately $2.5 million in insurance, an increase of approximately $2.0 million in public company costs, an increase of approximately $2.8 million in headcount cost due to bonuses earned upon the merger and the hiring of additional employees, an increase of approximately $1.2 million in recruiting fees, an increase of approximately $0.3 million in board of director fees, and an increase of approximately $0.2 million in franchise and other taxes.

Interest Income, Net. During the year ended December 31, 2020, interest income, net was approximately $0.5 million higher as compared to the year ended December 31, 2019. The increase was primarily due to us earning interest on the funds received in the Private Placements and Underwritten Offerings.

Liquidity and Capital Resources

Overview

As of December 31, 2020 and 2019, our cash and cash equivalents was approximately $168.6 million and $0.6 million, respectively. We have not generated revenues since our inception and have incurred net losses of approximately $34.0 million and $7.8 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had working capital of approximately $166.5 million and stockholder’s equity of approximately $199.2 million. During the year ended December 31, 2020, cash flows used in operating activities were approximately $23.4 million, consisting primarily of a net loss of approximately $34.0 million, which includes non-cash stock-based compensation charges of approximately $9.7 million. Since inception, we have met our liquidity requirements principally through the sale of our common stock and preferred stock in private placements and underwritten offerings.

Liquidity

In connection with the Merger, we consummated the Private Placements, raising gross proceeds of approximately $42.5 million. Upon the consummation of the Merger and the Private Placements, the post-merger combined company was expected to have cash of approximately $39.6 million.

Concurrently with the execution of the Merger Agreement, certain institutional investors (together, the "Investors") entered into a subscription agreement (as amended on November 19, 2019, the "Subscription Agreement") with Protara Therapeutics, Inc. and Private ArTara, pursuant to which (A) Protara Therapeutics, Inc. issued, in a private placement immediately after the Merger (the "Proteon Private Placement"), (i) 3,879.356 of shares of Protara Therapeutics, Inc.'s Series 1 Convertible Non-Voting Preferred Stock ("Series 1 Preferred Stock") at a purchase price of approximately $7,011.47 per share for gross proceeds of $27.2 million and proceeds, net of issuance costs, of $25.3 million, (ii) 1,896,888 shares of Protara Therapeutics, Inc.'s Common Stock at a purchase price of approximately $7.01 per share for gross proceeds of $13.3 million and proceeds, net of issuance costs, of $12.4 million and (B) Private ArTara issued, in a private placement immediately prior to the Merger (the "ArTara Private Placement"), 284,875 shares of Private ArTara common stock (post-Exchange Ratio (as defined in the Merger Agreement) basis) at a purchase price of approximately $7.01 per share (post-Exchange Ratio basis) (together with the Proteon Private Placement, the "Private Placements") for gross proceeds of $2.0 million and proceeds, net of issuance costs, of $1.9 million. The shares issued in the Proteon Private Placement were registered for resale on a registration statement on Form S-3 filed and declared effective by the U.S. Securities and Exchange Commission (the "SEC") on February 10, 2020.

In connection with the Preferred Offering on September 22, 2020, we filed a Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock of ours (the "Amendment") with the Secretary of State of the State of Delaware to increase the authorized number of shares of our Series 1 Convertible Preferred Stock that may be issued from 3,880 to 8,028.

On September 24, 2020, pursuant to an underwriting agreement, dated September 22, 2020, we issued and sold in an underwritten public offering (the "Common Offering") an aggregate of 4,600,000 shares of our common stock at an offering price of $16.87 per share, for gross and net proceeds of approximately $77.6 million and $73.6 million, respectively. The underwriters were granted an option to purchase up to 690,000 additional shares of common stock at the public offering price, less the underwriting discount. This option was exercisable for a period of 30 days. On October 6, 2020, the underwriters exercised their overallotment option in full, purchasing an additional 690,000 shares, resulting in the receipt of gross and net proceeds of approximately $11.6 million and $11.1 million, respectively.

On September 24, 2020, pursuant to an underwriting agreement, dated September 22, 2020, we issued and sold in an underwritten public offering (the "Preferred Offering") an aggregate of 4,148 shares of our Series 1 Preferred Stock at an offering price of $16,873.54 per share, for gross and net proceeds of approximately $70.0 million and $66.3 million, respectively.

The Common Offering and the Preferred Offering were made pursuant to our registration statement on Form S-3, declared effective by the Securities and Exchange Commission on May 26, 2020 (Registration No. 333-238273).

In December 2020, we filed a shelf registration statement on Form S-3, or the Shelf Registration Statement, which became effective in December 2020. The Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of $300.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination. No securities have been sold to date under the Shelf Registration Statement.

We are in the business of developing biopharmaceuticals and have no current or near term revenues. We have incurred substantial clinical and other costs in our drug development efforts. We will need to raise additional capital in order to fully realize management's plans.

We believe that our current financial resources, as of the date of the issuance of these condensed consolidated financial statements, are sufficient to satisfy our estimated liquidity needs for at least twelve months from the issuance of these condensed consolidated financial statements.

As a result of economic conditions, general global economic uncertainty, political change, global pandemics, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development activities. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Cash Flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,		Period-to-Period Change
	2020	2019	
Net cash used in operating activities	$ (23,407)	$ (5,011)	$ (18,396)
Net cash provided by/(used in) investing activities	2,835	(475)	3,310
Net cash provided by financing activities	189,401	500	188,901
Net increase/(decrease) in cash and cash equivalents, and restricted cash	$ 168,829	$ (4,986)	173,815

Comparison of the Years Ended December 31, 2020 and 2019

Net cash used in operating activities was approximately $23.4 million for the year ended December 31, 2020 compared to approximately $5.0 million for the year ended December 31, 2019. The increase of approximately $18.4 million in cash used in operating activities was primarily driven by an increase net loss of approximately $26.1 million and a decrease in accrued expenses of approximately $3.0 million, off-set by increases of approximately $9.3 million of stock-based compensation and approximately $1.4 million in prepaid expenses and other current assets.

Net cash provided by investing activities was approximately $2.8 million for the year ended December 31, 2020 compared to net cash used in investing activities of approximately $0.5 million in the year ended December 31, 2019. The increase of approximately $3.3 million was primarily due to the cash and restricted cash acquired in connection with the Merger with Protara Therapeutics, Inc. of approximately $3.7 million, off-set by an increase in purchases of property and equipment of approximately $0.4 million.

Net cash provided by financing activities was approximately $189.4 million for the year ended December 31, 2020 compared to approximately $0.5 million for the year ended December 31, 2019. The increase of approximately $188.9 million was primarily due to proceeds, net of offering costs, from the Common Offering of approximately $73.6 million, the Preferred Offering of approximately $66.3 million, the issuance of Series 1 Preferred Stock of approximately $25.3 million, the Proteon Private Placement of approximately $12.4 million, the underwriters overallotment option of approximately $11.1 million, and the ArTara Private Placement of approximately $1.9 million, offset by repayments of short-term debt of approximately $1.7 million.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the applicable regulations of the SEC.

Contractual Obligations

Our future contractual obligations as of December 31, 2020 are (in thousands):

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations	$ 9,824	$ 1,111	$ 2,671	$ 2,765	$ 3,277

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

No disclosure required.

Item 8. ***Financial Statements and Supplementary Data.***

The consolidated financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page 60.

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2017). Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2020, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control Over Financial Reporting

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance.***

The information required by this Item and not set forth below will be set forth in the section headed "—Election of Directors" and "Information Regarding the Board of Directors and Corporate Governance" in our definitive Proxy Statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC on or before April 30, 2021 (our "***Proxy Statement***") and is incorporated in this report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://www.protaratx.com* under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics by emailing the Company at info@protaratx.com.

Item 11. ***Executive Compensation.***

The information required by this Item will be set forth in the section headed "*Executive Compensation*" in our Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in the section headed "*Security Ownership of Certain Beneficial Owners and Management*" in our Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "*Executive Compensation*" in our Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in the section headed "*Transactions With Related Persons*" in our Proxy Statement and is incorporated in this report by reference.

Item 14. ***Principal Accountant Fees and Services.***

The information required by this Item will be set forth in the section headed "*—Ratification of Selection of Independent Registered Public Accounting Firm*" in our Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) Documents filed as part of this report.

1. The following financial statements of Protara Therapeutics, Inc. and Report of Marcum LLP, Independent Registered Public Accounting Firm, are included in this report:

2. List of financial statement schedules:

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

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated September 23, 2019, by and among the Registrant, ArTara Therapeutics, Inc. and REM 1 Acquisition, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K as filed on September 24, 2019, and incorporated herein by reference).
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated November 19, 2019, by and among the Registrant, ArTara Therapeutics, Inc. and REM 1 Acquisition, Inc. (filed as Exhibit 2.2 to the Registrant's Registration Statement on Amendment No. 2 to Form S-4 as filed on December 4, 2019, and incorporated herein by reference).
3.1	Sixth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 27, 2014).
3.2	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.3	Second Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2020).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.5	Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 23, 2020).
3.6	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of Current Report on Form 8-K, filed on August 3, 2017).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
4.2+	Description of securities registered under Section 12 of the Exchange Act of 1934
4.3	Registration Rights Agreement, dated as of September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
10.1†	2006 Equity Incentive Plan, as amended and restated August 21, 2014 (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2014 (File No. 333-198777)).
10.2†	Form of Stock Option Grant Notice and Stock Option Agreement under the Company's 2006 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed on September 16, 2014).

10.3	Assignment of Rights/License Agreement, effective as of February 4, 2002, by and between Johns Hopkins University and F. Nicholas Franano (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on September 16, 2014).
10.4	Letter Agreement, dated January 12, 2009, by and between F. Nicholas Franano and the Company (as successor-in-interest to Proteon Therapeutics, L.L.C.) (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on September 16, 2014).
10.5†	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.25 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2014).
10.6**	Subscription Agreement, dated September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
10.7**	First Amendment to Subscription Agreement, dated November 19, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 99.12 to the Registrant's Registration Statement on Form S-4).
10.8†	Amended and Restated 2014 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 10, 2020).
10.9†	Forms of Stock Option Agreement, Option Exercise, Restricted Stock Unit Grant and Restricted Stock Unit Agreement under the Amended and Restated 2014 Equity Incentive Plan of the Registrant, as amended (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on form 10-K on form 10-K for the fiscal year ended December 31, 2019 filed on March 20, 2020).
10.10†	2017 Equity Incentive Plan of ArTara Subsidiary, Inc. (incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.11†	Inducement Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2020).
10.12†	Form of Stock Option Grant Notice and Stock Option Agreement under the Inducement Plan of the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2020).
10.13†	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the Inducement Plan of the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2020).
10.14†	Executive Employment Agreement, dated as of November 5, 2019, as amended on December 4, 2019, by and between ArTara Subsidiary, Inc. and Jesse Shefferman. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.15†	Executive Employment Agreement, dated as of December 17, 2019, by and between ArTara Subsidiary, Inc. and Jacqueline Zummo, Ph.D., MPH, MBA. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.16†^	Separation Agreement and Release, dated as of July 23, 2020, by and between the Registrant and Julio Casoy (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2020).
10.17†	Executive Employment Agreement, effective as of February 11, 2020 by and between the Registrant and Blaine Davis (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 19, 2020).
10.18††	Choline License Agreement, by and between ArTara Subsidiary, Inc. and Alan L. Buchman, M.D. dated as of September 27, 2017. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.19††	Sponsored Research and License Agreement, by and between ArTara Subsidiary, Inc. and The University of Iowa dated as of November 28, 2018. (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.20††	License Agreement, by and between ArTara Subsidiary, Inc. and The Feinstein Institute for Medical Research dated as of December 22, 2017. (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.21††	Agreement, by and between ArTara Subsidiary, Inc. and Chugai Pharmaceutical Co., Ltd. dated as of June 17, 2019. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.22††	Amendment to Agreement, by and between Chugai Pharmaceutical Co., Ltd. and the Registrant, dated as of July 14, 2020 and effective as of June 30, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2020).

10.23†	Form of Indemnity Agreement between the Registrant and each of its directors and officers. (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.24†	Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2020).
10.25†† **+	Lease by and between 345 PAS HOLDING LLC, and the Registrant, dated as of December 7, 2020.
21.1+	List of Subsidiaries.
23.1+	Consent of Marcum LLP, independent registered public accounting firm.
31.1+	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2+	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1+	Principal Executive Officer Certification and Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Consolidated Balance Sheets as of December 31, 2020 and 2019; (ii) the Consolidated Statements of Operations for the years ended December 31, 2020 and 2019; (iii) the Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the years ended December 31, 2020 and 2019; (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019; and (v) the notes to the Consolidated Financial Statements.

+ Filed herewith.

** Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished to the SEC upon request.

† Indicates management contract or compensatory plan or arrangement.

†† Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

Item 16. ***Form 10-K Summary***

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Protara Therapeutics, Inc.

Date: March 11, 2021

/s/ Jesse Shefferman
Jesse Shefferman
President and Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Stephen Davis, his true and lawful attorney-in-fact and agent with full power of substitution, for him and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all 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 his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and 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/ JESSE SHEFFERMAN Jesse Shefferman	President and Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2021
/s/ BLAINE DAVIS Blaine Davis	Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2021
/s/ LUKE BESHAR Luke Beshar	Chairman of the Board of Directors	March 11, 2021
/s/ BARRY FLANNELLY, PHARMD Barry Flannelly, PharmD	Director	March 11, 2021
/s/ ROGER GARCEAU, M.D. Roger Garceau, M.D.	Director	March 11, 2021
/s/ RICHARD LEVY, M.D. Richard Levy, M.D.	Director	March 11, 2021
/s/ GREGORY P. SARGEN Gregory P. Sargen	Director	March 11, 2021
/s/ MICHAEL SOLOMON, PH.D. Michael Solomon, Ph.D.	Director	March 11, 2021
/s/ CYNTHIA SMITH Cynthia Smith	Director	March 11, 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Protara Therapeutics, Inc.
New York, New York

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Protara Therapeutics, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

We have served as the Company's auditor since 2019.

New York, New York
March 11, 2021

PROTARA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	As of December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 168,598	$ 564
Restricted cash	50	-
Deferred offering costs	-	122
Prepaid expenses and other current assets	787	78
Total current assets	169,435	764
Non-current assets:		
Restricted cash, long-term	745	-
Property and equipment, net	1,240	459
Goodwill	29,517	-
Other assets	2,220	-
Total assets	$ 203,157	$ 1,223
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 914	$ 716
Accrued expenses	1,913	2,635
Operating lease liability, current	88	-
Total current liabilities	2,915	3,351
Non-current liabilities:		
Operating lease liability, long-term	999	-
Total liabilities	3,914	3,351
Commitments and Contingencies (Note 7)		
Stockholders' Equity (Deficit)		
Preferred Stock, $0.001 par value, authorized 10,000,000 shares: Series 1 Convertible Preferred Stock, 8,028 and 0 shares authorized at December 31, 2020 and 2019, respectively, 8,027 and 0 shares issued and outstanding as of December 31, 2020 and 2019, respectively.	-	-
Common Stock, $0.001 par value, authorized 100,000,000 shares:		
Common Stock, 11,211,840 and 2,627,533 shares issued and outstanding as of December 31, 2020 and 2019, respectively.	11	3
Additional Paid in Capital	245,992	10,651
Accumulated Deficit	(46,760)	(12,782)
Total Stockholders' Equity (Deficit)	199,243	(2,128)
Total Liabilities and Stockholders' Equity (Deficit)	$ 203,157	$ 1,223

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

PROTARA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	For the Years Ended December 31,	
	2020	2019
Operating expense:		
Research & development	$ 11,982	$ 3,878
General & administrative	22,462	3,952
Total operating expenses	34,444	7,830
Operating loss	(34,444)	(7,830)
Other income, net		
Interest income, net	(466)	-
Total other income, net	(466)	-
Net Loss	$ (33,978)	$ (7,830)
Weighted Average Shares Outstanding, basic and diluted	7,233,913	2,577,493
Net loss per share, basic and diluted	$ (4.70)	$ (3.04)

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

PROTARA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019
(in thousands, except share and per share data)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	-	$ -	2,558,419	$ 3	$ 9,727	$ (4,952)	$ 4,778
Stock-based compensation - stock options	-	-	-	-	313	-	313
Stock-based compensation - restricted stock	-	-	-	-	75	-	75
Stock-based compensation - restricted stock units	-	-	-	-	36	-	36
Issuance of common stock in September capital raise	-	-	69,114	-	500	-	500
Net loss	-	-	-	-	-	(7,830)	(7,830)
Balance at December 31, 2019	-	$ -	2,627,533	$ 3	$ 10,651	$ (12,782)	$ (2,128)
Issuance of Common Stock in ArTara Private Placement, net of offering costs	-	-	284,875	-	1,867	-	1,867
Issuance of Common Stock in Proteon Private Placement, net of offering costs	-	-	1,896,888	2	12,411	-	12,413
Issuance of Series 1 Convertible Preferred Stock in Proteon Private Placement, net of offering costs	3,879	-	-	-	25,319	-	25,319
Reverse business combination	-	-	1,033,907	1	34,532	-	34,533
Issuance of Common Stock in Common Offering, net of offering costs	-	-	4,600,000	4	73,566	-	73,570
Issuance of Series 1 Convertible Preferred Stock in Preferred Offering, net of offering costs	4,148	-	-	-	66,284	-	66,284
Issuance of Common Stock in Common Offering (Underwriters Overallotment Option), net of offering costs	-	-	690,000	1	11,086	-	11,087
Settlement of restricted stock units	-	-	20,870	-	-	-	-
Exercise of stock options	-	-	57,767	-	530	-	530
Stock-based compensation - restricted stock units	-	-	-	-	6,357	-	6,357
Stock-based compensation - stock options	-	-	-	-	3,389	-	3,389
Net loss	-	-	-	-	-	(33,978)	(33,978)
Balance at December 31, 2020	8,027	$ -	11,211,840	$ 11	$ 245,992	$ (46,760)	$ 199,243

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

PROTARA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Years Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (33,978)	$ (7,830)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	9,746	424
Amortization of operating lease right-of-use asset	93	-
Depreciation	103	16
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,405	(37)
Other Assets	58	-
Accounts payable	198	366
Accrued expenses	(966)	2,050
Right-of-use liability	(66)	-
Net cash used in operating activities	(23,407)	(5,011)
Cash flows from investing activities:		
Cash and restricted cash acquired in connection with the reverse merger with ArTara Therapeutics, Inc.	3,719	-
Purchase of property and equipment	(884)	(475)
Net cash provided by/(used in) investing activities	2,835	(475)
Cash flows from financing activities:		
Proceeds from - ArTara Private Placement, net of offering costs	1,867	-
Proceeds from - Common Stock in Proteon Private Placement, net of offering costs	12,413	-
Proceeds from - Series 1 Convertible Preferred Stock in Proteon Private Placement, net of offering costs	25,319	-
Proceeds from Common Offering, net of offering costs	73,570	-
Proceeds from Preferred Offering, net of offering costs	66,284	-
Proceeds from Underwriters Overallotment Option	11,087	-
Repayments under short-term debt	(1,669)	-
Proceeds from the exercise of stock options	530	-
Proceeds from private placements	-	500
Net cash provided by financing activities	189,401	500
Net increase/(decrease) in cash and cash equivalents and restricted cash	168,829	(4,986)
Cash and cash equivalents and restricted cash - beginning of year	564	5,550
Cash and cash equivalents and restricted cash - end of year	$ 169,393	$ 564
Reconciliation of cash and cash equivalents and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	$ 168,598	$ 564
Restricted cash	50	-
Restricted cash, long-term	745	-
Cash and cash equivalents and restricted cash	$ 169,393	$ 564
Supplemental cash flow information		
Cash paid for:		
Interest	$ 34	$ -
Income Taxes	$ -	$ -
Non-cash investing and financing activities:		
Deferred offering costs recorded in accrued expenses	$ -	$ 122
Deferred offering costs recognized that were previously recorded in accrued expenses	$ 122	$ -
Purchase of insurance agreement with notes payable	$ 1,669	$ -
Common stock issued in connection with the reverse merger with ArTara Therapeutics, Inc.	$ 34,533	$ -

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

NOTE 1 – BUSINESS, LIQUIDITY AND CAPITAL RESOURCES

Overview

Protara Therapeutics, Inc. and its consolidated subsidiaries ("Protara" or the "Company") is committed to identifying and advancing transformative therapies for the treatment of cancer and rare diseases with significant unmet needs. Protara's portfolio includes two development programs utilizing TARA-002, an investigational cell therapy in development for the treatment of lymphatic malformations (LMs) and non-muscle invasive bladder cancer (NMIBC). The third program in the portfolio is Intravenous (IV) Choline Chloride, an investigational phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition (PN) who have intestinal failure associated liver disease (IFALD). The fourth program in the portfolio is Vonapanitase, a recombinant human elastase.

On January 9, 2020, privately-held ArTara Subsidiary, Inc. ("Private ArTara") and Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc.) completed the merger and reorganization (the "Merger"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 23, 2019, (the "Merger Agreement") by and among Protara Therapeutics, Inc., Private ArTara and REM 1 Acquisition, Inc., a wholly owned subsidiary of Protara Therapeutics, Inc ("Merger Sub"). Thereupon, Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of Protara Therapeutics, Inc. The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors, and the post-merger company retained the name ArTara Therapeutics, Inc., which on May 11, 2020 was changed to Protara Therapeutics, Inc.

On January 9, 2020, in connection with and prior to the completion of the Merger, Protara Therapeutics, Inc. effected a 1-for-40 reverse stock split of its common stock (the "Protara Reverse Stock Split"), Private ArTara changed its name from "ArTara Therapeutics, Inc." to "ArTara Subsidiary, Inc.", and ArTara Therapeutics, Inc. changed its name from "Proteon Therapeutics, Inc." to "ArTara Therapeutics, Inc" then subsequently changed its name from "ArTara Therapeutics, Inc" to "Protara Therapeutics, Inc." All share and per share amounts presented in this annual report on Form 10-K have been adjusted to reflect the Protara Reverse Stock Split and the Exchange Ratio (defined below). In addition, immediately following the closing of the Private Placements (defined below), all of the outstanding shares of Protara Therapeutics, Inc.'s Series A Preferred Stock were converted into shares of Protara Therapeutics, Inc.'s Common Stock (defined below). Shares of the Company's Common Stock commenced trading on The Nasdaq Capital Market under the new name and ticker symbol "TARA" as of market open on January 10, 2020. See Note 3 for the full discussion regarding the Merger, Exchange Ratio and recapitalization.

Liquidity, Capital Resources and Management Plans

As of December 31, 2020 and 2019, the Company's cash and cash equivalents was $168,598 and $564, respectively. The Company has not generated revenues since its inception and has incurred net losses of $33,978 and $7,830 for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the Company had working capital of $166,520 and stockholder's equity of $199,243. During the year ended December 31, 2020, cash flows used in operating activities were $23,407, consisting primarily of a net loss of $33,978, which includes non-cash stock-based compensation charges of $9,746. Since inception, the Company has met its liquidity requirements principally through the sale of its Common Stock and Series 1 Convertible Preferred Stock.

In connection with the Merger, the Company consummated the Private Placements, raising gross proceeds of $42.5 million and proceeds, net of offering costs, of $39.6 million.

On September 22, 2020, the Company entered into underwriting agreements with Cowen and Company, LLC and Guggenheim Securities, LLC, as representatives of several underwriters for separate, concurrent underwritten public offerings of the Company's Common Stock and Series 1 Convertible Preferred Stock. On September 24, 2020, gross and net proceeds from this offering were $147.6 million and $139.9 million, respectively. On October 6, 2020, the underwriters exercised their overallotment option, resulting in the receipt of gross and net proceeds of $11.6 million and $11.1 million, respectively (See Note 8).

NOTE 1 – BUSINESS, LIQUIDITY AND CAPITAL RESOURCES (Continued)

Liquidity, Capital Resources and Management Plans (Continued)

The Company is in the business of developing biopharmaceuticals and has no current or near term revenues. The Company has incurred substantial clinical and other costs in its drug development efforts. The Company will need to raise additional capital in order to fully realize management's plans.

The Company believes that its current financial resources are sufficient to satisfy the Company's estimated liquidity needs for at least twelve months from the date of issuance of these consolidated financial statements.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All inter-company balances and transactions have been eliminated in the accompanying consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, and also that affect the amount of expenses reported for each period. Actual results could differ from those which result from using such estimates. Management also utilizes various other estimates, including but not limited to income taxes, the valuation of deferred tax assets, determining the fair value of business combination considerations, determining the fair value and evaluation for impairment of goodwill, determining the fair value of the Company's Common Stock, and the valuation of securities and assumptions underlying stock-based compensation. The results of any changes in accounting estimates are reflected in the financial statements of the period in which the change becomes evident. Estimates and assumptions are reviewed periodically and the effects of revisions are reflected in the period that they are determined to be necessary.

Cash and cash equivalents

The Company considers all highly liquid instruments with an original maturity of three months or less when acquired to be cash equivalents. Cash and cash equivalents are held in depository and money market accounts and are reported at fair value.

Restricted Cash

Restricted cash as of December 31, 2020 and 2019 was $795 and $0, respectively. As of December 31, 2020, restricted cash consists of cash deposits of $795 to collateralize letter of credit obligations.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Property and Equipment

Property and equipment is recorded at cost. Major property additions, replacements, and betterments are capitalized, while maintenance and repairs that do not extend the useful lives of an asset or add new functionality are expensed as incurred. Property and equipment not placed into service is not depreciated until such time that it is placed into service. Depreciation is recorded using the straight-line method over the respective estimated useful lives of the Company's assets.

Goodwill

Goodwill represents the excess of purchase price over the fair value of identifiable net assets acquired in a business combination. Goodwill and other intangible assets acquired in a business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually. An entity has the option to first assess qualitative factors to determine whether events or circumstances lead to a conclusion that is more likely than not that the fair value of a reporting unit is greater than its carrying amount. If an entity determines that qualitative factors indicate that it is more likely than not that the fair value of the entity exceeds the carrying amount, the quantitative evaluation is not necessary. Under the quantitative impairment test, the evaluation of impairment involves comparing the current fair value of each reporting unit to its carrying value, including goodwill.

In the event the estimated fair value of the Company is less than the carrying value, the Company would recognize a goodwill impairment equal to the difference between the carrying value and its fair value, not to exceed the carrying value of goodwill.

On January 9, 2020, in connection with the Merger, the Company separately valued the assets and liabilities acquired, and then determined goodwill as the residual of the purchase price less identified net assets. On December 31, 2020, in connection with the finalization of the purchase price allocation, the Company recorded an adjustment of $150 to goodwill related to prepaid expenses and accrued expenses (See Note 3).

(amounts in thousands, except share and per share data)

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Net Loss per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding, plus the impact of common shares, if dilutive, resulting from the exercise of outstanding stock options.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Years Ended December 31,	
	2020	2019
Stock options	674,039	219,592
Restricted stock units	407,325	5,245
Conversion of Series 1 Convertible Preferred Stock	8,029,039	-
Total potentially dilutive shares	9,110,403	224,837

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consists principally of cash amounts on deposit with financial institutions. At times, the Company's cash in banks is in excess of the Federal Deposit Insurance Corporation insurance limit. The Company has not experienced any loss as a result of these deposits.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification, or ("ASC"), Topic 718, "Compensation - Stock Compensation" ("ASC 718"). ASC 718 establishes accounting for stock-based awards exchanged for employee and consultant services. Under the provisions of ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employee's requisite service period (generally the vesting period of the equity grant). The fair value of the Company's stock options are estimated using the Black Scholes option-pricing model with the following assumptions: fair value of the Company's Common Stock, expected volatility, dividend rate, risk free interest rate and the expected life. The Company calculates the expected volatility using the historical volatility for a pool of peer companies over the most recent period equal to the expected term and evaluates the extent to which available information indicate that future volatility may differ from historical volatility. The expected dividend rate is zero as the Company does not expect to pay or declare any cash dividends on its Common Stock. The risk-free rates for the expected terms of the stock options are based on the U.S. Treasury yield curve in effect at the time of the grant. The Company has not experienced significant exercise activity on stock options. Due to the lack of historical information, the Company determined the expected term of its stock option awards issued using the simplified method. The simplified method assumes each vesting tranche of the award has a term equal to the midpoint between when the award vests and when the award expires. Restricted stock awards generally vest over the requisite service periods (vesting on a straight–line basis). The fair value of a stock award is equal to the fair market value of a share of the Company's Common Stock on the grant date. The Company accounts for the forfeiture of equity awards as they occur.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Fair Value Measurements

The carrying amounts of cash and cash equivalents, prepaid expenses and accounts payable approximate their fair values due to the short-term nature of these instruments.

ASC Topic 820 “Fair Value Measurements and Disclosures” provides the framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements).

Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

- Ø Level 1 Quoted prices in active markets for identical assets or liabilities.
- Ø Level 2 Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly.
- Ø Level 3 Significant unobservable inputs that cannot be corroborated by market data.

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. The measurement of net deferred tax assets is reduced by the amount of any tax benefit that, based on available evidence, is not expected to be realized, and a corresponding valuation allowance is established.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for “unrecognized tax benefits” is recorded for any tax benefits claimed in the Company’s tax returns that do not meet these recognition and measurement standards. As of December 31, 2020 and 2019, no liability for unrecognized tax benefits was required to be recorded. The guidance also discusses the classification of related interest and penalties on income taxes. The Company’s policy is to record interest and penalties on uncertain tax positions as a component of income tax expense. No interest or penalties were recorded during the years ended December 31, 2020 and 2019.

Research and Development Costs

Research and development costs are expensed as incurred. These expenses include the costs of our proprietary research and development efforts, as well as costs incurred in connection with certain licensing arrangements. Before a compound receives regulatory approval, the Company records upfront and milestone payments made to third parties under licensing arrangements as expense. Upfront payments are recorded when incurred, and milestone payments are recorded when the specific milestone or progress has been achieved. Once a compound receives regulatory approval, the Company records any milestone payments in identifiable intangible assets, less accumulated amortization and, unless the asset is determined to have an indefinite life, the Company amortizes the payments on a straight-line basis over the remaining agreement term or the expected product life cycle, whichever is shorter.

Research and development expenses were $11,982 and $3,878 for the years ended December 31, 2020 and 2019, respectively.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Business Combinations

For a business combination, the assets acquired and the liabilities assumed are recognized at the acquisition date, measured at their fair values as of that date. In a business combination achieved in stages, the identifiable assets and liabilities are recognized at their fair values. In a bargain purchase in which the total acquisition-date fair value of the identifiable net assets acquired exceeds the fair value of the consideration transferred plus any non-controlling interest in the acquiree, that excess in fair value is recognized as a gain.

Deferred tax liabilities and assets are recognized for the deferred tax consequences of differences between the tax bases and the recognized values of assets acquired and liabilities assumed in a business combination in accordance with ASC Topic 740-10 “Income Taxes”. See Note 3 for the Company’s accounting for the reverse merger.

Recent Accounting Pronouncements Adopted

In January 2017, the FASB issued Accounting Standards Update (“ASU”) 2017-04 (“ASU 2017-04”), Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. ASU 2017-04 simplifies the subsequent measurement of goodwill by eliminating the second step of the goodwill impairment test. The second step measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount of that goodwill. Under ASU 2017-04, a company will record an impairment charge based on the excess of a reporting unit’s carrying amount over its fair value. ASU 2017-04 will be applied prospectively and is effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. On January 1, 2020, the Company adopted ASU 2017-04. The adoption of this standard did not have a material effect on the Company’s financial position, results of operations, or cash flows.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”), which removes, adds and modifies certain disclosure requirements for fair value measurements in Topic 820. The Company will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy as well as the valuation processes of Level 3 fair value measurements. The Company will be required to provide additional disclosure related to the changes in unrealized gains and losses included in other comprehensive loss for recurring Level 3 fair value measurements and the range and weighted average of assumptions used to develop significant unobservable inputs for Level 3 fair value measurements. On January 1, 2020, the Company adopted ASU 2018-13. The adoption of this standard did not have a material effect on the Company’s financial position, results of operations, or cash flows.

Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were available to be issued. The Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

NOTE 3 – REVERSE MERGER WITH PROTARA AND RECAPITALIZATION

On January 9, 2020, in connection with, and prior to the completion of the Merger, Protara Therapeutics, Inc. effected the Protara Reverse Stock Split, which resulted in 557,631 pre-merger shares of Protara Therapeutics, Inc. outstanding.

Under the terms of the Merger Agreement, Protara Therapeutics, Inc. issued shares of its common stock ("Common Stock") to the Company's stockholders, at an exchange ratio of 0.190756 (the "Exchange Ratio"), after taking into account the Protara Reverse Stock Split, for each share of Private ArTara common stock outstanding immediately prior to the Merger. Protara Therapeutics, Inc. assumed all of the unvested Private ArTara restricted stock awards, which were exchanged for a number of shares of Common Stock equal to 0.190756 multiplied by the number of shares of Private ArTara common stock previously represented by such Private ArTara restricted stock awards and unvested to the same extent as such Private ArTara restricted stock awards and subject to the same restrictions as such Private ArTara restricted stock awards. On account of the adjustment required pursuant to the Exchange Ratio, there were 2,627,533 shares of Private ArTara common stock outstanding immediately prior to the Merger.

Protara Therapeutics, Inc. assumed all of the outstanding and unexercised stock options of Private ArTara, with such stock options representing the right to purchase a number of shares of Common Stock equal to 0.190756 multiplied by the number of shares of Private ArTara common stock previously represented by such Private ArTara stock options. As a result, 219,699 shares were assumed under Private ArTara's 2017 Equity Incentive Plan. No additional awards will be made under the 2017 Equity Incentive Plan. On January 1, 2020, Protara Therapeutics, Inc. amended its Amended and Restated 2014 Equity Incentive Plan (the "2014 Equity Incentive Plan") to increase the number of shares of stock available for issuance under the 2014 Equity Incentive Plan to 1,048,300 shares and made conforming changes and updates pursuant to Section 162(m) of the Code.

Concurrently with the execution of the Merger Agreement, certain institutional investors (together, the "Investors") entered into a subscription agreement (as amended on November 19, 2019, the "Subscription Agreement") with Protara Therapeutics, Inc. and Private ArTara, pursuant to which (A) Protara Therapeutics, Inc. issued in a private placement immediately after the Merger (the "Proteon Private Placement") (i) 3,879.356 of shares of Protara Therapeutics, Inc.'s Series 1 Convertible Non-Voting Preferred Stock at a purchase price of approximately $7,011.47 per share for gross proceeds of $27,200 and proceeds, net of issuance costs, of $25,319, (ii) 1,896,888 shares of Protara Therapeutics, Inc.'s Common Stock at a purchase price of approximately $7.01 per share for gross proceeds of $13,300 and proceeds, net of issuance costs, of $12,413 and (B) Private ArTara issued in a private placement immediately prior to the Merger (the "ArTara Private Placement") 284,875 shares of Private ArTara common stock (post-Exchange Ratio basis) at a purchase price of approximately $7.01 per share (post-Exchange Ratio basis) (together with the Proteon Private Placement, the "Private Placements") for gross proceeds of $2,000 and proceeds, net of issuance costs, of $1,867. The shares issued in the Proteon Private Placement were registered for resale on a registration statement on Form S-3 filed and declared effective by the SEC on January 30, 2020.

Immediately following the closing of the Proteon Private Placement, 18,954 shares of Protara Therapeutics, Inc.'s Series A Convertible Preferred Stock outstanding were converted into 476,276 shares of Protara Therapeutics, Inc.'s Common Stock. These shares, combined with the 557,631 pre-merger shares of Protara Therapeutics, Inc. outstanding after the Protara Reverse Stock Split, resulted in an aggregate of 1,033,907 shares of Common Stock issued in connection with the Merger.

Immediately after the consummation of the Merger and prior to the consummation of the Proteon Private Placement, the former stockholders and option holders of Private ArTara owned, or held rights to acquire, approximately 75.2% of the fully-diluted Common Stock of Protara, with Protara Therapeutics, Inc.'s stockholders and option holders immediately prior to the Merger owning approximately 24.8% of the fully-diluted Common Stock of Protara.

(amounts in thousands, except share and per share data)

NOTE 3 – REVERSE MERGER WITH PROTARA AND RECAPITALIZATION (Continued)

Based on the terms of the Merger, the transaction was treated as a reverse merger of Protara Therapeutics, Inc. by Private ArTara. The Merger was accounted for using acquisition accounting under ASC Topic 805 “Business Combinations”. Under acquisition accounting, the assets and liabilities (including executory contracts, commitments and other obligations) of Protara Therapeutics, Inc. as of the effective time of the Merger were recorded at their respective fair values and added to those of Private ArTara. Any excess of purchase price consideration over the fair values of the identifiable net assets is recorded as goodwill. During the year ended December 31, 2020, the Company recorded an adjustment of $150 to goodwill. This adjustment was comprised of a decrease of $78 in prepaid expenses and other current assets, and an increase of $77 in accrued expenses, resulting in a final purchase price allocation as follows:

Cash	$	3,669
Restricted cash		50
Prepaid expenses and other current assets		1,662
Goodwill		29,517
Accrued expenses		(365)
Total purchase price consideration	$	34,533

The total fair value of the net assets of Protara Therapeutics Inc. was determined by the Company to be $34,533 based on the consideration transferred. The total consideration was based on the enterprise value of Protara Therapeutics Inc. as of January 9, 2020, based upon the number of common shares deemed outstanding, multiplied by the closing stock price on January 9, 2020.

Of the amount of goodwill acquired in the reverse merger, no portion is deductible for tax purposes.

The primary reasons for the reverse merger: the increased access to sources of capital and a broader range of investors to support the clinical development of Private ArTara’s product candidates, the potential to provide current stockholders with greater liquidity by owning stock in a public company, the potential for a more cost-effective means to access capital and the registration of Protara Common Stock issued to Private ArTara’s stockholders. In addition, Protara assumed the existing 2014 Equity Incentive Plan (the “2014 Plan”), and all outstanding stock options thereunder.

(amounts in thousands, except share and per share data)

NOTE 3 – REVERSE MERGER WITH PROTARA AND RECAPITALIZATION (Continued)

The following presents the unaudited pro forma combined financial information as if the reverse merger had occurred as of January 1, 2019.

	For the Years Ended December 31,	
	2020	2019
Net loss	$ (33,754)	$ (22,821)
Pro forma loss per common share, basic and diluted	$ (4.62)	$ (3.94)
Pro forma weighted average number of common shares outstanding, basic and diluted	7,304,201	5,793,024

The pro forma combined results of operations are not necessarily indicative of the results of operations that actually would have occurred had the reverse merger been completed as of January 1, 2019, nor are they necessarily indicative of future consolidated results.

(amounts in thousands, except share and per share data)

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	Useful Life (in years)	As of December 31, 2020	As of December 31, 2019
Computer equipment	5	$ 34	$ -
Furniture, fixtures and other	5	21	21
Laboratory equipment	7	601	446
Leasehold improvements	Over the shorter of the useful life or the lease term	200	-
Property and equipment not yet placed into service		503	8
Total property and equipment, gross		1,359	475
Less: Accumulated depreciation		(119)	(16)
Total property and equipment, net		$ 1,240	$ 459

Depreciation expense was $103 and $16 for the years ended December 31, 2020 and 2019, respectively. During the year ended December 31, 2020, $99 and $4 was included in research and development expense and general and administrative expense, respectively, within the consolidated statements of operations. For the year ended December 31, 2019, $16 was included in research and development expense within the consolidated statements of operations.

NOTE 5 – ACCRUED EXPENSES

Included in the Company's accrued expenses within the consolidated financial statements are:

	As of December 31, 2020	As of December 31, 2019
Employee bonus	$ 1,530	$ -
Taxes	159	-
Legal fees	156	1,573
Research and development costs	37	1,050
Other expenses	31	12
Total	$ 1,913	$ 2,635

NOTE 6 – SHORT-TERM DEBT

Financing Agreement

On February 19, 2020, the Company entered into a nine month financing agreement with AFCO Credit Corporation for its directors and officers ("D&O") liability insurance in the amount of $2,225. The Company made a down payment of $556, leaving a principal balance of $1,669. The financing bore interest at a rate of 4.25% per annum, and was repaid in monthly installments of $189, which included both principal and interest. As of December 31, 2020, the balance under this debt was $0. The Company recorded interest expense of $34 for the year ended December 31, 2020 under this financing agreement.

NOTE 7 – COMMITMENTS AND CONTINGENCIES

Lease Agreements

The Company has entered into operating leases for office and laboratory space. On January 1, 2019 ("Effective Date"), the Company adopted ASC Topic 842, Leases ("ASC 842"), which increases transparency and comparability by recognizing a lessee's rights and obligations resulting from leases. ASC 842 requires the recognition of the right-of-use ("ROU") assets and related operating lease liabilities on the balance sheet. The Company adopted the new guidance using the modified retrospective approach on January 1, 2019.

The adoption of ASC 842 on January 1, 2019 did not immediately result in the recognition of ROU assets as the Company did not have any leases at that time with a term of twelve months or more. However, on January 9, 2020, subsequent to the Merger and Private Placements, it became reasonably certain that the Company would maintain its quarter-to-quarter lease with its contract development and manufacturing organization for its manufacturing space for an expected term of approximately eight years, therefore resulting in the recognition of an ROU asset and related operating lease liability.

The Company elected the package of practical expedients permitted within the standard, which allow an entity to forgo reassessing (i) whether a contract contains a lease, (ii) classification of leases, and (iii) whether capitalized costs associated with a lease meet the definition of initial direct costs. Also, the Company elected the expedient to allow the Company to not have to separate lease and non-lease components. The Company has also elected the short-term lease accounting policy under which the Company would not recognize a lease liability or ROU asset for any lease that at the commencement date has a lease term of twelve months or less and does not include a purchase option that the Company is more than reasonably certain to exercise.

On July 1, 2020 and December 1, 2020, the Company entered into additional quarter-to-quarter leases for additional contract development and manufacturing space for expected terms of approximately seven years, therefore resulting in the recognition of additional ROU assets and related operating lease liabilities.

On December 1, 2020, the Company entered into a long-term lease for office space for a term of seven years. This lease was entered into with a related party of the Company, and its terms were determined by management to be on an arms-length basis. The lease will not commence until the second quarter of 2021 when the Company is granted access to the premises. Accordingly, as of December 31, 2020, the Company did not recognize an additional ROU asset and related operating lease liability for this lease.

For contracts entered into on or after the Effective Date, at the inception of a contract, the Company will assess whether the contract is, or contains, a lease. The Company's assessment is based on: (i) whether the contract involves the use of a distinct identified asset, (ii) whether the Company obtained the right to substantially all the economic benefit from the use of the asset throughout the period, and (iii) whether the Company has the right to direct the use of the asset. Leases entered into prior to January 1, 2019, which were accounted for under ASC 840, Leases, were not reassessed for classification.

(amounts in thousands, except share and per share data)

NOTE 7 – COMMITMENTS AND CONTINGENCIES (Continued)

Lease Agreements (Continued)

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The Company generally uses its incremental borrowing rate as the discount rate for leases, unless an interest rate is implicitly stated in the lease. The present value of the lease payments is calculated using the incremental borrowing rate for operating leases, which was determined using a rate of interest that the Company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term. The lease term for the Company's lease includes the noncancellable period of the lease plus any additional periods covered by either a Company option to extend the lease that the Company is reasonably certain to exercise, or an option to extend the lease controlled by the lessor. ROU assets, once recorded, are reviewed for impairment.

Lease expense for operating leases consists of the lease payments plus any initial direct costs and is recognized on a straight-line basis over the lease term.

Balance sheet information related to our leases is presented below:

		As of		
Operating leases:	Balance Sheet Location	December 31, 2020	January 9, 2020	December 31, 2019
Right-of-use assets	Other assets	$ 1,060	$ 403	$ -
Operating lease liability, current	Operating lease liability, current	88	9	-
Operating lease liability, long-term	Operating lease liability, long-term	999	394	-

The following provides details of the Company's lease expense:

Lease cost	For the Year Ended December 31, 2020
Operating lease cost	$ 93
Short-term lease cost	215
Total	$ 308

(amounts in thousands, except share and per share data)

NOTE 7 – COMMITMENTS AND CONTINGENCIES (Continued)

Lease Agreements (Continued)

Other information related to leases is presented below:

	As of December 31, 2020
Other information	
Weighted-average discount rate – operating lease	12.00%
Weighted-average remaining lease term – operating lease (in months)	87

As of December 31, 2020, the expected annual minimum lease payments of our operating lease liabilities and other short-term leases were as follows (includes long-term lease entered into on December 1, 2020 that does not commence until the second quarter of 2021):

For Years Ending December 31,	Operating lease
2021	$ 1,111
2022	1,333
2023	1,338
2024	1,342
2025	1,423
Thereafter	3,277
Total future minimum lease payments, undiscounted	9,824
Less: Imputed interest for leases in excess of one year	8,676
Present value of future minimum lease payments	$ 1,148
Present value of future minimum lease payments for our operating lease liabilities	$ 1,087
Present value of future minimum lease payments, short-term leases	$ 61

Employment Agreements

Executive Employment Agreements

The Company’s executive officers have entered into at-will employment agreements.

NOTE 7 – COMMITMENTS AND CONTINGENCIES (Continued)

Employment Agreements (Continued)

Temporary Employment Agreement

On December 6, 2018, the Company entered into a temporary employment agreement (the "Temporary Employment Agreement") with an individual who assisted with certain corporate development activities. Pursuant to the Temporary Employment Agreement, the individual was entitled to receive an annual base salary of $90. In addition, the individual would be entitled to a performance-based success fee which would be adjusted based on amounts of funding achieved and timing of when such funding was received. On January 9, 2020, the Company's capital raise triggered a performance-based compensation obligation and accordingly this individual was paid $462, which was included in general and administrative expenses within the Company's consolidated statements of operations for the year ended December 31, 2020.

Collaborations and License Agreements

Choline License Agreement

On September 27, 2017, the Company entered into a license agreement (the "Choline License Agreement") with Alan L. Buchman ("Dr. Buchman"). Pursuant to the Choline License Agreement, the Company received from Dr. Buchman the license rights in and to the "Licensed Orphan Designations", the "Licensed IND", "Existing Study Data" and the "Licensed Know-How" for one or more of the licensed indications. In consideration for the rights and licenses granted, Dr. Buchman received a payment of $50 on October 2, 2017, and license payments of $50 and $50 on December 12, 2018 and January 8, 2019, respectively, upon the Company meeting the criteria for certain meetings to be held with the Federal Drug Administration (the "FDA"). Pursuant to the Choline License Agreement, effective October 2017, the Company incurred a fixed obligation to Dr. Buchman of $400 (the "Choline License Fee"). Upon the Company receiving $5,000 in cumulative funding (as defined), Dr. Buchman would be entitled to receive payment of the Choline License Fee as a lump sum if the funds are received by April 15, 2019 and the Choline License Fee shall be increased to a one-time payment of $600 if the funds are received by October 15, 2019. On October 2, 2019, the Company made a payment of $50 to Dr. Buchman. On January 22, 2020, in connection with the closing of the Merger and concurrent financing, Dr. Buchman was paid $550 which was included in accrued expenses as of December 31, 2019.

During the years ended December 31, 2020 and 2019, the Company recorded research and development expense of $0 and $200 (representing the increase in the Choline License Fee obligation), respectively, for expenditures to Dr. Buchman in connection with obligations under the Choline License Agreement.

NOTE 7 – COMMITMENTS AND CONTINGENCIES (Continued)

Collaborations and License Agreements (Continued)

License Agreement

On December 22, 2017, the Company entered into an agreement (the "Feinstein Agreement") with The Feinstein Institute for Medical Research (the "Feinstein Institute"), a not-for-profit corporation with 50 research labs and 2,500 clinical research studies. Pursuant to the Feinstein Agreement, the Company acquired an exclusive license relating to treatment of fatty liver diseases in humans for which Choline may be an effective therapeutic. In consideration for the rights and license granted, the Feinstein Institute would receive a royalty of one percent (1%) of the first one hundred million dollars ($100,000) of net sales of IV Choline Chloride and a royalty of one and one-half percent (1.5%) of all net sales thereafter. In addition, the Company would pay the Feinstein Institute twelve and one-half percent (12.5%) of net proceeds resulting from agreements entered within 2 years from the effective date, and seven and one-half percent (7.5%) of net proceeds resulting from agreements entered into thereafter. Pursuant to the Feinstein Agreement additional payments would be due to the Feinstein Institute for license maintenance payments and for meeting milestone events. On January 9, 2020, the Company's raising of over $5,000 triggered a financing milestone obligation and accordingly the Feinstein Institute was paid $100. Pursuant to the Feinstein Agreement, upon the achievement of certain future new drug application milestones, the Company would be obligated to remit an aggregate of $275.

During the years ended December 31, 2020 and 2019, the Company recorded research and development expense of $115 and $1, respectively, in connection with the Feinstein Agreement.

Sponsored Research and License Agreement

On November 28, 2018, the Company entered into a sponsored research and license agreement (the "Iowa Agreement") with the University of Iowa. Pursuant to the Iowa Agreement, the University of Iowa, which is engaged in clinical research to improve the diagnosis and treatment of lymphangioma using a pharmaceutical product (OK-432), would assist the Company in collecting case reports, forms, source data, and safety data available to the University of Iowa in support of the development of the Company's proprietary *Streptococcus Pyogenes* investigational product, TARA-002 for the LMs indication. During the term of the services, the Company would pay the University of Iowa thirty thousand dollars ($30) per year to fund the project, plus additional amounts upon the realization of certain milestones. More specifically, upon forty-five (45) days of an approval of TARA-002 by the FDA, the Company would pay up to $1,750 to the University of Iowa for meeting these milestones. Furthermore, the Company would pay the University of Iowa royalties of up to 1.75% for net sales ranging from $0 - $25,000, 2.25% for net sales ranging from $25,000 to $50,000, and 2.50% for net sales in excess of $50,000. Pursuant to the Iowa Agreement, the University of Iowa would be entitled to additional payments for the Company achieving annual net sales of product according to the milestones. For annual net sales of product up to $25,000; $62; for annual net sales of product of up to $50,000; $62; and for annual net sales of product of up to $100,000; $125.

During the years ended December 31, 2020 and 2019, the Company recorded research and development expense of $30 and $30 respectively, in connection with the Iowa Agreement.

NOTE 7 – COMMITMENTS AND CONTINGENCIES (Continued)

Collaborations and License Agreements (Continued)

Chugai Agreement

On June 17, 2019, the Company entered into an agreement (the "Chugai Pharmaceutical Agreement") with Chugai Pharmaceutical Co., LTD ("Chugai"), a drug manufacturing firm with offices and operations in Japan. Pursuant to the Chugai Pharmaceutical Agreement, Chugai would help the Company in its goals to develop and commercialize a therapeutic product (the "New Product") which is comparable to the Chugai existing therapeutic product (the "Existing Product"). In addition, the Company would be entitled to the use of Chugai materials and technical support as necessary. On July 14, 2020, the Company and Chugai entered into an amendment (the "Chugai Amendment") to the Chugai Pharmaceutical Agreement. The Chugai Amendment is effective as of June 30, 2020. The Chugai Amendment extended the date through which Chugai will exclusively provide the Existing Product and materials to the Company from June 30, 2020 to June 30, 2021, extended the date through which Chugai will not provide materials or technical support to any third party for the purpose of development and commercialization in a given area from the fifth anniversary to the eleventh anniversary of the original effective date and provides that, in addition to the designated fee provided upon the initial indication approval in the Chugai Pharmaceutical Agreement, the Company will pay Chugai a designated fee for each additional indication approval. The Company is obligated to Chugai for certain payments upon the completion of agreed upon milestones. As of December 31, 2019, the Company recorded an obligation of $500 upon Chugai having completed an agreed upon milestone, which the Company paid on July 27, 2020.

During the years ended December 31, 2020 and 2019, the Company recorded research and development expense of $0 and $500, respectively, respectively, in connection with the Chugai Agreement, as amended.

Johns Hopkins University

In February 2002, Proteon entered into an agreement to license certain intellectual property in connection with vonapanitase with Johns Hopkins University. The agreement calls for payments to be made by the Company upon the commencement of vonapanitase related product sales, in the form of a royalty of 2.5% on net sales of the product. As of December 31, 2020, the Company has not commenced vonapanitase product sales and therefore has recognized no royalties on product sales.

NOTE 7 – COMMITMENTS AND CONTINGENCIES (Continued)

Litigation

From time to time, Protara may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Management is of the opinion that the ultimate outcome of these matters would not have a material adverse impact on the financial position of the Company or the results of its operations.

In the normal course of business, the Company enters into contracts in which it makes representations and warranties regarding the performance of its services and that its services will not infringe on third party intellectual rights. There have been no significant events related to such representations and warranties in which the Company believes the outcome could result in losses or penalties in the future.

NOTE 8 – STOCKHOLDERS' EQUITY

Authorized Common Stock

As of December 31, 2020, the Company has 100,000,000 shares of Common Stock authorized for issuance, $0.001 par value per share, of which 11,211,840 and 2,627,533 shares were issued and outstanding as of December 31, 2020 and 2019, respectively.

The holders of the Company's Common Stock are entitled to one vote per share.

Authorized Series 1 Convertible Preferred Stock

In connection with the Preferred Offering (defined below) on September 22, 2020, the Company filed a Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Preferred Stock of the Company (the "Amendment") with the State of Delaware to increase the authorized number of shares of the Company's Series 1 Convertible Preferred Stock that may be issued from 3,880 to 8,028. The Amendment was approved by a committee of the Company's Board of Directors and the requisite holders of outstanding shares of Series 1 Convertible Preferred Stock. No approval of the holders of the Company's Common Stock was required to effectuate the Amendment.

As of December 31, 2020 and 2019, the Company has 10,000,000 shares of preferred stock authorized for issuance, $0.001 par value per share of which 8,028 shares of Series 1 Convertible Preferred Stock are authorized for issuance and 8,027 and 0 shares were issued and outstanding, respectively.

NOTE 8 – STOCKHOLDERS' EQUITY (Continued)

Description of Series 1 Convertible Preferred Stock

Each share of Series 1 Convertible Preferred Stock is convertible into 1,000 shares of Common Stock, at a conversion price initially equal to approximately $7.01 per common share, subject to adjustment for any stock splits, stock dividends and similar events, at any time at the option of the holder, provided that any conversion of Series 1 Convertible Preferred Stock by a holder into shares of Common Stock would be prohibited if, as a result of such conversion, the holder, together with its affiliates and any other person or entity whose beneficial ownership of the Common Stock would be aggregated with such holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, would beneficially own more than 9.99% of the total number of shares Common Stock issued and outstanding after giving effect to such conversion. Upon written notice to the Company, the holder may from time to time increase or decrease such limitation to any other percentage not in excess of 19.99% specified in such notice. Each share of Series 1 Convertible Preferred Stock is entitled to a preference of $10.00 per share upon liquidation of the Company, and thereafter will share ratably in any distributions or payments on an as-converted basis with the holders of Common Stock. In addition, upon the occurrence of certain transactions that involve the merger or consolidation of the Company, an exchange or tender offer, a sale of all or substantially all of the assets of the Company or a reclassification of its Common Stock, each share of Series 1 Convertible Preferred Stock will be convertible into the kind and amount of securities, cash and/or other property that the holder of a number of shares of Common Stock issuable upon conversion of one share of Series 1 Convertible Preferred Stock would receive in connection with such transaction. The Company's Series 1 Convertible Preferred Stock are non-voting.

The terms of the Series 1 Convertible Preferred Stock provide that, in the event of a fundamental transaction (as such term is described in the certificate of designation of preferences, rights and limitations of series 1 convertible non-voting preferred stock), each share of Series 1 Convertible Preferred Stock outstanding shall thereafter be convertible into the kind and amount of securities, cash and/or other property which a holder of the number of shares of Common Stock of the Company issuable upon conversion of one share of Series 1 Convertible Preferred Stock immediately prior to such fundamental transaction would have been entitled to receive pursuant to such fundamental transaction, provided that, if the value of the aggregate of such securities, cash and/or other property the which the holder of one share of Series 1 Convertible Preferred Stock would be entitled to upon conversion thereof would be less than the stated value, then each outstanding share of Series 1 Convertible Preferred Stock shall instead be convertible into such kind of securities, cash and/or other property with an aggregate value equal to the stated value.

Common Stock

On September 23, 2019, the Company completed a placement of 69,114 shares of its common stock at a price of $7.23 per share for gross proceeds of $500.

NOTE 8 – STOCKHOLDERS' EQUITY (Continued)

Underwritten Public Offering

On September 24, 2020, pursuant to an underwriting agreement dated September 22, 2020, the Company issued and sold in an underwritten public offering (the "Common Offering") an aggregate of 4,600,000 shares of its Common Stock at an offering price of $16.87 per share, for gross and net proceeds of approximately $77.6 million and $73.6 million, respectively. The underwriters were granted an option to purchase up to 690,000 additional shares of Common Stock at the public offering price, less the underwriting discount. On October 6, 2020, the underwriters exercised their overallotment option in full, purchasing an additional 690,000 shares, resulting in the receipt of gross and net proceeds of $11.6 million and $11.1 million, respectively.

On September 24, 2020, pursuant to an underwriting agreement (dated September 22, 2020), the Company issued and sold in an underwritten public offering (the "Preferred Offering") an aggregate of 4,148 shares of its Series 1 Convertible Preferred Stock at an offering price of $16,873.54 per share, for gross and net proceeds of approximately $70.0 million and $66.3 million, respectively.

The Common Offering and the Preferred Offering were made pursuant to the Company's registration statement on Form S-3, declared effective by the Securities and Exchange Commission on May 26, 2020 (Registration No. 333-238273).

In December 2020, the Company filed a shelf registration statement on Form S-3, declared effective by the Securities and Exchange Commission on December 18, 2020 (Registration No. 333-251224) (the "Shelf Registration Statement"). The Shelf Registration Statement permits: (i) the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $300 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination. No securities have been sold to date under the Shelf Registration Statement.

NOTE 9 – STOCK-BASED COMPENSATION

2020 Inducement Plan

On March 26, 2020, the Compensation Committee of the Board of Directors (the "Compensation Committee") approved the ArTara Therapeutics, Inc. Inducement Plan (the "2020 Inducement Plan") in order to award nonstatutory stock options, restricted stock awards, restricted stock unit awards and other stock-based awards to persons not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company.

The 2020 Inducement Plan provides for a total of 600,000 shares for the issuance of the Company's Common Stock. The Compensation Committee also adopted a form of stock option grant notice and stock option agreement and forms of restricted stock unit grant notice and restricted stock unit agreement for use with the Inducement Plan.

As of December 31, 2020, 460,650 shares remain available to be issued under the 2020 Inducement Plan.

2017 Equity Incentive Plan

On August 10, 2017, Private ArTara, its Board of Directors and its shareholders approved the ArTara Therapeutics, Inc. 2017 Equity Incentive Plan (the "2017 Equity Incentive Plan") to enable Private ArTara and its affiliates to recruit and retain highly qualified personnel and to incentivize personnel for productivity and growth.

The 2017 Equity Incentive Plan provided for the grant of a total of 2,000,000 shares for the issuance of stock options, stock appreciation rights, restricted stock and restricted stock units to among others, members of the Board of Directors, employees, consultants and service providers to the Company and its affiliates. As of January 9, 2020, in connection with the Merger, no additional awards will be made under the 2017 Equity Incentive Plan.

NOTE 9 – STOCK-BASED COMPENSATION (Continued)

2014 Equity Incentive Plan

On October 3, 2014, the stockholders approved the 2014 Plan. On June 20, 2017, the Company's Board of Directors amended the 2014 Plan (the "Amended 2014 Plan"). On July 31, 2017, the stockholders approved this amendment.

The Amended 2014 Plan provides for the grant of incentive and non-statutory stock options, stock appreciation rights, restricted stock and stock unit awards, performance units, stock grants and qualified performance-based awards. The 2014 Plan provides that the number of shares reserved and available for issuance under the 2014 Plan will automatically increase each January 1, beginning January 1, 2015 by four percent of the outstanding shares of Common Stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's Board of Directors prior to each such January 1st. The Amended 2014 Plan clarifies that the number of shares for purposes of calculating the evergreen feature includes the number of shares of Common Stock issuable upon conversion of any security that the Company may issue that is convertible into or exchangeable for Common Stock, including, but not limited to, preferred stock or warrants. Pursuant to a special meeting of the Proteon stockholders held on January 9, 2020, the number of shares available for issuance under the Amended 2014 Plan increased by 900,002 shares from 148,298 shares to 1,048,300 shares on January 1, 2020. As of December 31, 2020, 227,850 shares remain available to be issued under the Amended 2014 Plan. On January 1, 2021, pursuant to the Amended 2014 Plan's annual evergreen feature, the number of shares authorized under the Amended 2014 Plan was increased by 812,889 shares to 1,861,189 shares.

Terms of the stock awards, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the plans. Certain awards provide for accelerated vesting if there is a change in control as defined in the plans.

2014 Employee Stock Purchase Plan

On October 3, 2014, the stockholders approved the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP initially authorized the issuance of up to 3,513 shares of Common Stock. The number of shares increases each January 1, commencing on January 1, 2015 and ending on (and including) January 1, 2024, by an amount equal to the lesser of one percent of the outstanding shares as of the end of the immediately preceding fiscal year, 7,025 shares or any lower amount determined by the Company's Board of Directors prior to each such January 1st. As of December 31, 2020, the authorized number of shares under the 2014 ESPP is 18,012 and the number of shares available for issuance is 13,340. During the years ended December 31, 2020 and 2019, no shares were issued under the 2014 ESPP. On January 1, 2021, pursuant to the increase per the 2014 ESPP, the number of share authorized under the 2014 ESPP was increased by 7,025 shares to 25,037 shares.

(amounts in thousands, except share and per share data)

NOTE 9 – STOCK-BASED COMPENSATION (Continued)

Restricted Stock Units

Awards to Directors

The following restricted stock units ("RSUs") were granted pursuant to the Amended 2014 Plan. Settlement for the RSUs is deferred until the earliest to occur of (i) the director's termination of service, (ii) death, (iii) disability or (iv) a change in control of the Company. In the event of a change in control of the Company, the RSUs will vest in full.

During the year ended December 31, 2020, the Board of Directors granted an aggregate of 316,000 RSUs to directors of the Company. Of these RSUs, 254,000 vest 12.5% on the date of grant and in twenty-one equal monthly installments thereafter and the remaining 62,000 RSUs vest 50% on the one year anniversary of the grant date and the remainder vest in 12 equal monthly installments thereafter. The grant date fair value of these RSUs was $9,480.

Awards to Others

During the year ended December 31, 2019, the Board of Directors granted of 5,245 RSUs to a consultant. The RSUs were granted under the Company's 2017 Equity Incentive Plan. The RSUs vested in five equal installments of 1,049 units on the 15th and 30th of each month, beginning on October 30, 2019. The grant date fair value of this RSU was $36.

During the year December 31, 2020, Board of Directors granted an aggregate of 163,325 RSUs to employees of the Company. These RSUs will vest 25% on each of the first, second, third and fourth year anniversaries of the date of grant. The grant date fair value of these RSUs was $4,887.

Following is a summary of restricted stock unit activities for the year ended December 31, 2020:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested 1/1/2020	-	$ -
Granted	479,325	29.97
Forfeited	(56,375)	30.00
Vested	(148,334)	30.00
Non-vested 12/31/2020	274,616	$ 29.95

NOTE 9 – STOCK-BASED COMPENSATION (Continued)

Restricted Stock Units (Continued)

The fair value of restricted stock units is amortized on a straight line basis over the requisite service periods of the respective awards. As of December 31, 2020, the unamortized value of RSUs was $6,299. As of December 31, 2020, the weighted average remaining amortization period was 1.81 years. As of December 31, 2020 and 2019, 132,709 and 5,245 RSUs, respectively, have vested that have not yet been settled into shares of the Company's Common Stock.

During the year ended December 31, 2020, the Company issued 20,870 shares of Common Stock from the settlement of RSUs.

Restricted Stock Units Modification

On July 23, 2020, the Company agreed to accelerate the vesting of 5,687 RSUs of a former executive. The Company recorded a charge of $152 during the year ended December 31, 2020 to research and development expense within the Company's consolidated statements of operations in connection with the modification of this award.

Stock Option Grants

Options to Directors

During the year ended December 31, 2019, the Board of Directors granted options for the purchase of 47,114 shares of the Company's common stock to members of the board of directors. These options were granted under the Company's 2017 Equity Incentive Plan, had an exercise price of $9.18 per share and a term of 10 years. These options vest ratably over approximately four years. The options had a grant date fair value of $317.

During the year ended December 31, 2020, the Board of Directors granted options for the purchase of 80,250 shares of the Company's common stock to members of the board of directors. These options were granted under the Company's 2014 Equity Incentive Plan, had an exercise price ranging from $26.70 to $35.00 per share and a term of 10 years. These options vest ratably over approximately one year. The options had a grant date fair value of $1,903.

Options to Employees

During the year ended December 31, 2019, the Board of Directors granted options for the purchase of 50,549 shares of the Company's common stock to employees of the Company. These options were granted under the Company's 2017 Equity Incentive Plan, had an exercise price of $9.18 per share and a term of 10 years. These options vest ratably over approximately four years. The options had a grant date fair value of $322.

During the year ended December 31, 2020, the Board of Directors granted options for the purchase of 484,850 shares of the Company's common stock to employees of the Company. These options were granted under the Company's 2014 Equity Incentive Plan, had an exercise price ranging from $17.84 to $51.12 per share and a term of 10 years. These options vest ratably over approximately four years. The options had a grant date fair value of $10,867.

(amounts in thousands, except share and per share data)

NOTE 9 – STOCK-BASED COMPENSATION (Continued)

Stock Option Modifications

Effective July 20, 2020, a former director notified the Company of his resignation from the Company's Board of Directors. In connection with his resignation, the Compensation Committee approved the accelerated vesting of all stock options issued to him prior to the Merger, and to extend the post-termination exercise period of vested options to 12 months from the date of resignation. Due to the modification of his options, the Company recorded the incremental value of $501 during the year ended December 31, 2020 to general and administrative expense within the Company's consolidated statements of operations.

Stock Options

The Company determined the fair value of stock options granted based upon the assumptions as provided below.

	For the Years Ended December 31,	
	2020	2019
Stock price	$ 17.84 - $ 51.12	$ 6.81 - $ 8.65
Exercise price	$ 17.84 - $ 51.12	$ 9.18
Dividend yield	0.00%	0.00%
Expected volatility	95.00% - 101.00%	97.00%
Risk-free interest rate	0.28% - 1.69%	1.71% - 2.37%
Expected life (in years)	5.27 - 6.08	5.58 - 6.02

Following is a summary of stock option activities for the year ended December 31, 2020:

	Options	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding 1/1/2020	219,592	$ 7.29	$ 9.18	9.72	$ -
Granted	565,100	22.61	29.23	-	-
Exercised	(57,767)	6.72	9.18	-	-
Forfeited	(52,886)	14.08	18.91	-	-
Outstanding 12/31/2020	674,039	$ 20.60	$ 25.23	9.06	$ 2,311
Exercisable as of 12/31/2020	109,117	$ 11.44	$ 15.63	8.25	$ 1,201

The weighted average grant date fair value of the options granted during the year ended December 31, 2019 was $6.55 per share. The fair value of stock options is amortized on a straight line basis over the requisite service periods of the respective awards. As of December 31, 2020, the unamortized value of stock options was $9,973. As of December 31, 2020, the weighted average remaining amortization period was 3.00 years.

(amounts in thousands, except share and per share data)

NOTE 9 – STOCK-BASED COMPENSATION (Continued)

Summary of Stock-Based Compensation Expense

The following tables summarize total stock-based compensation costs recognized:

	For the Years Ended December 31,	
	2020	2019
Restricted stock	$ -	$ 75
RSUs	6,357	36
Stock options	3,389	313
Total	$ 9,746	$ 424

Stock-based compensation expense was reflected within the statements of operations as:

	For the Years Ended December 31,	
	2020	2019
Research and development	$ 741	$ 200
General and administrative	9,005	224
Total	$ 9,746	$ 424

NOTE 10 – INCOME TAXES

Federal and State income tax expense is as follows:

	For the Years Ended December 31,	
	2020	2019
Current		
Federal	$ -	$ -
State	-	-
Total current	-	-
Deferred		
Federal	(6,211)	(1,614)
State	(2,439)	(930)
Total deferred	(8,650)	(2,544)
Change in valuation allowance	8,650	2,544
Total income tax expense (benefit)	$ -	$ -

(amounts in thousands, except share and per share data)

NOTE 10 – INCOME TAXES (Continued)

Deferred income taxes, if applicable, are provided for the differences between the basis of assets and liabilities for financial reporting and income tax purposes.

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

	As of December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carry forwards	$ 19,371	$ 3,806
Organization costs/legal fees	8	9
Stock option expense	443	111
Research and development credits	70	-
Operating lease liability	330	-
Restricted stock expense	-	238
RSU expense	1,796	12
Charitable contributions	2	2
Total deferred tax assets	22,020	4,178
Valuation allowance	(21,698)	(4,176)
Deferred tax assets, net of valuation allowance	322	2
Deferred tax liabilities:		
Operating right-of-use asset	(322)	-
Depreciation	-	(2)
Total deferred tax liabilities	(322)	(2)
Deferred tax assets, net of valuation allowance and deferred tax liabilities	$ -	$ -

A reconciliation of the provision for income taxes with the amounts computed by applying the statutory Federal income tax to income before provision for income taxes is as follows:

	For the Years Ended December 31,	
	2020	2019
U.S. federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(9.4)%	(12.1)%
Option expense	1.2%	0.5%
Other	1.9%	0.1%
True-up to prior years return	1.8%	-%
Change in valuation allowance	25.5%	32.5%
Effective tax rate	-%	-%

NOTE 10 – INCOME TAXES (Continued)

As of December 31, 2020 for U.S. federal and state income tax reporting purposes, the Company has approximately $63.7 million of unused net operating losses ("NOLs") available for carry forward to future years. The 2018 - 2020 federal NOLs may be carried forward indefinitely. The Company does not have the ability to carry any of these losses back. The New York state and city NOLs may be carried forward through the year 2040 and may be applied against future taxable income. Because United States tax laws limit the time during which NOL carry forwards may be applied against future taxable income, the Company may be unable to take full advantage of its NOLs for federal and state income tax purposes when the Company does generate taxable income. Further, the benefit from utilization of NOL carry forwards could be subject to limitations due to material ownership changes that could occur as the Company continues to issue additional shares of common stock pursuant to its capital raising plans. Based on such limitations, the Company has significant NOLs for which realization of tax benefits is uncertain.

On January 9, 2020, the Company completed the Merger. In connection with the Merger, the Company acquired NOL's from Proteon of $41.6 million. These NOLs were determined to be impaired by $12.4 million, with an annual limitation of $0.5 million on the remaining $29.2 million of NOLs. The general business credits of $3.6 million acquired in the merger were determined to be fully impaired.

As a result of the Merger, the company performed a study to review the application of IRC §382 to the Company. It was determined there was an ownership change as of January 9, 2020 and the Company's NOLs generated prior to January 9, 2020 would be limited. The annual limitation of the Company's NOL's after application of the IRC §382 are $1.4 million.

The Company remains subject to examination by tax authorities for tax years 2018 through 2020. The Company has identified its federal tax return and its state tax return in New York state and New York City as its "major" tax jurisdictions.

Based on a history of cumulative losses at the Company and the results of operations for the years ended December 31, 2020 and 2019, the Company determined that it is more likely than not that it will not realize benefits from the net deferred tax assets. The Company will not record income tax benefits in the financial statements until it is determined that it is more likely than not that the Company will generate sufficient taxable income to realize the deferred income tax assets. As a result of the analysis, the Company determined that a full valuation allowance against the deferred tax assets was required. As of December 31, 2020 and 2019, the Company has recorded a valuation allowance of $21.7 million and $4.2 million, respectively.

As of December 31, 2020 and 2019, management does not believe that the Company has any material uncertain tax positions that would require it to measure and reflect the potential lack of sustainability of a position on audit in its consolidated financial statements. The Company will continue to evaluate its uncertain tax positions in future periods to determine if measurement and recognition in its financial statements is necessary. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

NOTE 11 – EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Under the 401(k) Plan, the Company matches 100% up to a 4% contribution. The 401(k) Plan was implemented in June of 2020. For the year ended December 31, 2020, the Company recorded expense of $69 under the 401(k) Plan.

NOTE 12 – COVID-19

The ultimate impact of the current COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. The Company has experienced minimal delays, but may experience future delays that impact its business, research and development activities, healthcare systems and the global economy as a whole. However, the Company will continue to monitor the COVID-19 situation closely should the effects have a material impact on its operations, liquidity and capital resources.

In response to public health directives and orders, the Company has implemented work-from-home policies for its employees and temporarily modified its operations to comply with applicable social distancing recommendations. Similar health directives and orders are affecting third parties with whom the Company does business, including the third parties that the Company has contracted with to conduct studies for TARA-002. The effects of the orders and the Company's related adjustments in its business are likely to negatively impact productivity, disrupt the Company's business and delay its timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct its business in the ordinary course.

Severe and/or long-term disruptions in the Company's operations will negatively impact its business, operating results and financial condition in other ways, as well. Specifically, the Company anticipates that the stress of COVID-19 on healthcare systems around the globe will negatively impact its ability to conduct clinical trials in the near term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in the trials. The Company also anticipates that the global impact of COVID-19 will negatively impact its ability to conduct nonclinical studies due primarily to laboratory closures and limited availability of personnel. In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit the Company's ability to access capital, which could in the future negatively affect its liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business and the value of its Common Stock.

Exhibit 4.2

DESCRIPTION OF COMMON STOCK

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. For a complete description of the matters set forth in this "Description of Common Stock," you should refer to our sixth amended and restated certificate of incorporation, as amended (the "certificate of incorporation"), and second amended and restated bylaws (the "bylaws"), which are included as exhibits to our Annual Report on Form 10-K, and to the applicable provisions of Delaware law. Our authorized capital stock consists of 100,000,000 shares of common stock, $0.001 par value per share, 8,028 shares of Series 1 Preferred Stock, $0.001 par value per share and 9,991,972 shares of undesignated preferred stock, $0.001 par value per share. Our board of directors is authorized, without stockholder approval, except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock. In addition, our board of directors may, without further action by our stockholders, designate the rights, preferences, privileges, and restrictions of our preferred stock in one or more series.

Voting Rights. Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. An election of directors by our stockholders shall be determined by a plurality of votes cast by the stockholders entitled to vote on the election.

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

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

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

Delaware Anti-Takeover Law and Provisions of Our Amended and Restated Certificate of Incorporation, as amended, and Bylaws, as amended

Our certificate of incorporation and our bylaws contain certain provisions that could have the effect of delaying, deterring or preventing another party from acquiring control of us, and therefore could adversely affect the market price of our common stock. These provisions and certain provisions of Delaware General Corporation Law (the "DGCL"), which are summarized below, may also discourage coercive takeover practices and inadequate takeover bids, and are 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 more favorable terms with an unfriendly or unsolicited acquirer outweigh the disadvantages of potentially discouraging a proposal to acquire us.

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL ("Section 203"). Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of 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) those shares owned (i) by persons who are directors and also officers and (ii) 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 such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control unless such takeover or change in control is approved by the board of directors. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control. These provisions include:

Classified board of directors.

Our certificate of incorporation provides that the board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. Any additional directorships resulting from an increase in the number of directors will be apportioned by the board of directors among the three classes. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of the board of directors.

Our certificate of incorporation provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

Action by Written Consent; Special Meetings of Stockholders.

Our certificate of incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors.

Our certificate of incorporation provides that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class and entitled to vote in the election of directors. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of the board of directors.

Advance Notice Procedures.

Our bylaws include an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Super Majority Approval Requirements.

The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our certificate of incorporation and bylaws provide that the affirmative vote of holders of at least 75% of the outstanding shares of capital stock, voting together as a single class and entitled to vote in the election of directors will be required to amend, alter, change or repeal the bylaws and the certificate of incorporation. This requirement of a supermajority vote to approve amendments to our bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares.

Our authorized but unissued shares of common stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum.

Our certificate of incorporation provides that, subject to limited exceptions, the state or federal courts located in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against our that is governed by the internal affairs doctrine; provided, that these provisions will not apply to actions or proceedings brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believes these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. 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, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "TARA."

Exhibit 10.25

"CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED."

Execution Version

345 PAS HOLDING LLC,

Landlord,

TO

PROTARA THERAPEUTICS INC.,

Tenant

LEASE

Premises at:

345 Park Avenue South
New York, New York

TABLE OF CONTENTS

THIS INSTRUMENT IS AN INDENTURE OF LEASE in which the Landlord and the Tenant are the parties hereinafter named, and which relates to space in the building (the "Building") known as, and with an address at, 345 Park Avenue South, New York, New York 10010.

The parties to this instrument hereby agree with each other as follows:

ARTICLE 1

BASIC LEASE PROVISIONS AND ENUMERATION OF EXHIBITS

1.1 INTRODUCTION. The following sets forth the basic data and identifying Exhibits, elsewhere hereinafter referred to in this Lease, and, where appropriate, constitutes definitions of the terms hereinafter listed.

1.2 BASIC DATA.

Date:	December 1, 2020
Landlord:	345 PAS HOLDING LLC, a Delaware limited liability company
Present Mailing Address of Landlord:	c/o Deerfield Management Company, L.P. 780 Third Avenue New York, New York 10017 Attn.: Karen Noy with a copy to: Vinson & Elkins LLP The Grace Building 1114 Avenue of the Americas, 32nd Floor New York, New York 10036 Attn: Adam M. Endick, Esq.
Landlord's Construction Representative:	MLP Ventures 201 King of Prussia Road, Suite 501 Radnor, PA 19087 Attn: Joseph Kelly with a copy to: Campbell Rocco Law 2701 Renaissance Boulevard, 4th Floor King of Prussia, Pennsylvania 19406 Attn: Joseph Rocco, Esq.

Tenant:	ProTara Therapeutics Inc., a Delaware corporation
Present Mailing Address of Tenant:	1 Little West 12th Street New York, New York 10014 Attn.: Blaine Davis, CFO with a copy to: Cooley LLP 55 Hudson Yards New York, New York 10001 Attn: Daniel A. Goldberger, Esq.
Commencement Date:	As defined in Section 3.1 hereof.
Rent Commencement Date:	The date which is one (1) month after the Commencement Date.
Rent Concession Period:	As defined in Section 5.5 hereof.
Initial Expiration Date:	As defined in Section 3.2 hereof.
Expiration Date:	As defined in Section 3.2 hereof.
Lease Term:	As defined in Section 3.1 hereof.
Lease Year:	A period of twelve (12) consecutive calendar months commencing on the Commencement Date and ending on the day preceding the first (1st) anniversary of the Commencement Date, and each succeeding period of twelve (12) consecutive calendar months thereafter during the Lease Term commencing on each anniversary of the Commencement Date and ending on the day preceding the next anniversary of the Commencement Date, except that the last Lease Year shall end on the Expiration Date or such earlier date upon which the Lease Term may expire or be terminated pursuant to any of the conditions of limitation or other provisions of this Lease or pursuant to law.
Building:	The building and other improvements erected on the Land known as and by the street number 345 Park Avenue South, New York, New York.

Premises:	That portion of the Building depicted in Exhibit B hereto.
Annual Fixed Rent:	From the Rent Commencement Date through the day preceding the fourth (4th) anniversary of the Rent Commencement Date, the sum of One Million One Hundred Seventeen Thousand Four Hundred Sixty-Eight and 00/100 Dollars ($1,117,468.00); and from the fourth (4th) anniversary of the Rent Commencement Date through the Expiration Date, the sum of One Million Two Hundred Nineteen Thousand Nine Hundred Eighty-Eight and 00/100 Dollars ($1,219,988.00).
Additional Rent:	All charges and other sums payable by Tenant as set forth in this Lease, other than and in addition to Annual Fixed Rent.
Tenant's Share:	[***]%.
GAAP:	United States generally accepted accounting principles consistently applied.
Security Deposit:	At all times, an amount equal to $[***] (subject to reduction as provided in Section 20.22).
Brokers:	CBRE, Inc.
Guarantor:	None.

1.3 ENUMERATION OF EXHIBITS. The following Exhibits are a part of this Lease, are incorporated herein by reference, attached hereto, and are to be treated as a part of this Lease for all purposes. Undertakings contained in such Exhibits are agreements on the part of Landlord and Tenant, as the case may be, to perform the obligations stated therein.

Exhibit A	--	Description of the Land.
Exhibit B	--	Floor Plans of Premises.
Exhibit C	--	Work Letter.
Schedule C-1	--	Base Work.
Schedule C-2	--	Scheduled Tenant Changes
Schedule C-3	--	Test Fit
Exhibit D	--	Landlord's Services.

Exhibit E -- Rules and Regulations.

Exhibit F -- Form of Letter of Credit.

Exhibit G -- Form of Commencement Date Agreement.

Exhibit H -- Rider to Tenant Lease Agreement.

Exhibit I -- Form of Living Wage Agreement.

Exhibit J -- HireNYC Requirements.

Schedule 6.1.4(c) -- Agency Lease PILOT Payment Schedule.

1.4 OTHER DEFINITIONS. The following additional terms, wherever used in this Lease (unless the context requires otherwise), shall have the respective meanings specified in the Sections of this Lease set forth below after such Terms:

"AAA"	Section 3.4.3(b)
"Additional Insureds"	Section 11.7
"Additional Tenant Changes"	Exhibit C
"Affiliate"	Section 13.1
"Agency Lease"	Section 6.1
"Alterations"	Section 8.1
"Anticipated Delivery Date""	Section 3.1
"available for leasing"	Section 20.34(f)
"Base Taxes"	Section 6.1
"Base Work"	Exhibit C
"BID Surcharge"	Section 6.1
"Burn Down Amount"	Section 20.22
"Burn Down Conditions"	Section 20.22
"Burn Down Date"	Section 20.22
"Cash Deposit"	Section 20.22
"Conversion"	Section 20.25
"Change Cost"	Exhibit C
"Date of the taking"	Section 12.6
"Due date"	Section 5.4
"Electronic signature"	Section 20.28
"Event of Default"	Section 19.1
"Excess Operating Expenses"	Section 6.2
"Fair Market Rent"	Section 3.4.3(a)
"Fair Market Rent Proposal"	Section 3.4.3(b)
"Fitness Center"	Section 10.8
"Force Majeure"	Section 14.3
"Hazardous Substance"	Section 10.6
"Impositions"	Section 6.1

“Incoming Deliveries”	Schedule D-2
“Initiating Party”	Section 3.4.3(b)
“ISO”	Section 11.3
“Lab Area”	Section 7.4
“Lab Costs”	Section 7.4
“Lab Rules and Regulations”	Section 20.13
“Lab Systems”	Section 20.33
“Land”	Section 2.1
“Landlord Parties”	Section 11.1
“Landlord’s Statement”	Section 6.2.2
“Latent Defect”	Section 7.1
“Lease Interest Rate”	Section 5.4
“Leasehold Improvements”	Section 8.1
“Letter”	Section 20.22
“Letter of Credit”	Section 20.22
“Lien”	Section 8.4
“LW Agreement”	Section 20.30
“Non-Common Expenses”	Section 6.2
“Non-Common Services”	Section 6.2
“Non-Qualified Use”	Section 10.1
“notice”	Section 20.9; Exhibit C
“Messenger Center”	Schedule D-2
“Messenger Center Operating Hours”	Schedule D-2
“Mortgagee”	Section 17.1
“OFAC”	Section 20.27
“Offer Notice”	Section 13.2
“Offered Space”	Section 20.34
“Operating Days”	Exhibit D
“Operating Expense Statement Date”	Section 6.2
“Operating Expenses”	Section 6.2
“Operating Hours”	Exhibit D
“Operating Year”	Section 6.2
“Original Tenant”	Section 13.1
“Outside Date”	Section 3.1
“Outgoing Deliveries”	Schedule D-2
“Overlandlord”	Section 17.1
“Overtime Service”	Exhibit D
“Permitted Capital Expenditures”	Section 6.2
“PILOT”	Section 6.1
“PILOT Commencement Date”	Section 6.1
“PILOT Percentage”	Section 6.1
“PILOT Program”	Section 6.1
“PILOT Term”	Section 6.1
“Plans and Specifications”	Exhibit C
“Prohibited Person”	Section 20.27
“Projected Annual Savings”	Section 6.2

“Property”	Section 6.2
“Punchlist Items”	Exhibit C
“Qualified Arbitrator”	Section 3.4.3(b)
“Qualified Life Science Uses”	Section 10.1
“Regulated Medical Waste”	Section 20.33
“REIT”	Section 7.3
“Renewal Notice”	Section 3.4.1
“Renewal Term”	Section 3.4.1
“Renewal Term Commencement Date”	Section 3.4.1
“Renewal Term Expiration Date”	Section 3.4.1
“Renewal Option”	Section 3.4.1
“rent”	Section 5.3
“Replacement Letter”	Section 20.22
“Rider”	Section 20.30
“ROFO Conditions”	Section 20.34
“ROFO Election Notice”	Section 20.34
“ROFO Delivery Date”	Section 20.34
“ROFO Notice”	Section 20.34
“ROFO Offer”	Section 20.34
“ROFO Option”	Section 20.34
“Rules and Regulations”	Section 20.13
“Service Provider”	Section 7.3
“Scheduled Tenant Changes”	Exhibit C
“Space Occupant”	Section 13.1(e)
“Specialty Alterations”	Section 8.1
“Substantial Completion”	Exhibit C
“Taxes”	Section 6.1
“Tax Expenses”	Section 6.1
“Tax Year”	Section 6.1
“Tenant Changes”	Exhibit C
“Tenant Delay”	Exhibit C
“Tenant Parties”	Section 11.1
“Tenant Advertisement”	Exhibit E
“Tenant’s Architect”	Exhibit C
“Tenant’s Costs”	Exhibit C
“Tenant’s Property”	Section 8.6
“Tenant’s Share of BID”	Section 6.1
“Tenant’s Share of Impositions”	Section 6.1
“Tenant’s Share of PILOT”	Section 6.1
“Tenant’s Share of Taxes”	Section 6.1
“Tenant’s Tax Payment”	Section 6.1
“Tenant’s Termination Notice”	Section 3.1
“Tenant’s Work”	Exhibit C
“Test Fit”	Exhibit C
“Underlying Lease”	Section 17.1
“Untenantable”	Section 20.12
“Wet Installations”	Section 10.10
“Work”	Exhibit C
“Work Letter”	Exhibit C

ARTICLE 2

PREMISES

2.1 DEMISE – PREMISES. Landlord hereby demises and leases to Tenant, and Tenant hereby takes and hires from Landlord, a portion of the Building erected on the land (the "Land") more particularly described in Exhibit A hereto, which portion of the Building (the "Premises") is depicted in the floor plan(s) annexed hereto as Exhibit B, for the term hereinafter stated, for the rent hereinafter reserved and upon and subject to the covenants, agreements, terms, conditions, limitations, exceptions and reservations contained in this Lease.

2.2 APPURTENANT RIGHTS AND RESERVATIONS.

(a) Tenant shall have, as appurtenant to the Premises, the non-exclusive right to use in common with others, subject to reasonable rules of general applicability to tenants of the Building from time to time made by Landlord of which Tenant is given notice: (i) the common lobbies, corridors, stairways and elevators of the Building, and (ii) if the Premises includes less than the entire rentable floor area of any floor, the common toilets, corridors and elevator lobby of such floor.

(b) Landlord reserves the right from time to time: (i) to install, use, maintain, repair, replace and relocate, for service to the Premises and/or other parts of the Building, shafts, pipes, ducts, conduits, wires, risers and other facilities and appurtenant fixtures, in the Premises or in other parts of the Building, and (ii) to alter or relocate other common facilities, whether located in the Premises or in other parts of the Building; provided that, with respect to clauses (i) and (ii): (A) any replacements, substitutions or alterations are, in the reasonable opinion of Landlord, substantially equivalent to or better than then existing facilities, (B) installations, replacements and relocations shall be located so far as practicable in the central core area of the Building, above ceiling surfaces (if available and practicable), below floor surfaces, within perimeter walls of the Premises or otherwise in boxed enclosures, and (C) all such work within the Premises shall be performed at such times and in such manner, as to create the least practicable interference with Tenant's use of the Premises (it being understood that the foregoing shall in no event obligate Landlord to do such work on an "overtime" basis). Tenant acknowledges that the Building is located in a residential district and certain construction work on weekends and on weekdays is prohibited between the hours of 6:00 p.m. and 7:00 p.m. Except in the case of emergencies, Landlord agrees to give Tenant reasonable advance notice of any of the foregoing activities which require work in the Premises.

ARTICLE 3

LEASE TERM

3.1 COMMENCEMENT DATE.

(a) The term of this Lease and the estate hereby granted (the "Lease Term") shall commence on the date that Landlord makes possession of the Premises available to Tenant with the Base Work Substantially Complete pursuant to the Work Letter. Such date of commencement is hereinafter called the "Commencement Date". If Landlord fails to cause the Commencement Date to occur on or before the date that is [***] following the later to occur of (x) the date hereof and (y) the date on which the Plans and Specifications are finalized and approved by Landlord and Tenant in accordance with the terms of the Work Letter (as such date shall be extended on a day for day basis for Force Majeure and Tenant Delay, the "Anticipated Delivery Date"), then the Rent Commencement Date shall be postponed by (i) [***] for each day that occurs during the period commencing on the day immediately following the Anticipated Delivery Date to but not including the earlier to occur of (A) [***] and (B) the date that is [***] after the Anticipated Delivery Date, and (ii) [***] for each day that occurs during the period commencing on the [***] after the Anticipated Delivery Date to but not including the Commencement Date, and any delay in such date shall be Tenant's sole remedy at law or in equity (Tenant hereby waiving any right to rescind this Lease and/or to recover any damages on account of such delay other than as expressly set forth in Section 3.1(b) below). Landlord hereby agrees to use commercially reasonable efforts to cause the Commencement Date to occur prior to the Anticipated Delivery Date and Landlord shall keep Tenant reasonably apprised of any anticipated delay in the Substantial Completion of the Base Work. The foregoing is intended to be "an express provision to the contrary" under Section 223¬a of the New York Real Property Law or any successor statute of similar import. If Tenant occupies all or any portion of the Premises prior to the Commencement Date specified above for the normal operation of its business therein (and not for the purpose of installing Tenant's furniture, fixtures or equipment prior to the Commencement Date, if the same is permitted hereunder), the Commencement Date shall be treated as having occurred on such date of occupancy.

(b) If the Commencement Date does not occur on or before the date that is twelve (12) months following the later to occur of (i) the date hereof and (ii) the date on which the Plans and Specifications are finalized and approved by Landlord and Tenant in accordance with the terms of the Base Work Letter (as such date shall be extended on a day-for-day basis for Force Majeure (but in no event shall such Force Majeure extension exceed ninety (90) days in the aggregate) and Tenant Delay, the "Outside Date"), then Tenant, in Tenant's sole discretion, shall have the right to terminate this Lease upon written notice ("Tenant's Termination Notice") delivered to Landlord within ten (10) days after the Outside Date, time being of the essence. If Tenant does not deliver Tenant's Termination Notice within the aforesaid ten (10) day period, then Tenant shall be deemed to waived such termination right. If Tenant exercises such termination right and Landlord does not deliver the Premises to Tenant within thirty (30) days after the giving of Tenant's Termination Notice (time being of the essence and Force Majeure notwithstanding), then this Lease shall cease and come to an end without further liability or obligation on the part of either party; provided, however, if Landlord shall cause the Commencement Date to occur within thirty (30) days after receipt of Tenant's Termination Notice, this Lease shall not be so terminated and Tenant's termination right under this Section 3.1(b) shall be void and of no further force or effect.

3.2 EXPIRATION DATE. The Lease Term shall end on the day immediately preceding the seventh (7^{th}) anniversary of the Rent Commencement Date, which ending date is hereinafter called the "Initial Expiration Date", or shall end on such earlier date upon which the Lease Term may expire or be terminated pursuant to any of the conditions of limitation or other provisions of this Lease or pursuant to law. Notwithstanding the foregoing, if the Rent Commencement Date is other than the first day of a month, the Initial Expiration Date shall be the last day of the calendar month in which the seventh (7^{th}) anniversary of the Rent Commencement Date occurs. The Initial Expiration Date, as the same may be extended to the Renewal Term Expiration Date, is referred to herein as the "Expiration Date".

3.3 COMMENCEMENT DATE AGREEMENT. As soon as may be convenient after the Commencement Date has been determined, Landlord and Tenant agree to join with each other in the execution of a written agreement, in the form of Exhibit G hereto, in which the Commencement Date, the Rent Commencement Date and the Expiration Date shall be stated, but the failure by either party to so execute or deliver such agreement shall not in any way reduce the respective obligations or rights of Landlord or Tenant under this Lease.

3.3.1 RENEWAL OPTION. If on the date on which Tenant delivers the Renewal Notice to Landlord (a) this Lease is in full force and effect, (b) no Event of Default (or any state of facts that, with the giving of notice or the passage of time, would constitute an Event of Default) shall have occurred and then be continuing, and (c) Tenant actually occupies one hundred percent (100%) of the Premises, then Original Tenant shall have the right, at its option (the "Renewal Option"), to renew the initial Term of this Lease with respect to the entire Premises for one (1) additional period of five (5) years (the "Renewal Term") commencing on the day immediately succeeding the Initial Expiration Date (the "Renewal Term Commencement Date") and expiring on the fifth (5th) anniversary of the Renewal Term Commencement Date or such earlier date upon which the Lease Term may expire or be terminated pursuant to any of the conditions of limitation or other provisions of this Lease or pursuant to law (the "Renewal Term Expiration Date"). Tenant shall exercise the Renewal Option by delivering a written notice (the "Renewal Notice") to Landlord no later than twelve (12) months prior to the Expiration Date, time being of the essence. If Tenant timely exercises the Renewal Option, then the Lease Term shall be extended for the Renewal Term without the requirement of any further instrument, upon all of the same terms, provisions and conditions set forth in this Lease, except as otherwise set forth in this Section 3.4. If Tenant fails to timely give the Renewal Notice, Tenant shall have no further rights under this Section 3.4, and Landlord shall be under no further obligation to offer to renew or extend the Term. There shall be no further right to extend the Lease Term beyond the Renewal Term.

3.3.2 RENEWAL TERM RENT. Annual Fixed Rent for the Renewal Term shall be the Fair Market Rent for the Premises as of the commencement of the Renewal Term; provided, however, in no event shall the Annual Fixed Rent for the Renewal Term be less than the Annual Fixed Rent on a per rentable square foot basis in effect for the twelve (12) month period immediately preceding the Renewal Term.

3.3.3 RENEWAL TERM RENT DETERMINATION.

(a) The term "Fair Market Rent" shall mean the fair market rental value per annum for the Renewal Term as of the date that is one hundred eighty (180) days prior to the Renewal Term Commencement Date, taking into account all relevant factors. A determination of the Fair Market Rent payable for the Renewal Term shall be made in the manner described in Section 3.4.3(b) below.

(b) If Tenant shall have exercised the Renewal Option, then no later than six (6) months prior to the then Expiration Date, Landlord, in a notice given to Tenant, shall specify its initial determination of the Fair Market Rent. Within twenty (20) Operating Days after delivery by Landlord to Tenant of Landlord's notice, Tenant shall specify its initial determination of the Fair Market Rent (it being agreed that if Tenant fails to send to Landlord a written notice specifying Tenant's initial determination of the Fair Market Rent for the Renewal Term within such twenty (20) Operating Day period, then Fair Market Rent shall be deemed to be Landlord's initial determination thereof; and if Tenant does not send Landlord a written notice specifying Tenant's initial determination of the Fair Market Rent within such five (5) Operating Day period, then Fair Market Rent for the Renewal Term shall be deemed to be Landlord's initial determination thereof). If, within sixty (60) days after delivery by Tenant to Landlord of Tenant's notice, Landlord and Tenant fail to reach agreement on the determination of the Fair Market Rent, then either Landlord or Tenant (the "Initiating Party") may initiate arbitration proceedings for such determination by notice to the other, and Fair Market Rent shall be determined pursuant to such arbitration proceedings. Such arbitration proceedings, including the selection of a commercial real estate broker unaffiliated with either Landlord or Tenant and who shall have at least fifteen (15) years' experience in the leasing of office space in first class office and/or laboratory buildings in the vicinity of the Building (the "Qualified Arbitrator"), shall be conducted pursuant to the rules, regulations and procedures from time to time in effect as promulgated by the American Arbitration Association (the "AAA") by a single Qualified Arbitrator in the City, County and State of New York and otherwise in accordance with the Commercial Arbitration Rules of the AAA, as then in effect, with hearings conducted as expeditiously as practicable and with no undue delay, and in no event later than thirty (30) days after the date on which the Initiating Party gives such notice to the other party of its desire to initiate such arbitration proceedings. Prior written notice of application by either party for arbitration shall be given to the other at least ten (10) days before submission of the application to the AAA's office in the City, County and State of New York. The Qualified Arbitrator, forthwith upon his or her appointment, shall (i) hear the parties to this Lease and their respective witnesses, and each of the parties shall upon the conclusion of their presentation be required to submit a complete statement (the "Fair Market Rent Proposal") setting forth in detail all of the relevant economic terms of the party's proposed determination of the Fair Market Rent (which terms shall not differ from the economic terms initially proposed by such party), (ii) examine the records relating to the Building and such other documents and records as may, in his or her judgment, be necessary and (iii) select as the Fair Market Rent either Landlord's Fair Market Rent Proposal or Tenant's Fair Market Rent Proposal, whichever the Qualified Arbitrator determines to be closest to the Fair Market Rent. The Qualified Arbitrator shall have no power to vary or modify the provisions of this Lease or to determine any matter other than the Fair Market Rent for the Renewal Term. The determination of the Qualified Arbitrator shall be final and binding on Landlord and Tenant and may be enforced in any court of competent jurisdiction.

(c) Any determination of Fair Market Rent pursuant to this Section 3.4 shall be made taking into consideration (i) the fair market rental value of space of similar size and comparable condition in any first class office and/or laboratory building (including the Building) available for leasing for a comparable term, by a ready, willing and able tenant from a ready, willing and able landlord, neither of whom is under compulsion to enter into a lease, (ii) Tenant's payment with respect to Taxes, Impositions, PILOT and Operating Expenses as provided in Article 6 of this Lease (provided that base years for determining Base Operating Expenses shall be updated in connection with determining the Fair Market Rent, and accordingly, during the applicable Renewal Term, Tenant shall calculate its payments under Article 6 hereof using such updated Base Operating Expenses) and (iii) all other relevant factors.

(d) The cost of the arbitration shall be shared equally by Landlord and Tenant. Each of Landlord and Tenant shall pay the legal fees and expenses of their respective counsel and witnesses.

3.3.4 (a) If, pursuant to Section 3.4.3 above, Fair Market Rent has not been determined as of the date the same is to become effective, Tenant shall pay on account of Annual Fixed Rent Landlord's Fair Market Rent Proposal until such determination is made. If, based upon the final determination of such Fair Market Rent as provided herein, such payments made by Tenant on account of Annual Fixed Rent for the Renewal Term are greater than the Fair Market Rent as finally determined in accordance with the provisions hereof, Landlord shall either pay such excess to Tenant within thirty (30) days after final determination of the Fair Market Rent, or credit the amount of such excess against the next installments of rent due under this Lease.

(b) If Tenant shall validly exercise the Renewal Option, Landlord and Tenant shall promptly after such election and determination of the Fair Market Rent enter into an amendment to this Lease incorporating the terms of such leasing, but failure to do so shall have no effect on Tenant's agreement to extend the Lease Term as set forth herein.

ARTICLE 4

COMPLETION OF THE PREMISES

4.1 PERFORMANCE OF WORK.

(a) Tenant has inspected the Premises, and, subject to completion of the Work and Landlord's repair and maintenance obligations under this Lease, the Premises are being leased in "AS IS" condition, without representation or warranty by Landlord except as expressly set forth herein, and Landlord has no obligation to perform any other work, construct any other improvements or make any contribution available to prepare the Premises for Tenant's occupancy.

(b) Prior to the Commencement Date, Landlord, at Landlord's sole cost and expense, shall Substantially Complete the Base Work. The Base Work shall be performed using building standard materials (or such above building standard materials as are indicated in the Test Fit, if any).

4.2 QUALITY AND PERFORMANCE OF WORK. All construction work required or permitted by this Lease shall be done in a good and workmanlike manner and in compliance with all applicable laws and requirements of public authorities and insurance bodies related to, or arising out of the performance of, such construction work. Each party may inspect the work of the other at reasonable times, and the Construction Representative of each party shall promptly give notice of any approvals and other actions on the party's behalf required to be given in connection with design and construction.

ARTICLE 5

ANNUAL FIXED RENT AND ADDITIONAL RENT

5.1 FIXED RENT. Tenant agrees to pay to Landlord on the Commencement Date (but subject to the provisions of Section 5.2) and thereafter monthly, in advance, on the first day of each and every calendar month during the Lease Term, a sum equal to one twelfth of the Annual Fixed Rent specified in Section 1.2 hereof in lawful money of the United States, without any set-off or deduction whatsoever. Until notice of some other designation is given, Annual Fixed Rent and all other charges for which provision is herein made shall be paid by remittance to or to the order of "345 PAS HOLDING LLC" at the following address: Deerfield Management Company, L.P., 345 Park Avenue South, New York, NY 10010. All remittances by Tenant shall be drawn on a member bank of The Clearing House Association, or, at Tenant's election, by wire transfer of immediately available funds or ACH electronic transfer to:

Bank Name:	[***]
	[***]
	[***]
	[***]
Bank Routing #:	[***]
Account #:	[***]
Account Name:	[***]
Reference:	[***]
Contact Person:	[***]

5.2 ADVANCE PAYMENT OF ONE MONTH'S RENT. Tenant shall, simultaneously with the execution and delivery of this Lease, pay to Landlord an amount equal to one twelfth of the Annual Fixed Rent, to be applied to the monthly installment of Annual Fixed Rent due on the first (1st) day of the month next following the Rent Commencement Date. Landlord shall hold the amount paid by Tenant under this Section 5.2 in trust until the same is applied pursuant to this Section or any other provision of this Lease.

5.3 ADDITIONAL RENT.

(a) All amounts over and above, or in addition to, the Annual Fixed Rent which are payable by Tenant to Landlord under the terms of this Lease or otherwise in connection with the use and occupancy of the Premises including, without limitation, sums payable under work orders issued by the managing agent for the Building, shall be deemed Additional Rent hereunder and shall be paid by Tenant in lawful money of the United States, without any set-off or deduction whatsoever and otherwise in the same manner as an installment of the Annual Fixed Rent as elsewhere provided in this Lease; and Landlord shall have all the rights and remedies in the event of the non-payment thereof as it would have had in the event of the non-payment of any installment of the Annual Fixed Rent. Tenant's obligation to pay any Annual Fixed Rent or any Additional Rent which shall have theretofore become due and payable shall survive the expiration or earlier termination of this Lease. (The Annual Fixed Rent and Additional Rent are sometimes collectively referred to in this Lease as "rent.") Rent for any partial months during the Lease Term shall be prorated on a per diem basis. Except as otherwise expressly set forth in this Lease, to the extent that Tenant shall fail to dispute any invoice for Additional Rent within ninety (90) days after receipt thereof, such invoice shall be conclusive and binding upon Tenant and Tenant shall be deemed to have waived any right to dispute the same.

(b) Any Additional Rent for which no due date is specified in this Lease shall be due and payable within thirty (30) days after the date of invoice. Whenever pursuant to this Lease either Landlord or Tenant, as applicable, requests reimbursement for its out-of-pocket costs (as opposed to specified costs), (i) such reimbursement shall be limited to those out-of-pocket expenses actually paid to unaffiliated third parties and (ii) such party shall deliver to the reimbursing party reasonable supporting documentation evidencing such costs promptly after delivery to such party of a written request therefor.

5.4 LATE PAYMENT.

(a) If Landlord shall not have received any payment or installment of rent on or before the date that is five (5) days after the date (the "due date") on which the same first becomes payable under this Lease, the amount of such payment or installment shall bear interest from the due date through and including the date such payment or installment is received by Landlord, at a rate (the "Lease Interest Rate") equal to the lesser of (i) the rate announced by Citibank, N.A. or its successor from time to time as its prime or base rate (the "Base Rate"), plus [***], or (ii) the maximum applicable legal rate, if any. Such interest shall be deemed Additional Rent and shall be paid by Tenant to Landlord upon demand; provided, however, that the foregoing five (5) day grace period set forth above shall not apply in the event Tenant has failed to pay any installment of rent when due more than once in any twelve (12) month period, in which event such grace period shall not apply again until Tenant shall have timely paid all installments of rent for twelve (12) consecutive months.

(b) In addition to the interest set forth in Section 5.4(a) above, if any installment of rent or any other sum due from Tenant shall not be received by Landlord on or before its due date, then Tenant shall pay to Landlord a late charge equal to [***] of the overdue amount. The late charge shall be deemed Additional Rent and shall be paid by Tenant to Landlord upon demand. The late charge shall be in addition to all of Landlord's other rights and remedies hereunder or at law and shall not be construed as liquidated damages or as limiting Landlord's remedies in any manner.

5.5 RENT CONCESSION. Anything contained in this Article to the contrary notwithstanding, provided no Event of Default exists, Landlord hereby waives payment of Annual Fixed Rent for the period (the "Rent Concession Period") from and including the Commencement Date through and including the date that is one (1) day prior to Rent Commencement Date, and payment of Annual Fixed Rent shall commence on the Rent Commencement Date.

ARTICLE 6

TAXES, IMPOSITIONS, PILOT AND OPERATING EXPENSES

6.1 TAXES, IMPOSITIONS AND PILOT.

6.1.1 DEFINITIONS. For the purposes of this Section 6.1, the following terms shall have the respective meanings set forth below:

(a) "Agency Lease" shall mean that certain Agency Lease Agreement, dated as of September 1, 2019, by and between the New York City Industrial Development Agency (the "IDA"), as lessor, and Landlord, as lessee.

(b) "Annual Administrative Fee" shall having the meaning set forth in the Agency Lease.

(c) "BID Surcharge" shall mean any payments due and owing by Landlord to any Business Improvement District ("BID") organization that has jurisdiction over any area that includes the Building.

(d) "Impositions" shall mean the aggregate amount of all real estate and personal property taxes and any general or special assessments (exclusive of penalties thereon but inclusive of interest on assessments payable in installments) assessed or imposed upon or with respect to the Building and the Land, if any, during the PILOT Term, and including, without limitation, (i) taxes or assessments made upon or with respect to any development rights now or hereafter appurtenant to or used in connection with the construction of the Building, (ii) any fee, tax or charge imposed by any governmental authority for, on or in respect of any vaults, vault space or other space within or outside the boundaries of the Land, (iii) any assessments for public improvement or benefit to the Building, the Land, or the locality in which the Land is situated, and (iv) any tax, assessment or charge imposed on or with respect to any fixtures, equipment or personal property serving or used in connection with the Building or the Land. There shall be excluded from Impositions all amounts included in the definition of "PILOT" or "Bid Surcharge" and all income, estate, succession, inheritance, transfer and franchise taxes imposed upon Landlord; provided, however, that if at any time during the Lease Term the method of taxation of real estate shall be changed and as a result any other tax or assessment, however denominated and including, without limitation, any franchise, income, profit, use, occupancy, gross receipts or rental tax, shall be imposed upon Landlord or the owner of the Building and the Land, or the rents or income therefrom, in substitution for or in addition to, in whole or in part, any of the taxes or assessments listed in the preceding sentence, such other tax or assessment shall be included in and deemed part of Impositions, but only to the extent that the same would be payable if the Building, the Land and all appurtenances thereto (including development rights) were the only property of Landlord. The amount of any special assessments for public improvements or benefits to be included in Impositions for any year, in the case where the same may, at the option of the taxpayer, be paid in installments, shall be limited to the amount of the installment due in respect of such year, together with any interest payable in connection therewith (other than interest payable by reason of the delinquent payment of such installment).

(e) "PILOT" shall mean (i) the payment in lieu of taxes to be paid by Landlord pursuant to Section 5.1 of the Agency Lease, and (ii) the Annual Administrative Fee.

(f) “PILOT Commencement Date” shall have the meaning set forth in the Agency Lease.

(g) “PILOT Percentage” shall mean, as reasonably determined by Landlord from time to time, a fraction, expressed as a percentage, the numerator of which is the rentable square footage of the portion of the Premises, if any, in respect of which PILOT is payable under the Agency Lease, and the denominator of which is the aggregate rentable square footage of all space in the Building in respect of which PILOT is payable at such time.

(h) “PILOT Program” shall mean the payment of PILOT in an amount less than actual Taxes pursuant to the Agency Lease.

(i) “PILOT Term” shall have the meaning set forth in the Agency Lease.

(j) “Taxes” shall mean the aggregate amount of all real estate and personal property taxes and any general or special assessments (exclusive of penalties thereon but inclusive of interest on assessments payable in installments) assessed or imposed upon or with respect to the Building and the Land and including, without limitation, (i) taxes or assessments made upon or with respect to any development rights now or hereafter appurtenant to or used in connection with the construction of the Building, (ii) any fee, tax or charge imposed by any governmental authority for, on or in respect of any vaults, vault space or other space within or outside the boundaries of the Land, (iii) any assessments for public improvement or benefit to the Building, the Land, or the locality in which the Land is situated, and (iv) any tax, assessment or charge imposed on or with respect to any fixtures, equipment or personal property serving or used in connection with the Building or the Land. There shall be excluded from Taxes all income, estate, succession, inheritance, transfer and franchise taxes imposed upon Landlord; provided, however, that if at any time during the Lease Term the method of taxation of real estate shall be changed and as a result any other tax or assessment, however denominated and including, without limitation, any franchise, income, profit, use, occupancy, gross receipts or rental tax, shall be imposed upon Landlord or the owner of the Building and the Land, or the rents or income therefrom, in substitution for or in addition to, in whole or in part, any of the taxes or assessments listed in the preceding sentence, such other tax or assessment shall be included in and deemed part of Taxes, but only to the extent that the same would be payable if the Building, the Land and all appurtenances thereto (including development rights) were the only property of Landlord. The amount of any special assessments for public improvements or benefits to be included in Taxes for any year, in the case where the same may, at the option of the taxpayer, be paid in installments, shall be limited to the amount of the installment due in respect of such year, together with any interest payable in connection therewith (other than interest payable by reason of the delinquent payment of such installment).

(k) “Tenant’s Tax Payment” shall mean, collectively, Tenant’s Share of Impositions, Tenant’s Share of Taxes, Tenant’s Share of PILOT and Tenant’s Share of BID.

(l) “Tax Year” shall mean each period from July 1 through June 30 (or such other fiscal period as may hereafter be adopted by the City of New York as the fiscal year for any tax, levy or charge included in Taxes), any part or all of which occurs during the Lease Term.

(m) “Tax Expenses” shall mean all expenses, including, without limitation, attorney’s fees and disbursements and experts’ and other witnesses’ fees, incurred by Landlord in seeking to reduce the amount of any assessed valuation of the Land and/or Building, in contesting the amount or validity of any Taxes or Impositions, or in seeking a refund of Taxes or Impositions, or in contesting, negotiating or otherwise reporting to the IDA in connection with the PILOT.

6.1.2 TENANT’S SHARE OF TAXES, IMPOSITIONS, PILOT AND BID. Tenant shall pay, as Additional Rent for each Tax Year, all or any portion of which shall be within the Term:

(i) during the period commencing on the Rent Commencement Date through and including the day immediately preceding the PILOT Commencement Date, an amount (“Tenant’s Share of Taxes”) equal to Tenant’s Share of the Taxes applicable to each Tax Year (or portion thereof) occurring during such period;

(ii) during the period commencing on the PILOT Commencement Date through and including the earlier to occur of (x) the Expiration Date or (y) the expiration of the PILOT Term, (A) an amount (“Tenant’s Share of PILOT”) equal to the product of (1) the PILOT Percentage times (2) the PILOT applicable to each Tax Year (or portion thereof) occurring during such period, and (B) an amount (“Tenant’s Share of Impositions”) equal to Tenant’s Share of the Impositions applicable to each Tax Year (or portion thereof) occurring during such period;

(iii) during the period commencing on the day after the PILOT Term expires or if ever Section 6.1.4(a) hereof becomes applicable, then for the period during which such Section becomes applicable, and in each case until the Expiration Date, Tenant’s Share of Taxes applicable to such period, subject to Section 6.1.4(b) hereof; and

(iv) during the period commencing on the Commencement Date and thereafter throughout the Term, an amount (“Tenant’s Share of BID”) equal to the BID Surcharge applicable to each Tax Year occurring during such period times Tenant’s Share.

From and after the Rent Commencement Date, Tenant shall also pay to Landlord, as Additional Rent, Tenant's Share of Tax Expenses. Tenant's Tax Payment for each Tax Year shall be payable in monthly installments as follows:

(a) Estimated payments by Tenant on account of PILOT, Impositions, Taxes, BID Surcharge and Tax Expenses shall be made on the first day of each and every calendar month during the Lease Term, and otherwise in the same fashion herein provided for the payment of Annual Fixed Rent. The monthly amount so to be paid to Landlord shall be sufficient to provide Landlord by the time PILOT, Impositions, Taxes, BID Surcharge and Tax Expenses are due a sum equal to Tenant's required payments, as estimated by Landlord from time to time, on account of PILOT, Impositions, Taxes, BID Surcharge and Tax Expenses for the then current Tax Year. Promptly after receipt by Landlord of bills for such PILOT, Impositions, Taxes, BID Surcharge and Tax Expenses, Landlord shall advise Tenant of the amount thereof and the computation of Tenant's payment on account thereof. If estimated payments theretofore made by Tenant for the Tax Year covered by such bills exceed the required payments on account thereof for such Tax Year, Landlord shall credit the amount of overpayment against subsequent obligations of Tenant on account of PILOT, Impositions, Taxes, BID Surcharge and Tax Expenses (or refund such overpayment if the Lease Term has ended and Tenant has no further obligation to Landlord); but if the required payments on account thereof for such Tax Year are greater than estimated payments theretofore made on account thereof for such Tax Year, Tenant shall make payment to Landlord within thirty (30) days after being so advised by Landlord. Tenant's Tax Payment for each Tax Year shall, at Landlord's option, be payable on a monthly basis as provided above, or at such other time as Landlord shall render a statement therefor.

(b) It is understood that the provisions of this Section 6.1 are based upon the method of payment (i) with respect to PILOT, set forth in the Agency Lease, to wit, in semi-annual installments in advance on the first days of July and January of each Tax Year, and (ii) with respect to Taxes, Impositions, Tax Expenses and the BID Surcharge, of New York City real property taxes in effect at the date of this Lease, to wit, in semi-annual installments in advance on the first days of July and January of each Tax Year; provided, however, that the amounts payable by Tenant in respect thereof shall be payable monthly in advance as described in Section 6.1.2(a) hereof. If such method of payment is hereafter changed, Landlord shall have the right to change the method by which Tenant pays Tenant's Share of PILOT or Tenant's Share of Impositions, Tenant's Share of Taxes, Tenant's Share of Tax Expenses, and Tenant's Share of BID, as applicable, to a method of periodic payments that provides Landlord with the full amount of Tenant's Tax Payment in respect of any installment of PILOT, Impositions, Taxes, BID Surcharge or Tax Expenses by the date on which such installment becomes due.

6.1.3 TAX REDUCTION PROCEEDINGS. Only Landlord shall have the right to institute tax reduction or other proceedings to reduce the assessed valuation of the Land and Building. Should Landlord be successful in any such reduction proceedings and obtain a refund for any Tax Year or Years in respect of which Tenant shall have made a payment to Landlord, pursuant to this Section 6.1, Landlord shall credit Tenant's Share (applicable to Taxes) of such refund (or, in the case of a refund of Taxes for a Tax Year, only a fraction of which is included in the Lease Term, such fraction thereof) against the monthly installment or installments of Annual Fixed Rent next falling due under this Lease, or if the Lease Term has then expired and Tenant has no further obligations to Landlord, such amount shall be refunded by Landlord to Tenant. In calculating the amount of any such credit or payment, Landlord shall have the right to deduct from such refund all Tax Expenses incurred by Landlord in obtaining the same. The provisions of this subsection 6.1.3 shall survive the expiration of the Lease Term.

6.1.4 PILOT PROGRAM TERMINATION.

(a) In the event that the Agency Lease is terminated or the Property otherwise ceases to be exempt from the payment of Taxes and becomes subject to the payment of Taxes on substantially the same basis as other privately owned office buildings in Manhattan, then, from and after the date (the "PILOT Early Termination Date") on which Taxes first becomes payable, (i) Tenant's Share of PILOT and Tenant's Share of Impositions shall cease to be payable hereunder with respect to any period occurring after the PILOT Early Termination Date, and (ii) Tenant shall commence to make the payments of Tenant's Share of Taxes pursuant to this Section 6.1.

(b) If the Property shall cease to be exempt from the payment of Taxes and becomes subject to the payment of Taxes on substantially the same basis as other privately owned office buildings in Manhattan prior to the expiration of the PILOT Term as a result of Landlord's breach of the terms of the Agency Lease, then, until the earlier to occur of (x) the expiration of the PILOT Term or (y) the end of the initial Term of this Lease (i.e., prior to the commencement of any renewal term), in lieu of Tenant's Share of Taxes, Tenant shall pay an amount equal to the amount of the applicable Tenant's Tax Payment that Tenant would have been paying if the Pilot Program were still in effect. If the Property or the Premises shall cease to be exempt from the payment of Taxes and becomes subject to the payment of Taxes on substantially the same basis as other privately owned office buildings in Manhattan prior to the expiration of the PILOT Term as a result of any act or omission of Tenant (including, without limitation, Tenant or any other Tenant's Party's use of the Premises for a Non-Qualified Use), then Tenant shall indemnify, defend and hold Landlord harmless from and against all costs, losses, claims or expenses incurred by Landlord in connection therewith, including, without limitation, any incremental amounts that Landlord is required to repay under the Agency Lease as a result thereof. If the Property or the Premises shall cease to be exempt from the payment of Taxes and becomes subject to the payment of Taxes on substantially the same basis as other privately owned office buildings in Manhattan prior to the expiration of the PILOT Term as a result of any act or omission of any other tenant in the Building, then any net amounts recovered on account of Taxes by Landlord from other tenants in the Building shall be passed on to Tenant such that the same are applied to Tenant's tax payments due pursuant Section 6.1.2(iii); provided, however, that in no event shall any such net amounts to be applied in accordance with the foregoing exceed the amount due from Tenant pursuant to Section 6.1.2(iii).

(c) Landlord hereby represents and warrants to Tenant that (i) the Agency Lease provides that the term "PILOT Abatement" means, with respect to any semi-annual period, an amount equal to the product of (y) 100% less the Non-Qualified Use Percentage (as defined in the Agency Lease), and (z) the Full PILOT Amount (as defined in the Agency Lease) with respect to the Facility Realty (as defined in the Agency Lease) (without duplication of any Additional Improvements PILOT (as defined in the Agency Lease)) and (ii) pursuant to Section 5.1(c) of the Agency Lease, Landlord is obligated to pay PILOT with respect to the Facility Realty as described on Schedule 6.1.4(c) attached hereto.

6.2 OPERATING EXPENSE ESCALATION.

6.2.1 DEFINITIONS. For the purposes of this Section 6.2, the following terms shall have the respective meanings set forth below:

(a) "Base Operating Expenses" shall mean the actual Operating Expenses for the Operating Year commencing on January 1, 2021 and ending on December 31, 2021.

(b) "Operating Expenses" shall mean the aggregate of all costs and expenses (including taxes, if any, thereon) paid or incurred by or on behalf of Landlord (whether directly or through independent contractors) in connection with the operation and maintenance of the Property, including all expenses incurred by Landlord as a result of its compliance with any of its obligations under Sections 7.1 and 7.3 hereof, but excluding those items set forth as excluded from Operating Expenses at the end of this subsection 6.2.1(b). Operating Expenses shall be calculated on the accrual basis of accounting (but subject to the further provisions of this Section 6.2) and shall include, without limitation, the following expenses:

(i) salaries, wages, medical, surgical and general welfare benefits (including group life insurance), pension and welfare payments or contributions and all other fringe benefits paid to, for or with respect to all persons (whether they be employees of Landlord or its managing agent) for their services in the operation (including, without limitation, security services), maintenance, repair, or cleaning of the Property, and payroll taxes, workers' compensation, uniforms and dry cleaning costs for such persons;

(ii) payments under service contracts with independent contractors for operating (including, without limitation, providing security services), maintaining, repairing, replacing or cleaning of the Property or any portion thereof or any fixtures or equipment therein;

(iii) all costs or charges for steam, hot water, heat, ventilation, air conditioning and water (including sewer rents) furnished to the Property and/or used in the operation of the Property and all costs or charges for electricity furnished to the public and service areas of the Property and/or used in the operation of the service facilities of the Property, including any taxes on any such utilities;

(iv) ordinary repairs that are appropriate to the continued operation of the Property as a first-class Manhattan office building and, where applicable, a first-class laboratory and research building;

(v) costs of lobby decoration, painting and decoration of non-tenant areas;

(vi) cost of snow removal and landscaping in and about the Property;

(vii) cost of building and cleaning supplies and equipment, cost of replacements for tools and equipment used in the operation, maintenance and repair of the Property and charges for telephone service for the Property;

(viii) financial expenses, including software charges, incurred in connection with the operation of the Property, such as insurance premiums (including, without limitation, liability insurance, fire and casualty insurance, rent insurance and any other insurance that is then generally carried by owners of major first-class office, laboratory and research buildings in Manhattan or may be required by the holder of any mortgage on the Property), attorneys' fees and disbursements (exclusive of any such fees and disbursements incurred in applying for any reduction of Taxes or in connection with the leasing of space in the Property), auditing and other professional fees and expenses, Landlord's reasonable home office accounting charges, association dues and any other ordinary and customary financial expenses incurred in connection with the operation of the Property;

(ix) management fees payable to a management company which is unrelated to Landlord or, if to a management company which is owned or controlled by Landlord or Landlord's principals, then for all purposes of this Lease at a rate of three percent (3%) of actual gross rentals of the Property per annum;

(x) the cost of capital improvements ("Permitted Capital Expenditures") made by Landlord either (1) to reduce Operating Expenses, or (2) pursuant to a requirement of law, ordinance, order, rule or regulation of any public authority having jurisdiction or the requirement of any insurance carrier or insurance rating organization or underwriting board now or hereafter in effect, whether or not such requirement is valid or mandatory, in either case (x) that is first enacted or first enforced after the date hereof and (y) calculated as follows: the cost of any such capital improvement shall be included in Operating Expenses for the Operating Year in which such improvement was made, provided that such cost shall be amortized on a straight-line basis over the useful life thereof determined reasonably by Landlord in accordance with GAAP and practices in effect at the time of the capital improvement, and the annual amortization of such capital improvement, together with interest on the unamortized balance of such cost at the Base Rate, shall be included in Operating Expenses; provided, however, if Landlord reasonably concludes on the basis of engineering estimates that a particular capital expenditure will effect savings in other Operating Expenses, including, without limitation, energy related costs, and that such projected savings will, on an annual basis ("Projected Annual Savings"), exceed the annual amortization therefor, then and in such event the amount of amortization for such capital expenditure shall be increased to an amount equal to the Projected Annual Savings, and in such circumstance, the increased depreciation (in the amount of the Projected Annual Savings) shall be made for such period of time as it would take to fully amortize the cost of the item in question, together with interest thereon at the Lease Interest Rate in equal monthly payments, each in the amount of one-twelfth (1/12th) of the Projected Annual Savings, with such payment to be applied first to interest and the balance to principal;

(xi) rental payments made for equipment used in the operation and maintenance of the Property;

(xii) the cost of governmental licenses and permits, or renewals thereof, necessary for the operation of the Property;

(xiii) all costs of reporting for the Building or any part thereof to maintain certification under the U.S. EPA's Energy Star® rating system, the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar system or standard (but excluding costs of seeking, applying for and obtaining any initial certification);

(xiv) the costs of any operations and maintenance program pursuant to Section 10.7 hereof;

(xv) subject to clause (x) above, all costs incurred by Landlord to comply with applicable laws and requirements of public authorities (including, without limitation, New York City Local Law 11); and

(xvi) all other reasonable and necessary expenses paid in connection with the operation, maintenance, repair and cleaning of the Property which are properly chargeable against income.

Any cost or expenses of the nature described above shall be included in Operating Expenses for any Operating Year no more than once, notwithstanding that such cost or expenses may fall under more than one of the categories listed above. Subject to the limitation set forth in subdivision (ix) above, Landlord may use related or affiliated entities to provide services or furnish materials for the Property provided that the rates or fees charged by such entities are competitive with those charged by unrelated or unaffiliated entities in the Borough of Manhattan for the same services or materials.

The following costs and expenses shall be excluded from Operating Expenses:

(1) Impositions, Taxes, Tax Expenses, PILOT and BID Surcharge, and any net income, capital stock, succession, transfer, franchise, gift, estate, inheritance or mortgage taxes imposed upon Landlord;

(2) franchise and income taxes imposed upon Landlord;

(3) principal and interest payments and other costs incurred in connection with any financing or refinancing of the Property or any portions thereof;

(4) leasing costs (including leasing and brokerage commissions and similar fees, lease marketing and advertising, lease takeover or rental assumption obligations and legal fees in connection with lease negotiations) and the cost of tenant improvements or tenant allowances or inducements made for tenants of the Building (including permit, license and inspection fees and any other contribution by Landlord to the cost of tenant improvements);

(5) capital improvements to the Property other than those provided in clause (x) above or to rentable spaces at the Property (even if not leased);

(6) the cost of electrical energy furnished directly to tenants of the Property;

(7) the cost of tenant installations and decorations incurred in connection with preparing space for any tenant;

(8) salaries or fringe benefits of personnel above the grade of senior property manager;

(9) rent payable under any Underlying Lease;

(10) the cost of any items to the extent to which such cost is reimbursed to Landlord by tenants of the Property (other than pursuant to this Section 6.2), insurance or condemnation proceeds or third parties;

(11) depreciation of the building, amortization (except as provided in clause (x) above) and other non-cash charges;

(12) management fees payable to a management company owned or controlled by Landlord or Landlord's principals, in excess of three percent (3%) of actual gross rentals of the Property per annum, and all amounts paid by Landlord to any other Affiliates of Landlord for services to the extent the same exceeds the costs of such services as rendered by unaffiliated third party service providers in other first class office buildings in the vicinity of the Building on a competitive basis;

(13) salaries, wages, fringe benefits and other compensation (including judgments, settlements or arbitration awards relating to the same) of Landlord's employees above the grade of property manager;

(14) any costs of acquiring or leasing sculptures, paintings or other objects of fine art and insuring such artwork to the extent such insurance cost is in excess of similar costs incurred in first class office buildings in the vicinity of the Building;

(15) any compensation paid to clerks, attendants or other Persons in commercial concessions operated by Landlord for a profit;

(16) any interest, fine, penalty or other late charges payable by Landlord, incurred as a result of late payments, except to the extent the same was with respect to a payment, part or all of which was (i) the responsibility of Tenant hereunder and with respect to which Tenant did not make in a timely fashion or did not make at all or (ii) related to a dispute by Landlord in good faith with respect to costs otherwise includable in Operating Expenses;

(17) any contributions to charitable organizations, except to the extent the same are customarily included as operating expenses in office leases of first class office buildings in the vicinity of the Building;

(18) costs and expenses incurred in connection with specialty improvements to the Building (including private cafeterias, lodging or private dining facilities or private athletic or recreational clubs) with respect to which Tenant is not given access in common with other tenants or occupants of the Building and other tenants or occupants of the Building are given exclusive access to use and occupy;

(19) costs and expenses in connection with any judgment, settlement or arbitration award resulting from the gross negligence or willful misconduct of Landlord giving rise to tort liability;

(20) costs relating to withdrawal liability or unfunded pension liability under the Multi-Employer Pension Plan Act;

(21) any costs incurred in connection the remedying of any violations of applicable legal requirements existing as of the date hereof (excluding, for the avoidance of doubt, any costs in connection with Section 20.31 hereof);

(22) expenses and disbursements relating to disputes with Tenant and other tenants or other occupants of the Building;

(23) Non-Common Expenses; and

(24) Lab Costs.

Operating Expenses shall be net of rebates, credits and similar items of which Landlord receives the benefit.

If Landlord is not furnishing any particular work or service (the cost of which if performed by Landlord would constitute an Operating Expense (including with respect to the determination of Base Operating Expenses)) to a tenant who has undertaken to perform such work or service in lieu of the performance thereof by Landlord, Operating Expenses for any Operating Year (including the year based on which Base Operating Expenses are determined) during all or any part of which such work or service is not so furnished by Landlord shall be increased by an amount equal to the additional Operating Expenses which reasonably would have been incurred during such period by Landlord if it had at its own expense furnished such work or service to such tenant. Notwithstanding anything to the contrary contained herein, Base Operating Expenses shall not include (I) increases due to extraordinary circumstances, including but not limited to, Force Majeure, boycotts, strikes, conservation surcharges, security concerns, embargoes or shortages (provided that in the event that any of the extraordinary circumstances contemplated by this clause (I) shall also be applicable in the Operating Year so compared, then Base Operating Expenses shall be deemed to include the costs and expenses associated with such event, solely with respect to such Operating Year in which the extraordinary circumstances continues or otherwise applies) or (II) Permitted Capital Expenditures.

In determining the amount of Operating Expenses for any Operating Year (including the determination of Base Operating Expenses), if less than one hundred percent (100%) of the rentable area of the Building shall have been occupied by tenant(s) at any time during such Operating Year, Operating Expenses shall be determined for such Operating Year to be an amount equal to the Operating Expenses which would normally be expected to have been incurred had such occupancy been one hundred percent (100%) throughout such Operating Year.

(c) "Operating Year" shall mean the calendar year within which the Commencement Date occurs and each subsequent calendar year, any part or all of which falls within the Lease Term.

(d) "Property" shall mean the Land, the Building, and any other land contiguous to the Land, and any improvements constructed on such land, whether above or below ground, which Landlord may operate or maintain or may contribute to the cost of the operation or maintenance thereof.

(e) "Non-Common Expenses" shall mean all expenses relating to (i) services or other benefits ("Non-Common Services") that are not provided to office tenants of the Building generally without a separate charge (including, without limitation, any incremental services that Tenant requires in order to operate a laboratory within the Premises), and/or (ii) all charges that Tenant is required to pay directly to Landlord pursuant to a separate meter or by other means.

6.2.2 TENANT'S SHARE OF OPERATING EXPENSES. If the Operating Expenses for any full Operating Year falling within the Lease Term shall exceed the Base Operating Expenses or if, in the case of an Operating Year only a fraction of which is included in the Lease Term, the amount of the Operating Expenses for such Operating Year multiplied by such fraction exceeds the Base Operating Expenses multiplied by such fraction (the amount of such excess in either case being hereafter referred to as the "Excess Operating Expenses"), then Tenant shall pay to Landlord, as Additional Rent, Tenant's Share of the Excess Operating Expenses for such Operating Year or portion thereof. Tenant's Share of the Excess Operating Expenses for each Operating Year shall be payable in monthly installments as follows:

(a) Estimated payments by Tenant on account of Operating Expenses shall be made on the first day of each and every calendar month during the Lease Term, and otherwise in the same fashion herein provided for the payment of Annual Fixed Rent. The monthly amount so to be paid to Landlord shall be sufficient to provide Landlord by the end of each Operating Year with a sum equal to Tenant's required payments, as estimated by Landlord from time to time, on account of Operating Expenses for such Operating Year. After the end of each Operating Year, Landlord shall submit to Tenant a reasonably detailed statement (a "Landlord's Statement") of Operating Expenses for such Operating Year. If estimated payments theretofore made for such Year by Tenant exceed Tenant's required payment on account therefor for such Operating Year, according to such statement, Landlord shall credit the amount of overpayment against subsequent obligations of Tenant with respect to Operating Expenses (or refund such overpayment if the Lease Term has ended and Tenant has no further obligation to Landlord); but, if the required payments on account thereof for such Operating Year are greater than the estimated payments (if any) theretofore made on account thereof for such Operating Year, Tenant shall make payment to Landlord within thirty (30) days after being so advised by Landlord. Except as otherwise provided herein, Landlord's failure to render a Landlord's Statement with respect to any applicable payment period as provided herein shall not prejudice Landlord's right to thereafter render a Landlord's Statement with respect thereto or with respect to any subsequent payment period, nor shall the rendering of a Landlord's Statement prejudice Landlord's right (subject to the terms hereof) to thereafter render a corrected Landlord's Statement for that payment period. Subject to the terms hereof, nothing herein contained shall restrict Landlord from issuing a Landlord's Statement at any time there is an increase in Operating Expenses during any payment period or any time thereafter. Notwithstanding the foregoing provisions of this Section 6.2.2, Landlord shall not be entitled to issue a Landlord's Statement with respect to Operating Expenses for any Operating Year after the date that is three (3) years after the applicable Operating Year.

(b) If the Operating Expenses for any Operating Year (as adjusted, if applicable, pursuant to the last two (2) paragraphs of subsection 6.2.1(b)) shall equal or be less than the Base Operating Expenses, Tenant shall not be obligated to make any payments to Landlord pursuant to this Section 6.2 in respect of such Operating Year, but in no event shall Tenant be entitled to any refund or reduction in the Annual Fixed Rent by reason of such fact.

6.2.3 AUDIT RIGHT. Subject to the provisions of this Section and provided that no Event of Default exists, Tenant shall have the right to examine the correctness of the Landlord's Operating Expense statement or any item contained therein. Any request for examination in respect of any Operating Year may be made by notice from Tenant to Landlord no more than one hundred eighty (180) days after the date (the "Operating Expense Statement Date") Landlord provides Tenant a statement of the actual amount of the Operating Expenses in respect of such Operating Year and only if Tenant shall have fully paid such amount. Such notice shall set forth in reasonable detail the matters questioned. Any examination must be completed and the results communicated to Landlord no more than two hundred ten (210) days after the Operating Expense Statement Date. Tenant hereby acknowledges and agrees that Tenant's sole right to contest the Operating Expense statement shall be as expressly set forth in this Section. Tenant hereby waives any and all other rights pursuant to applicable law to inspect Landlord's books and records and/or to contest the Operating Expense statement. If Tenant shall fail to timely exercise Tenant's right to inspect Landlord's books and records as provided in this Section, or if Tenant shall fail to timely communicate to Landlord the results of Tenant's examination as provided in this Section, with respect to any Operating Year, Landlord's statement of Operating Expenses shall be conclusive and binding on Tenant. So much of Landlord's books and records pertaining to the Operating Expenses for the specific matters questioned by Tenant for the Operating Year included in Landlord's statement shall be made available to Tenant within a reasonable time after Landlord timely receives the notice from Tenant to make such examination pursuant to this Section during normal business hours at the offices in New York, New York where Landlord keeps such books and records. Tenant shall have the right to make such examination no more than once in respect of any Operating Year in which Landlord has given Tenant a statement of the Operating Expenses. Such examination may be made only by a qualified employee of Tenant or a qualified independent certified public accounting firm approved by Landlord, and in no event shall such examination be performed by BDO Seidman, LLP or its successors. No examination shall be conducted by an examiner who is to be compensated, in whole or in part, on a contingent fee basis. As a condition to performing any such examination, Tenant and its examiners shall be required to execute and deliver to Landlord an agreement, in form acceptable to Landlord, agreeing to keep confidential any information which it discovers about Landlord or the Building in connection with such examination. No subtenant shall have any right to conduct any such examination and no assignee may conduct any such examination with respect to any period during which the assignee was not in possession of the Premises. All costs and expenses of any such examination shall be paid by Tenant. If as a result of such examination Landlord and Tenant agree that the amounts paid by Tenant to Landlord on account of the Operating Expenses exceeded the amounts to which Landlord was entitled hereunder, or that Tenant is entitled to a credit with respect to the Operating Expenses, Landlord, at its option, shall refund to Tenant the amount of such excess or apply the amount of such credit, as the case may be, within thirty (30) days after the date of such agreement. Similarly, if Landlord and Tenant agree that the amounts paid by Tenant to Landlord on account of Operating Expenses were less than the amounts to which Landlord was entitled hereunder, then Tenant shall pay to Landlord, as additional rent hereunder, the amount of such deficiency within thirty (30) days after the date of such agreement. All costs and expenses of any such examination made pursuant to this Section 6.2.3 shall be paid by Tenant except insofar as Landlord and Tenant agree as a result of such examination that Landlord overstated Operating Expenses by more than seven percent (7%), in which case Landlord shall pay any reasonable out-of-pocket fees and expenses charged by Tenant's public accounting firm, but in no case more than the amount overpaid by Tenant for such Operating Year.

6.2.4 GENERAL APPLICABILITY. The imposition on Landlord by any portion of this Lease of an obligation to perform any work, repairs or other acts with respect to the Property shall not be construed as preventing Landlord from including the cost of such work, repairs or other acts in Operating Expenses, to the extent the same is otherwise properly includible therein pursuant to this Section 6.2.

ARTICLE 7

REPAIRS AND SERVICES

7.1 LANDLORD'S OBLIGATION TO REPAIR. Except as otherwise provided in this Lease, Landlord shall, throughout the Lease Term, keep and maintain in good order, condition and repair:

(a) the roof, the exterior and load bearing walls (including exterior windows), the foundation, the structural floor slabs and other structural elements of the Building; and

(b) the common facilities of the Building, including HVAC, plumbing and other Building systems and equipment servicing the Premises (other than any supplementary or accessory HVAC, and telecommunication/computer systems and/or any item of such equipment exclusively serving the Premises) up to the point of connection to the Premises and electricity servicing Common Areas.

Landlord shall not be responsible to make any improvements or repairs to the Building or the Premises other than as expressly provided in this Section 7.1, unless expressly otherwise provided in this Lease. Tenant shall promptly give Landlord notice of any damage to the Premises or the Building (whether or not caused by Tenant) or of any Latent Defects in any portion thereof or in any fixtures or equipment therein promptly after Tenant first learns thereof. In making any repairs, alterations, additions or improvements in the Premises, Landlord shall, use reasonable efforts to minimize interference with Tenant's use and occupancy of the Premises; provided, however, that Landlord shall have no obligation to employ contractors or labor at so-called overtime or other premium pay rates or to incur any other overtime costs or expenses whatsoever. Subject to the foregoing, Landlord will correct any such Latent Defects promptly after receipt of such notice from Tenant; provided, however, if Tenant does not notify Landlord of any Latent Defect within twelve (12) months after the Commencement Date, then Landlord shall have no obligation to repair or correct such Latent Defect. "Latent Defects" shall mean defects in the Work that adversely affect Tenant's use of the Premises for the Permitted Use in any material respect, which defects, despite the exercise of commercially reasonable efforts by Tenant, are not susceptible of being detected (and are not detected) as of the Commencement Date.

7.2 TENANT'S REPAIRS AND MAINTENANCE.

(a) Tenant covenants and agrees that, from and after the date that possession of the Premises is delivered to Tenant and until the end of the Lease Term, Tenant, at its expense, will keep neat and clean and maintain in good order, condition and repair the Premises, Alterations and all fixtures or facilities contained in the Premises which do not constitute part of the common areas or the Building systems, including, without limitation, any distribution conduits for the HVAC system serving the Premises, any supplemental air conditioning units installed by or on behalf of Tenant or any other Tenant Party, any private lavatory and any public lavatories located on floors leased entirely to Tenant, shower, toilet, washbasin and kitchen facilities, and all plumbing serving or connected to such systems or facilities, and will make all required repairs thereto and/or replacements of portions thereof, excepting only for those repairs or replacements for which Landlord is responsible under the terms of Section 7.1 or Article 12 of this Lease. Tenant shall not permit or commit any waste, and, notwithstanding anything to the contrary set forth in Section 7.1, Tenant shall be responsible for the cost of all repairs and replacements to the Premises, the Building and the facilities of the Building, whether ordinary or extraordinary, structural or, non-structural, when necessitated by Tenant's, or its subtenant's or assignee's, moving property in or out of the Building or installation or removal of furniture, fixtures or other property or by the performance by Tenant, or its subtenant or assignee, of any alterations or other work in the Premises, or when necessitated by the acts, omission, misuse, neglect or improper conduct of Tenant, its assignee or subtenant, or its or their agents, employees, contractors or invitees or the use or occupancy or manner of use or occupancy of the Premises other than in accordance with the terms of this Lease. All of said repairs and any restorations or replacements required in connection therewith shall be of a quality and class at least equal to the original work or installations and shall be done in a good and workmanlike manner to the satisfaction of Landlord.

(b) If repairs or replacements are required to be made by Tenant pursuant to the terms hereof, Landlord may demand that Tenant make the same forthwith, and (except in cases of emergency, where no notice or demand shall be required) if Tenant refuses or neglects to commence such repairs or replacements within thirty (30) days after such demand or to complete the same with reasonable diligence thereafter, Landlord may (but shall not be required to do so) make or cause such repairs or replacements to be made and shall not be responsible to Tenant for any loss or damage that may accrue to Tenant's stock or business by reason thereof. If Landlord makes or causes such repairs or replacements to be made, Tenant agrees that Tenant will forthwith, on demand, pay to Landlord as Additional Rent the cost thereof, together with interest thereon at the Lease Interest Rate.

7.3 SERVICES. Subject to the provisions of Sections 14.3 and 20.12, Landlord agrees to provide the services set forth in Exhibit D annexed hereto to the Building and the Premises during Operating Hours (as defined in Exhibit D). In the event that Tenant purchases any utility service directly from the provider, Tenant shall promptly provide to Landlord copies of the utility bills for Tenant's usage of such services in a format reasonably acceptable to Landlord. Notwithstanding anything in this Lease to the contrary, if Landlord or any affiliate of Landlord has elected to qualify as a real estate investment trust ("REIT"), any service required or permitted to be performed by Landlord pursuant to this Lease, the charge or cost of which may be treated as impermissible tenant service income under the laws governing a REIT, may be performed by a taxable REIT subsidiary that is affiliated with either Landlord or Landlord's property manager, an independent contractor of Landlord or Landlord's property manager (the "Service Provider"). If Tenant is subject to a charge under this Lease for any such service, then, at Landlord's direction, Tenant will pay such charge either to Landlord for further payment to the Service Provider or directly to the Service Provider, and, in either case, (i) Landlord will credit such payment against Additional Rent due from Tenant under this Lease for such service, and (ii) such payment to the Service Provider will not relieve Landlord from any obligation under the Lease concerning the provisions of such service. Landlord shall not be obligated to provide any services to the Premises other than as set forth on Exhibit D annexed hereto; provided, however, Landlord shall be obligated to provide any Non-Common Services reasonably requested by Tenant and approved by Landlord (such approval not to be unreasonably withheld, conditioned or delayed). The consumption of any such Non-Common Services required by Tenant and provided by Landlord may be measured by one or more submeters installed by Landlord at Tenant's sole cost and expense. Tenant shall pay the charges for such services within thirty (30) days after rendition of bills therefor, which bills shall be rendered by or on behalf of Landlord separately for any such charge and shall be delivered no less frequently than monthly. Landlord's failure to render or delay in rendering a bill with respect to any month shall not prejudice Landlord's right to thereafter render a bill with respect to any such month, nor shall the rendering of a bill for any month prejudice Landlord's right to thereafter render a corrected bill for such month.

7.4 LAB COSTS. Solely in the event that Tenant operates a laboratory in the Premises, Tenant shall pay to Landlord, as Additional Rent, the Lab Costs for each Operating Year or, in the case of an Operating Year only a fraction of which is included in the Lease Term, the applicable portion thereof. Lab Costs for each Operating Year shall be payable in monthly installments as follows: estimated payments by Tenant on account of Lab Costs shall be made on the first day of each and every calendar month during the Lease Term, and otherwise in the same fashion herein provided for the payment of Annual Fixed Rent. The monthly amount so to be paid to Landlord shall be sufficient to provide Landlord by the end of each Operating Year with a sum equal to Tenant's required payments, as estimated by Landlord from time to time, on account of Lab Costs for such Operating Year. Landlord shall deliver to Tenant an annual estimate of Lab Costs for each calendar year during the term, which may be revised by Landlord from time to time during such calendar year, including, without limitation, to increase such estimate as a result of any item of expense or cost reimbursable by Tenant that relates to a repair, replacement or service benefiting the Lab Area or a portion of the Building that includes the Lab Area or that varies with occupancy or use. After the end of each Operating Year, Landlord shall submit to Tenant a reasonably detailed statement of Lab Costs for such Operating Year. If estimated payments theretofore made for such Operating Year by Tenant exceed Tenant's required payment on account therefor for such Operating Year, according to such statement, Landlord shall credit the amount of overpayment against subsequent obligations of Tenant with respect to Lab Costs (or refund such overpayment if the Lease Term has ended and Tenant has no further obligation to Landlord); but, if the required payments on account thereof for such Operating Year are greater than the estimated payments (if any) theretofore made on account thereof for such Operating Year, Tenant shall make payment to Landlord within thirty (30) days after being so advised by Landlord. Lab Costs shall be calculated on the accrual basis of accounting. As used herein, the term (i) "Lab Costs" shall mean the aggregate of all costs and expenses (including taxes, if any, thereon) paid or incurred by or on behalf of Landlord (whether directly or through independent contractors) in connection with the operation and maintenance of the Lab Area and the Lab Systems, including all expenses incurred by Landlord as a result of its compliance with any of its obligations under Sections 20.31, but excluding Operating Expenses, and (ii) "Lab Area" shall mean the portion of the Premises dedicated solely to laboratory uses (and not office uses) qualifying as Qualified Life Sciences Uses. Landlord acknowledges and agrees that Tenant's initial use of the Premises will be for office space for a life sciences company; accordingly, so long as Tenant does not operate any laboratory in the Premises, then Tenant will not be obligated to pay any Lab Costs under this Lease.

ARTICLE 8

ALTERATIONS

8.1 TENANT'S RIGHTS. Tenant may from time to time during the Lease Term, at its expense, make such alterations, additions, installations, substitutions, improvements and decorations (collectively, with Tenant's Work, referred to as "Alterations") in and to the Premises as Tenant may consider necessary or desirable for the conduct of its business in the Premises, subject to the following conditions:

(a) the outside appearance or the strength of the Building or any of its structural parts shall not be affected;

(b) no part of the Building outside of the Premises shall be physically affected;

(c) no other tenant or occupant of the Building, and no common area of the Building, shall be affected;

(d) the proper and economical functioning of the Building systems or facilities of the Building or any portion thereof shall not be affected;

(e) before proceeding with any Alterations, Tenant shall obtain Landlord's written consent and submit to Landlord for approval plans and specifications for the work to be performed; it being agreed that Landlord shall not unreasonably withhold, condition or delay its consent if the proposed Alteration is not a Material Alteration. For purposes of this Article 8, the term "Material Alteration" means any Alteration that (i) affects the outside appearance of the Building or the structure of the Building, including the structural elements of the walls, floors, ceiling or columns of the Building, (ii) would physically affect any components of the exterior of the Building, (iii) would affect the Building systems or services, (iv) would adversely affect the provision of services to other Building occupants, (v) would involve excessive noise or fumes (including, but not limited to any Alterations(s) involving (A) demolition, (B) cutting, trenching, chopping and drilling of floor slabs, (C) shooting fasteners into slab, floor or overhead, (D) spraying of paint or other coatings, (E) disconnects or shutdowns affecting other tenants or other parts of the Building, (F) burning or welding of steel which causes fumes to be transmitted to other parts of the Building or (G) the use of air-hammers or concrete saws) or (vi) would include work that requires the removal of a portion of the floor slab in any portion of the Premises, or access to, or penetration of the floor slab adjacent to, any space occupied by any other tenant or occupant of the Building (other than Tenant's subtenants). Landlord's prior written consent shall not be required for any Alterations that are purely decorative or cosmetic Alterations (and that are not otherwise Material Alterations) such as painting, wall coverings and floor coverings and that do not cost in excess of Fifty Thousand and 00/100 Dollars ($50,000.00). Landlord may as a condition of its consent require Tenant (i) to perform all such work at such times and in such manner as to create the least practicable interference with the use of the Building by the other tenants and occupants thereof, including, but without limitation, on an "overtime" basis, (ii) to make revisions in and to its plans and specifications, and/or (iii) to agree to remove, at or prior to the Expiration Date, any item of work shown on such plans of an unusual nature, such as, but not limited to, internal stairways, pantries, lavatories, vaults, special flooring for computer areas and the like ("Specialty Alterations"), and to restore the affected portion of the Premises;

(f) before proceeding with any Alterations, any required consent from any Mortgagee and/or Overlandlord shall have been obtained; provided, however, with respect to any future Mortgagee or Overlandlord, the provisions of the mortgage or Underlying Lease, as applicable, requiring such future Mortgagee or Overlandlord's consent shall be commercially reasonable; and

(g) in performing the work involved in such Alterations, Tenant shall perform, observe and comply with all of the conditions and covenants set forth in the provisions of this Article 8.

Landlord's review and approval of Tenant's plans and specifications and consent to the performance of the work described therein shall not be deemed an agreement by Landlord that such plans, specifications and work conform with applicable law and insurance requirements, nor shall it be deemed a waiver by Landlord of compliance by Tenant with any provisions of this Lease, nor shall it impose upon Landlord any liability or obligation with respect to such work or the performance thereof. All Alterations together with the Work and other non-base Building improvements in the Premises are collectively referred to herein as the "Leasehold Improvements". If Landlord fails to respond within ten (10) Business Days after Tenant's submittal of Tenant's plans and specifications, Tenant may provide Landlord with an additional notice which shall set forth in bold capital letters the following statement: "**IF LANDLORD FAILS TO RESPOND WITHIN FIVE (5) BUSINESS DAYS AFTER RECEIPT OF THIS NOTICE, THEN TENANT SHALL BE ENTITLED TO COMMENCE CONSTRUCTION IN ACCORDANCE WITH THE PLANS AND SPECIFICATIONS SUBMITTED TO LANDLORD WITH THIS REQUEST**". If Landlord fails to respond to such notice within five (5) Business Days after receipt by Landlord, then Tenant's plans and specifications for which the request is submitted shall be deemed to be approved by Landlord and Tenant shall be entitled to perform the Alterations to which such plans and specifications relate, provided that, as to commencing such Alterations, such plans and specifications have been appropriately filed in accordance with all applicable law and insurance requirements, all permits and approvals required to be issued by any governmental authority with respect to such phase of construction work shall have been duly issued, and Tenant shall otherwise have complied with all provisions of this Lease relating to such Alterations.

8.2 CONFORMITY WITH LAW. Tenant covenants and agrees that any Alterations made by it to or upon the Premises shall be done in a good and workmanlike manner and in conformity and compliance with all applicable laws, ordinances, regulations and requirements of all public authorities having jurisdiction, and with all applicable requirements of insurers and insurance rating or underwriting organizations, that new materials and equipment of at least equal quality and class to the original installations in the Building shall be employed therein, that the structure of the Building shall not be endangered or impaired thereby and that the Premises shall not be diminished in value thereby.

8.3 PERFORMANCE OF WORK, GOVERNMENTAL APPROVALS, INSURANCE.

(a) All Alterations and installation of furnishings by Tenant (i) shall be coordinated with any work being performed by Landlord and in such manner as to maintain harmonious labor relations and not to damage the Building or interfere with or delay Building construction or operation or increase the cost thereof, (ii) shall not interfere with the use or occupancy of any other tenant or occupant of the Building (iii) to the extent connected to or involving any portion of the HVAC, plumbing, electrical, life safety, proprietary or other systems of the Building, shall be performed by a contractor designated by Landlord in its sole and absolute discretion, and (iv) with respect to all Alterations and installations which are not the subject of the foregoing clause (iii), shall be performed by contractors and subcontractors first approved by Landlord (which approval shall not be unreasonably withheld, delayed or conditioned).

(b) Tenant shall (i) procure all necessary governmental permits, licenses and certificates, (ii) make all required filings of plans with governmental authorities before making any Alterations, (iii) obtain all required governmental approvals upon the completion thereof, and (iv) deliver copies of the items set forth in subsections (i) through (iii) above to Landlord for inspection by Landlord, and, if applicable, for Landlord's approval. Upon completion of any Alterations, Tenant shall deliver to Landlord (i) an architect's certificate from Tenant's architect certifying that the Alterations have been completed in accordance with the approved plans and specifications and (ii) three (3) complete "as built" sets of Tenant's plans and specifications prepared on an AutoCAD Computer Assisted Drafting and Design System (or such other system or medium reasonably approved by Landlord and generally used in the industry) using naming conventions issued by the American Institute of Architects in June, 1990 (or such other naming conventions as Landlord may reasonably accept) and digital files of such record drawings and specifications, translated into in a format compatible with AutoCAD Release 2000 or later or another format reasonably acceptable to Landlord. Tenant shall use an expediter designated by Landlord in connection with making such filings and obtaining such permits, licenses, certificates and approvals. At any and all times during the period of construction of any Alterations, Landlord shall be entitled to have a representative or representatives on the site to inspect such Alterations, and such representative or representatives shall have free and unrestricted access to any and every part of the Premises. Tenant shall keep full and accurate records of the cost of any Alterations in and to the Premises and shall, if requested by Landlord, make the same available to Landlord for use in connection with any proceeding to review the assessed valuation of the Building or any proceedings to acquire the Land and Building for public or quasi-public use.

(c) Tenant agrees to save harmless and indemnify Landlord and all other Landlord Parties from and against any and all injury, loss, claims, damage and expense (including attorneys' fees and disbursements) to any person or property occasioned by or arising out of the performance of any Alterations pursuant to the provisions of Section 11.1 hereof. In addition, Tenant shall carry or cause each contractor to carry the insurance required pursuant to Section 11.13 hereof.

(d) In connection with the making of any Alterations, Tenant shall (i) make all arrangements for, and shall pay all expenses incurred in connection with, use of the freight elevator(s) serving the Premises, (ii) comply with Landlord's alteration rules and regulations for the Building and (iii) pay to Landlord its actual out-of-pocket costs for reviewing Tenant's plans and specifications and to reimburse Landlord for its actual out-of-pocket costs of other services performed or other actual out-of-pocket costs reasonably incurred by Landlord in connection with such Alterations. Notwithstanding anything to the contrary contained herein or in Exhibit D attached hereto, Landlord shall waive all charges for Tenant's use of the freight elevator(s) during non-Operating Hours for the first thirty (30) hours of aggregate usage by Tenant in connection with Tenant's initial move in to the Premises or Tenant's surrender of the Premises in accordance with Section 20.4.

8.4 LIENS. Tenant shall promptly pay and discharge all costs and expenses of any work done in or on the Premises by Tenant or its subtenants, and its and their agents, employees or contractors, and shall not do or fail to do any act which shall or may render the Building or any part thereof, or the Premises or any part thereof subject to any mechanic's lien or other lien or security agreement or charge or chattel mortgage or conditional bill of sale or title retention agreement (hereinafter collectively called "Lien"), and if any Lien be filed against the Building, the Premises, any Alterations, or any portion of any of the foregoing, Tenant shall, at Tenant's own cost and expense, cause the same to be removed of record by bonding or otherwise within twenty (20) days after the filing of any such Lien; and, in default thereof, Landlord may, in addition to any other rights and remedies it may have by reason of Tenant's default, cause any such Lien to be removed of record by payment or bond or otherwise, as Landlord may elect, and Tenant shall reimburse Landlord as Additional Rent for all costs and expenses incidental to the removal of any such Lien incurred by Landlord, together with interest thereon at the Lease Interest Rate.

8.5 VIOLATIONS; DISRUPTION. Tenant, at its expense, and with diligence and dispatch, shall cause to be discharged or cancelled all notices of violation arising from any Alterations which are issued by the Department of Buildings of The City of New York or any other public or quasi-public authority having jurisdiction. Nothing contained in this Section 8.5 shall prevent Tenant from contesting, in good faith and at its own expense, any such notices of violation, provided that Tenant shall comply with the provisions of Section 9.3 hereof. In addition, Tenant shall not exercise any of its rights under this Article 8 or any other provision of this Lease, or use or occupy the Premises, in such manner as would create any work stoppage, picketing, labor disruption or dispute or a violation of any of Landlord's union contracts affecting the Land or Building, or which would unreasonably interfere with the business of Landlord or of any tenant or occupant of Building. In the event of the Tenant's failure to comply with the preceding sentence, Tenant shall, immediately upon notice from Landlord, cease all manner of exercise of such rights which give rise to such failure to comply. If Tenant shall fail to cease such manner of exercise of its rights as aforesaid, Landlord, in addition to any other rights available to it under this Lease and pursuant to law, shall have the right to seek an injunction without notice to the Tenant.

8.6 TENANT'S PROPERTY. Except as otherwise provided in this Section 8.6, all work, construction, repairs, Alterations, other improvements or installations made to or upon the Premises (including, but not limited to, the construction performed by Landlord or Tenant under Article 4 and Exhibit C), whether or not at the expense of Tenant, shall become part of the Premises and shall become the property of Landlord and remain upon and be surrendered with the Premises as a part thereof upon the Expiration Date or earlier termination of the Lease Term:

(a) Tenant's movable business equipment and movable partitions, telephone and other communications equipment, laboratory equipment, computer systems, furniture, trade fixtures, furnishings, goods, supplies, wares, merchandise and other items of personal property (excluding Lab Systems, property which is built into the Premises and custom-fitted furniture or cabinetry) and personal property of third parties in the Premises in Tenant's care, custody, use or control, including but not limited to leased or rented property, in each case paid for without any contribution to the cost thereof from Landlord, which are removable without damage to the Premises or Building (collectively, "Tenant's Property") shall remain the property of Tenant (or such third parties) and may be removed by Tenant or any person claiming under Tenant at any time or times during the Lease Term and shall be removed by Tenant at the expiration or earlier termination of the Lease Term. Tenant shall repair any damage to the Premises occasioned by the removal by Tenant or any person claiming under Tenant of any Tenant's Property from the Premises.

(b) At the Expiration Date or earlier termination of the Lease Term, unless otherwise specified in writing by Landlord, Tenant shall remove from the Premises any Specialty Alterations made to the Premises for which such removal was made a condition of such consent under Section 8.1 or Exhibit C. Upon such removal Tenant shall restore the Premises to their condition prior to installation of such Specialty Alterations and repair any damage occasioned by such removal and restoration.

(c) Any items of Tenant's Property which remain on the Premises after the Expiration Date or earlier termination of the Lease Term may, at the option of Landlord, be deemed to have been abandoned and in such case may either be retained by Landlord as its property or may be disposed of without accountability, at Tenant's expense, in such manner as Landlord may see fit.

8.7 SURVIVAL. The provisions of this Article 8 shall survive the expiration or sooner termination of this Lease.

ARTICLE 9

LAWS, ORDINANCES, REQUIREMENTS OF PUBLIC AUTHORITIES

9.1 CERTIFICATE OF OCCUPANCY. Landlord covenants and agrees that throughout the Lease Term, Landlord will not amend the certificate of occupancy issued for the Building so as to prohibit Tenant from using the Premises for the Permitted Use.

9.2 TENANT'S OBLIGATIONS. Except as otherwise set forth herein, Tenant shall, at its expense, comply with all laws and requirements of public authorities, all licenses and permits required for the proper and lawful conduct of Tenant's business in the Premises (including all applicable environmental laws) and all requirements of insurance bodies now or hereafter in effect which shall, with respect to the Premises or the occupancy, use or manner of use of the Premises or to any abatement of nuisance, impose any violation, order or duty upon Landlord or Tenant, including without limitation, any violation, order or duty arising from (i) Tenant's use of the Premises, (ii) the manner of conduct of Tenant's business in the Premises or the operation by Tenant of its installations, equipment or other property thereon, (iii) any cause or condition created by or at the instance of Tenant, (iv) the making or performance of any Alterations, installations or other work by Tenant in or on the Premises, including, without limitation, any Tenant's Work, or (v) the breach by Tenant of any of its obligations under this Lease; and Tenant shall make all repairs or Alterations required thereby, whether structural (in which event all such repairs or Alterations shall be performed by Landlord and the reasonable cost thereof shall be paid by Tenant) or nonstructural, ordinary or extraordinary; provided, however, Tenant shall only be required to make any such structural Alterations to the extent the need for the same arises as a result of (A) Tenant's particular manner of use of the Premises or the manner of conduct of Tenant's business in the Premises or the operation by Tenant of its installations, equipment or other property thereon, where such manner of use, conduct or operation shall be reasonably distinguishable from the ordinary use, conduct or operation of a business using the Premises for ordinary office purposes or (B) any of the circumstances described in clauses (iii) through (v) above. In addition to the foregoing, Tenant agrees to participate in all fire and other safety compliance procedures instituted by Landlord and/or public authorities for the Building.

9.3 TENANT'S RIGHT TO CONTEST. If Tenant receives notice of any violation of any law or requirement of public authority or requirement of insurance bodies applicable to the Premises, it shall give prompt notice thereof to Landlord. Tenant may, at its expense, contest the validity or applicability of any such law or requirement of public authority or requirement of insurance bodies by appropriate proceedings prosecuted diligently and in good faith, and may defer compliance therewith, provided that (i) no Landlord Party is thereby subjected to criminal prosecution or criminal or civil penalty of any nature, (ii) no unsafe or hazardous condition remains unremedied, (iii) the Premises, or any part thereof, shall not be subject to being condemned or vacated by reason of such non-compliance or such contest, (iv) no insurance policy carried in respect of the Property by Landlord is cancelled and no premium for any such policy is increased by reason of such non-compliance or such contest, (v) Landlord shall not be prevented from obtaining or maintaining any permits or licenses in connection with the operation of the Building or the Property or any portion thereof, nor shall the certificate of occupancy be suspended or threatened by reason of such non-compliance or such contest, (vi) such non-compliance or contest shall not constitute or result in any violation of any Underlying Lease or any mortgage on the Building or on an Underlying Lease thereof, and Tenant complies with all requirements of all such Underlying Leases or mortgages including those, if any, relating to the furnishing of security, and (vii) if Landlord so requires, Tenant furnishes to Landlord the bond of a surety company, in form and substance satisfactory to Landlord, in an amount at least equal to [***] of the cost of such compliance (as estimated by Landlord), or such other security reasonably satisfactory in all respects to Landlord. Tenant hereby agrees to indemnify and save the Landlord Parties harmless from and against any loss, liability, damage and expense arising out of any such deferral of compliance or contest, including, without limitation, attorneys' fees and disbursements and other expenses reasonably incurred by Landlord, and Tenant shall keep Landlord advised as to all settlements of such contest. Landlord agrees to execute any document reasonably required by Tenant in order to permit Tenant effectively to carry on any such contest, provided Landlord is not thereby subjected to any cost or expense or exposed to any liability or obligation on account thereof.

9.4 WINDOW CLEANING. Tenant will not clean, nor require, permit, suffer or allow any window in the Premises to be cleaned, from the outside in violation of Section 202 of the New York Labor Law or of the rules of the New York City Board of Standards and Appeals or of any other board or body having or asserting jurisdiction.

ARTICLE 10

USE

10.1 PERMITTED USE. Tenant shall use and occupy the Premises only for one or more of the following uses: (i) "turnkey" floor space outfitted in a manner consistent with wet laboratory space dedicated to life sciences research and development where chemicals, drugs, or other material or biological matter are tested and analyzed requiring water, direct ventilation, and specialized piped utilities, and including laboratory support and ancillary office space, (ii) life sciences research and development space where chemicals, drugs, or other material or biological matter are tested and analyzed requiring water, direct ventilation and specialized piped utilities, and including wet or dry laboratory space, laboratory support and ancillary office space required in connection with such research and development use or (ii) life sciences, applied science, physical science, medical technology, digital health, and bioinformatics spaces in the form of offices and/or dry laboratories (collectively, "Qualified Life Science Uses"). Subject to the other provisions of this Lease (including all exhibits) and such regulations and procedures as may from time to time be in effect, Tenant shall have access to the Premises twenty-four (24) hours per day, seven (7) days per week. In no event shall Tenant use or permit to be used any portion of the Premises for a Non-Qualified Use (as defined in the Agency Lease) during the PILOT Term.

10.2 ADDITIONAL PERMITTED USES. Tenant may, in addition to using the Premises for the purposes permitted by Section 10.1 but subject to Tenant's compliance in respect thereof with the provisions of Section 9.2, also use portions of the Premises for the installation, maintenance and operation in the Premises of (i) electronic data processing equipment, word processing equipment and business machines, (ii) duplicating equipment, (iii) one Fitness Center (subject to Section 10.8), (iv) file rooms, pantries (subject to Section 10.9), meeting, training and conference centers and rooms, and (v) a private bathroom and shower (subject to Section 10.10), in each case used for purposes incidental to the business of Tenant with electrical loads and floor loads not to exceed the respective load capacities set forth in Exhibit D.

10.3 RESTRICTIONS. Tenant shall not suffer or permit the Premises or any part thereof to be used in any manner, or anything to be done therein, or suffer or permit anything to be brought into or kept in the Premises, which would in any way (i) violate any law or requirement of public authorities or requirement of insurance bodies, (ii) cause structural injury to the Building or any part thereof, (iii) interfere with the normal operation of the HVAC, plumbing, electrical or other mechanical or electrical systems of the Building or the elevators installed therein, (iv) constitute a public or private nuisance, (v) alter the appearance of the exterior of the Building, (vi) affect in any adverse way any portion of the interior of the Building other than the Premises, (vii) unreasonably interfere with the use or occupancy of any other tenant or occupant of the Building, (viii) create any offensive odors or noise or (ix) result in the leakage of fluid or the growth of mold or the creation of any other condition which causes, or in Landlord's reasonable opinion would be likely to cause, an internal air quality problem in the Premises or the Building. Tenant shall not solicit other occupants of the Building to use wireless internet service that emanates from the Premises. Tenant shall use reasonable efforts to prevent the signals of Tenant's wireless internet service (if any) from emanating beyond the Premises or otherwise interfering in any material respect with any Building systems. Tenant shall not, nor permit any Tenant Party to, photograph, broadcast, record or otherwise make, use or transmit images of the Premises or the Building for any reason including, without limitation, for use in movies, television, the internet, newspapers, magazines or other publications or media; provided that the foregoing shall not prohibit (A) the making or use of images of the Premises or the Building by Tenant and its permitted assignees and subtenants solely in connection with advertising approved by Landlord for marketing the Premises or a portion thereof for assignment or subletting (subject to the provisions of Article 13 hereof) or (B) the photographing and transmission of images of the Premises by Tenant for advertising its own business; provided, further, that in no event shall Tenant use any such images in a manner disparaging to the Premises, the Building, Landlord or any Landlord Party.

10.4 PROHIBITED USES. Without limiting the restriction on use set forth in Section 10.1, Tenant shall not under any circumstance use or permit the use of the Premises or any part thereof for any of the following which are expressly prohibited:

(a) sale at retail of any products or materials whatsoever;

(b) the conduct of a public auction of any kind;

(c) the conduct of a commercial bank, trust company, savings bank, safe deposit or savings and loan association or any branches of any of the foregoing or a loan company business (except for the conduct of a credit union or benefit plan for Tenant's employees);

(d) the issuance and sale of traveler's checks, foreign drafts, letters of credit, foreign exchange or domestic money orders or the receipt of money for transmission;

(e) an employment agency;

(f) offices or agencies of a foreign government or political subdivisions thereof;

(g) offices of any governmental bureau or agency of the United States or any state or political subdivision thereof;

(h) offices of any charitable, religious, union or other not-for-profit or any tax exempt entity within the meaning of Section 168(j)(4)(A) of the Internal Revenue Code of 1986, as amended, or any successor statute, or rule or regulation applicable thereto (provided, however, that this Section 10.4(h) shall not prohibit use of the Premises by a not-for-profit or tax exempt entity (such as a university research group) for Qualified Life Sciences Uses);

(i) offices of any public utility company, other than corporate, executive or legal staff offices;

(j) data processing services rendered primarily to others than Tenant and which are not strictly ancillary to Tenant's business;

(k) health care professionals seeing patients on an off-the-street basis;

(l) schools or other training or educational uses (other than those which are strictly ancillary to the Tenant's business, such as training of Tenant's personnel to be employed in the Building);

(m) a clerical support business rendering clerical support services primarily to others than Tenant or performing functions other than those which are strictly ancillary to Tenant's business;

(n) reservation centers for airlines or for travel agencies;

(o) broadcasting centers for communications firms, such as radio and television stations;

(p) any pornographic or obscene purposes, any commercial sex establishment, any pornographic, obscene, nude or semi-nude performances, modeling, materials, activities or sexual conduct or any other use that has or could reasonably be expected to have a material adverse effect on Landlord's financial condition, the value of the Building or the income therefrom;

(q) a showroom;

(r) except as expressly set forth herein, gyms and exercise facilities and equipment including, without limitation, cardiovascular and weight/resistance machines, free weights, exercise and physical training rooms;

(s) any other use or purpose which, in the reasonable judgment of Landlord, is not in keeping with the character and dignity of the Building or which is prohibited under the Rules and Regulations; and

(t) any other use or purpose that, in the reasonable judgment of Landlord, is prohibited under, or inconsistent with, the Lab Rules and Regulations.

10.5 LICENSES AND PERMITS. If any governmental license or permit (other than the Building certificate of occupancy which permits general office use and the Qualified Life Sciences Uses) shall be required for the proper and lawful conduct of Tenant's business in the Premises, or any part thereof, including, specifically, but without limitation, any place of assembly permit or any amendment to the Building certificate of occupancy, Tenant, at its expense, shall duly apply for, procure and thereafter maintain such license or permit and submit the same to Landlord for inspection by Landlord. Tenant's application for and procurement of any such license, permit or amendment shall be subject to Landlord's review and approval, which shall not be unreasonably withheld or delayed. Tenant shall at all times comply with each such license and permit and shall not at any time use or occupy, or suffer or permit anyone to use or occupy, the Premises, or do or permit anything to be done in the Premises, in violation of the certificate of occupancy for the Building.

10.6 HAZARDOUS SUBSTANCES. No Tenant Party shall store, place, generate, manufacture, refine, handle, or locate on, in, under or around the Premises, the Building or Property any "Hazardous Substance" (as defined below), except for storage, handling and use of reasonable quantities and types of biologics, pharmaceuticals, cleaning fluids and office supplies in the Premises in the ordinary course and the prudent conduct of Tenant's business in the Premises. Tenant agrees that (a) the storage, handling, use and disposal of such permitted Hazardous Substances must at all times conform to all applicable laws and requirements of public authorities and to applicable fire, safety and insurance requirements; and (b) the types and quantities of permitted Hazardous Substances which are stored in the Premises must be reasonable and appropriate to the nature and size of Tenant's operation in the Premises and reasonable and appropriate for similar first-class office, laboratory and research buildings in the midtown south area of Manhattan. Tenant shall furnish to Landlord evidence reasonably acceptable to Landlord of Tenant's compliance with this Section 10.6 from time to time upon Landlord's request. Tenant shall indemnify, defend and hold harmless Landlord Parties from and against any and all claims, damages, losses, actions, causes of actions, proceedings, liens, fines, penalties, costs, expenses and liabilities arising out of any breach of any provision of this paragraph, which expenses shall also include laboratory testing fees, personal injury claims, clean-up costs and environmental consultants' fees and attorneys' fees, and such indemnity shall survive the expiration or earlier termination of this Lease. Tenant agrees that Landlord may be irreparably harmed by Tenant's breach of this paragraph and that an injunction and/or specific performance action may appropriately be brought by Landlord; provided that, Landlord's election to bring or not bring any such injunction and/or specific performance action shall in no way limit, waive, impair or hinder Landlord's other remedies against Tenant. If Hazardous Materials are present in the Premises or on any floor containing a portion of the Premises and such presence is not caused by a Landlord Party, a Tenant Party or anyone claiming by, through or under a Tenant Party, Landlord shall, at Landlord's sole cost and expense, use commercially reasonable efforts to enforce all of its rights and remedies (including, without limitation, the exercise of any self-help rights) against the party that caused such presence (provided that the foregoing shall not require Landlord to evict any Tenant or commence or prosecute any litigation). As used in this Lease, the term "Hazardous Substance" shall mean and include any chemical, material, element, compound, solution, mixture, substance or other matter of any kind whatsoever which is now or later designated, classified, listed or regulated under any law, statute, ordinance, rule, regulation, order or ruling of any agency of the State of New York, the United States Government or any local governmental authority, including, without limitation, asbestos, petroleum, petroleum hydrocarbons and petroleum based products, urea formaldehyde foam insulation, biologics and pharmaceuticals, polychlorinated biphenyls and freon and other chlorofluorocarbons. Landlord covenants that, as of the Commencement Date, the Premises shall be free of Hazardous Materials that violate applicable laws or requirements of public authorities. Landlord shall be responsible, at its sole cost and expense, to remove or remediate any Hazardous Substances found in the Premises during the Lease Term to the extent due to a breach of the foregoing covenants by Landlord or introduced into the Premises by Landlord by a Landlord Party.

10.7 OPERATIONS AND MAINTENANCE PROGRAMS. Tenant shall implement and comply with any reasonable operations and maintenance program with respect to the Premises, which program (i) shall address any asbestos-containing material, lead-based paint, mold and/or other applicable conditions that may now or in the future be detected at or on the Premises, and (ii) shall be subject to Landlord's approval. Without limiting the generality of the preceding sentence, with respect to such operations and maintenance program, Landlord may require (a) periodic notices or reports to Landlord in form, substance and at such intervals as Landlord may reasonably specify, (b) an amendment to such operations and maintenance program to address changing circumstances or laws and (c) at Tenant's sole cost and expense, supplemental examination of the Premises by consultants.

10.8 FITNESS CENTER. Any fitness center facility permitted to be operated in the Premises (the "Fitness Center") shall only be located in a location designated by Tenant and acceptable to Landlord. There shall only be one (1) Fitness Center. The Fitness Center may only be used by personnel of Tenant and any permitted subtenants and licensees ordinarily working in the Building (and with respect to employees of Tenant or a permitted subtenant subleasing all or substantially all of the Premises, visiting the Premises from another location and short-term invitees of Tenant; provided, however, in no event shall the Fitness Center be held open for use by the general public. Tenant specifically agrees to perform or have performed on its behalf and its own expense all prudent and necessary analysis and work to ensure that the Fitness Center (including, without limitation, any and all weight machines, treadmills and other equipment) is designed and constructed (1) such that the use, operation and maintenance thereof does not result in any noise that can be heard outside the Premises or any vibrations that can be felt outside the Premises, (2) to be properly integrated into and not have any adverse impact upon the structure of the Building and its harmonics, and (3) not to have any adverse impact upon any area of the Building outside the Premises, including, without limitation, the Lab Areas, common areas or facilities, space demised to any other tenant or occupant and space controlled by Landlord. Notwithstanding Tenant's compliance with the foregoing and with the other provisions of this Lease, Landlord shall have the right, if Landlord has received a complaint by any other tenant or occupant of the Building of interference or material adverse impact caused by such exercise facilities and Landlord reasonably believes such complaint arises from a condition violative of the immediately preceding sentence, to require Tenant to immediately discontinue use of the Fitness Center upon notice from Landlord, and Tenant shall discontinue such use, until such time as Tenant rectifies the cause of and eliminates such interference or material adverse impact to the reasonable satisfaction of Landlord.

10.9 PANTRIES. Incidental to the primary use of the Premises for executive, administrative and general offices as provided in this Article 10, subject to the provisions of this Lease (including the provisions of Article 8), applicable laws and requirements of public authorities, the Rules and Regulations or the Lab Rules and Regulations, one or more portions of the Premises may be used as pantries and/or warming kitchens, which may contain reheating (but not cooking) equipment, such as microwaves, coffee makers, sinks, ice makers, soda machines, vending machines, tables and chairs, dishwashers, hot water heaters and refrigerators; provided that: (i) no cooking of food (other than the reheating of food by microwave or warming ovens that do not require venting) shall be done in any such pantry, (ii) no food or beverages will be kept or served in the Premises in a manner or under any conditions which result in fumes or odors being emitted from, or detectable outside of, the Premises such that same may unreasonably affect other tenants or occupants of the Building, and (iii) such portion or portions of the Premises shall be at all times maintained by Tenant in a clean and sanitary condition and free of refuse, insects and rodents (including required use of extermination services).

10.10 WET INSTALLATIONS. Ancillary to the use of the Premises for executive, administrative and general office use pursuant to Section 10.1 hereof, Tenant may install, or cause to be installed, one (1) private bathroom and one (1) shower (collectively, the "Wet Installations"), at its sole cost and expense; provided, however, that (i) Tenant install, or cause to be installed, in connection therewith a membrane waterproofing system throughout all areas of the Premises containing such Wet Installations, which shall be maintained by Tenant throughout the Term in good working order, (ii) Tenant shall be solely responsible at its expense throughout the Term for (1) preserving the watertight integrity of the Wet Installations and (2) all leaks from the Wet Installations to all areas of the Building beneath the Premises and any damage caused thereby, (iii) Tenant shall promptly cease the use of any Wet Installation in the event of any water leaks occurring from such the Wet Installation, and shall promptly inform Landlord of the same and diligently perform, at Tenant's sole cost and expense, any work or alteration reasonably requested by Landlord to remedy such problem and (iv) the indemnity in Section 11.1 shall apply with respect to any and all claims arising out of any such leak.

ARTICLE 11

TENANT'S INDEMNITY AND INSURANCE

11.1 TENANT'S INDEMNITY.

(a) Indemnity. To the fullest extent permitted by law, Tenant waives any right to contribution against the Landlord Parties (as hereinafter defined) and agrees to indemnify and save harmless the Landlord Parties from and against all claims of whatever nature arising from or claimed to have arisen from (i) any act, omission or negligence of the Tenant Parties (as hereinafter defined); (ii) any accident, injury or damage whatsoever caused to any person, or to the property of any person, occurring in or about the Premises from the earlier of (A) the date on which any Tenant Party first enters the Premises for any reason or (B) the Commencement Date, and thereafter throughout and until the end of the Lease Term and after the end of the Lease Term for as long after the Lease Term as any of Tenant's Property remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of any part of, or have access to the Premises or any portion thereof; (iii) any accident, injury or damage whatsoever occurring outside the Premises but within the Building, or on common areas or the Property, where such accident, injury or damage results, or is claimed to have resulted, from any act, omission or negligence on the part of any of the Tenant Parties; or (iv) any breach of this Lease by Tenant; except, in each case, to the extent that any such claim results from the gross negligence or willful misconduct of Landlord or any other Landlord Party. Tenant shall pay such indemnified amounts as they are incurred by the Landlord Parties. This indemnification shall not be construed to deny or reduce any other rights or obligations of indemnity that a Landlord Parties may have under this Lease or the common law. Notwithstanding anything to the contrary herein, in no event shall Tenant be liable for any loss of business or any other consequential, special or punitive damages under this Section 11.1(a) unless a Landlord Party shall be required to pay the same to a third party.

(b) Breach. In the event that Tenant breaches any of its indemnity obligations hereunder or under any other contractual or common law indemnity: (i) Tenant shall pay to the Landlord Parties all liabilities, losses, costs and expenses (including attorney's fees) incurred as a result of said breach; and (ii) the Landlord Parties may deduct and offset from any amounts due to Tenant under this Lease any amounts owed by Tenant pursuant to this Section.

(c) No limitation. The indemnification obligations under this Section shall not be limited in any way by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant or any subtenant or other occupant of the Premises under workers' compensation acts, disability benefit acts, or other employee benefit acts. Tenant waives any immunity from or limitation on its indemnity or contribution liability to the Landlord Parties based upon such acts.

(d) Subtenants and other occupants. Tenant shall require its subtenants and other occupants of the Premises to provide similar indemnities to the Landlord Parties in a form acceptable to Landlord.

(e) Survival. The terms of this Section shall survive any termination or expiration of this Lease.

(f) Costs. The foregoing indemnity and hold harmless agreement shall include indemnity for all costs, expenses and liabilities (including, without limitation, attorneys' fees and disbursements) incurred by the Landlord Parties in connection with any such claim or any action or proceeding brought thereon, and the defense thereof. In addition, in the event that any action or proceeding shall be brought against one or more Landlord Parties by reason of any such claim, Tenant, upon request from the Landlord Party, shall resist and defend such action or proceeding on behalf of the Landlord Party by counsel appointed by Tenant's insurer (if such claim is covered by insurance without reservation) or otherwise by counsel reasonably satisfactory to the Landlord Party. The Landlord Parties shall not be bound by any compromise or settlement of any such claim, action or proceeding without the prior written consent of such Landlord Parties.

(g) Landlord Parties and Tenant Parties. The term "Landlord Party" or "Landlord Parties" shall mean Landlord, any affiliate of Landlord, Landlord's managing agents and leasing agents for the Building, Landlord's asset manager for the Building, each Overlandlord, each Mortgagee, and each of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents or representatives. For the purposes of this Lease, the term "Tenant Party" or "Tenant Parties" shall mean Tenant, any affiliate of Tenant, any permitted subtenant or any other permitted occupant of the Premises, and each of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents, invitees or representatives.

11.2 TENANT'S RISK. Tenant agrees to use and occupy the Premises, and to use such other portions of the Building and the Property as Tenant is given the right to use by this Lease at Tenant's own risk, subject to Landlord's obligations under this Lease. Except to the extent arising out of the gross negligence or willful misconduct of Landlord or any other Landlord Party, the Landlord Parties shall not be liable to the Tenant Parties for any damage, injury, loss, compensation, or claim (including, but not limited to, claims for the interruption of or loss to a Tenant Party's business) based on, arising out of or resulting from any cause whatsoever, including, but not limited to, repairs to any portion of the Premises or the Building or the Property, any fire, robbery, theft, mysterious disappearance, or any other crime or casualty, the actions of any other tenants of the Building or of any other person or persons, or any leakage in any part or portion of the Premises or the Building or the Property, or from water, rain or snow that may leak into, or flow from any part of the Premises or the Building or the Property, or from drains, pipes or plumbing fixtures in the Building or the Property, or from any electrical failure in the Building or the Property. Any goods, property or personal effects stored or placed in or about the Premises shall be at the sole risk of the Tenant Party, and neither the Landlord Parties nor their insurers shall in any manner be held responsible therefor. The Landlord Parties shall not be responsible or liable to a Tenant Party, or to those claiming by, through or under a Tenant Party, for any loss or damage that may be occasioned by or through the acts or omissions of persons occupying adjoining premises or any part of the premises adjacent to or connecting with the Premises or any part of the Building or otherwise. The provisions of this Section shall be applicable to the fullest extent permitted by law, and until the expiration or earlier termination of the Lease Term, and during such further period as any of Tenant's Property remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of any part of, or have access to the Premises or of the Building. None of the foregoing shall be deemed to excuse Landlord from its maintenance, repair, restoration or other obligations under this Lease.

11.3 TENANT'S COMMERCIAL GENERAL LIABILITY INSURANCE. Tenant agrees to maintain in full force on or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Commencement Date and thereafter throughout and until the end of the Lease Term of this Lease and after the end of the Lease Term for as long after the Lease Term as any of Tenant's Property remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of any part of, or have access to the Premises or any portion thereof, a policy of commercial general liability insurance, on an occurrence basis, issued on a form at least as broad as Insurance Services Office ("ISO") Commercial General Liability Coverage "occurrence" form CG 00 01 10 01 or another ISO Commercial General Liability "occurrence" form providing equivalent coverage. Such insurance shall include contractual liability coverage, specifically covering but not limited to the indemnification obligations undertaken by Tenant in this Lease. The minimum limit of liability of such insurance shall be $[***] per occurrence, which may be satisfied through a combination of primary and excess/umbrella insurance. In addition, in the event Tenant hosts a function in the Premises, Tenant agrees to obtain, and cause any persons or parties providing services for such function to obtain, the appropriate insurance coverages as determined by Landlord (including liquor liability coverage, if applicable) and provide Landlord with evidence of the same.

11.4 TENANT'S PROPERTY INSURANCE. Tenant shall maintain at all times during the Term of the Lease, and during such earlier or later time as Tenant may be performing work in or to the Premises or have property, fixtures, furniture, equipment, machinery, goods, supplies, wares or merchandise on the Premises, and continuing thereafter so long as any of Tenant's Property remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of or have access to, any part of the Premises, business interruption insurance and insurance against loss or damage covered by the so-called "all risk" type insurance coverage with respect to Tenant's Property and all Leasehold Improvements in the Premises (subject to a deductible not to exceed [***]). The business interruption insurance required by this Section shall be in minimum amounts typically carried by prudent tenants engaged in similar operations, but in no event shall be in an amount less than the Annual Fixed Rent then in effect during any Lease Year, plus any Additional Rent due and payable for the immediately preceding Lease Year. The "all risk" insurance required by this Section shall be in the amount of the full replacement cost of Tenant's Property and all Leasehold Improvements in the Premises, and other property of Tenant located at the Premises. In addition, during such time as Tenant is performing any Alterations in or to the Premises, Tenant, at Tenant's expense, shall also maintain, or shall cause its contractor(s) to maintain, builder's risk insurance for the full insurable value of such Alterations. Landlord and such additional persons or entities as Landlord may reasonably request shall be named as loss payees, as their interests may appear, on the policy or policies required by this Section. In the event of loss or damage covered by the "all risk" insurance required by this Section, the responsibilities for repairing or restoring the loss or damage shall be determined in accordance with Section 12.2. To the extent that Landlord is obligated to pay for the repair or restoration of the loss or damage covered by the policy, Landlord shall be paid the proceeds of the "all risk" insurance covering the loss or damage. To the extent Tenant is obligated to pay for the repair or restoration of the loss or damage, covered by the policy, Tenant shall be paid the proceeds of the "all risk" insurance covering the loss or damage. If both Landlord and Tenant are obligated to pay for the repair or restoration of the loss or damage covered by the policy, the insurance proceeds shall be paid to each of them in the pro rata proportion of their obligations to repair or restore the loss or damage. If the loss or damage is not repaired or restored (for example, if the Lease is terminated pursuant to Article 12), the insurance proceeds shall be paid to Landlord and Tenant in the pro rata proportion of their relative contributions to the cost of the Leasehold Improvements covered by the policy, and this provision shall survive the expiration or earlier termination of this Lease.

11.5 TENANT'S OTHER INSURANCE. Tenant agrees to maintain in full force on or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Commencement Date and thereafter throughout and until the end of the Lease Term of this Lease and after the end of the Lease Term for as long after the Lease Term as any of Tenant's Property remains on the Premises or as Tenant or anyone acting by, through or under Tenant may use, be in occupancy of, or have access to the Premises or any portion thereof, (1) intentionally omitted; (2) worker's compensation insurance; and (3) employer's liability insurance. Such worker's compensation insurance shall carry minimum limits as defined by the law of the jurisdiction in which the Premises are located (as the same may be amended from time to time). Such employer's liability insurance shall be in an amount not less than [***] for each accident, [***] disease-policy limit, and [***] disease-each employee.

11.6 REQUIREMENTS FOR INSURANCE. All insurance required to be maintained by Tenant pursuant to this Lease shall be maintained with responsible companies that are admitted to do business, and are in good standing, in the jurisdiction in which the Premises are located and that have a rating of at least "A-" and are within a financial size category of not less than "Class VIII" in the most current Best's Key Rating Guide or such similar rating as may be reasonably selected by Landlord. All such insurance shall: (1) [intentionally omitted]; (2) be primary and noncontributory (including all primary and excess/umbrella policies); and (3) provided that Tenant's insurer then regularly provides the same to landlords of tenants, contain an endorsement prohibiting cancellation, failure to renew, reduction of amount of insurance, or change in coverage without the insurer first giving Landlord thirty (30) days' prior written notice (by certified or registered mail, return receipt requested, or by fax or email) of such proposed action. No such policy shall contain any self-insured retention greater than $[***] for property insurance and $[***] for commercial general liability insurance. Any deductibles and such self-insured retentions shall be deemed to be "insurance" for purposes of the waiver in Section 11.12 below. Landlord reserves the right from time to time to require Tenant to obtain higher minimum amounts of insurance based on such limits as are customarily carried with respect to similar properties in the area in which the Premises are located. The minimum amounts of insurance required by this Lease shall not be reduced by the payment of claims or for any other reason. In the event Tenant shall fail to obtain or maintain any insurance meeting the requirements of this Article, or to deliver such policies or certificates as required by this Article, Landlord may, at its option, on five (5) days' notice to Tenant, procure such policies for the account of Tenant, and the cost thereof shall be paid to Landlord within five (5) days after delivery to Tenant of bills therefor.

11.7 ADDITIONAL INSUREDS. To the fullest extent permitted by law, the commercial general liability and auto insurance carried by Tenant pursuant to this Lease, and any additional liability insurance carried by Tenant pursuant to Section 11.5 of this Lease or any other provision of this Lease, shall name Landlord, Landlord's managing agent, each Mortgagee and Overlandlord and such other persons as Landlord may reasonably request from time to time as additional insureds with respect to liability arising out of or related to this Lease or the operations of Tenant (collectively "Additional Insureds"). Such insurance shall provide primary coverage without contribution from any other insurance carried by or for the benefit of Landlord or the Additional Insureds. Such insurance shall also waive any right of subrogation against each Additional Insured. For the avoidance of doubt, each primary policy and each excess/umbrella policy through which Tenant satisfies its obligations under this Section must provide coverage to the Additional Insureds that is primary and non-contributory.

11.8 CERTIFICATES OF INSURANCE. On or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Commencement Date, Tenant shall furnish Landlord with certificates evidencing the insurance coverage required by this Lease, and renewal certificates shall be furnished to Landlord at least annually thereafter, and at least ten (10) Operating Days prior to the expiration date of each policy for which a certificate was furnished. (Acceptable forms of such certificates for liability and property insurance are ACORD 25 and ACORD 27, respectively, as of the date hereof, however other forms of certificates may satisfy the requirements of this Section.) In jurisdictions requiring mandatory participation in a monopolistic state workers' compensation fund, the insurance certificate requirements for the coverage required for workers' compensation will be satisfied by a letter from the appropriate state agency confirming participation in accordance with statutory requirements. Such current participation letters required by this Section shall be provided every six (6) months for the duration of this Lease. Failure by the Tenant to provide the certificates or letters required by this Section shall not be deemed to be a waiver of the requirements in this Section. Upon request by Landlord, a true and complete copy of any insurance policy required by this Lease shall be delivered to Landlord within ten (10) days following Landlord's request.

11.9 SUBTENANTS AND OTHER OCCUPANTS. Tenant shall require its subtenants and other occupants of the Premises to provide written documentation evidencing the obligation of such subtenant or other occupant to indemnify the Landlord Parties to the same extent that Tenant is required to indemnify the Landlord Parties pursuant to Section 11.1 above, and to maintain insurance that meets the requirements of this Article, and otherwise to comply with the requirements of this Article, provided that the terms of this Section 11.9 shall not relieve Tenant of any of its obligations to comply with the requirements of this Article. Tenant shall require all such subtenants and occupants to supply certificates of insurance evidencing that the insurance requirements of this Article have been met and shall forward such certificates to Landlord on or before the earlier of (i) the date on which the subtenant or other occupant or any of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents, invitees or representatives first enters the Premises or (ii) the commencement of the sublease. Tenant shall be responsible for identifying and remedying any deficiencies in such certificates or policy provisions.

11.10 NO VIOLATION OF BUILDING POLICIES. Tenant shall not commit or permit any violation of the policies of fire, boiler, sprinkler, water damage or other insurance covering the Property and/or the fixtures, equipment and property therein carried by Landlord, or do or permit anything to be done, or keep or permit anything to be kept, in the Premises, which in case of any of the foregoing (i) would result in termination of any such policies, (ii) would adversely affect Landlord's right of recovery under any of such policies, or (iii) would result in reputable and independent insurance companies refusing to insure the Property or the property of Landlord in amounts reasonably satisfactory to Landlord.

11.11 TENANT TO PAY PREMIUM INCREASES. If, because of anything done, caused or permitted to be done, or omitted by Tenant (or its subtenant or other occupants of the Premises) not in keeping with the primary use of the Premises for general, executive and administrative offices, the rates for liability, fire, boiler, sprinkler, water damage or other insurance on the Property or on the property and equipment of Landlord or any other tenant or subtenant in the Building shall be higher than they otherwise would be, Tenant shall reimburse Landlord and/or the other tenants and subtenants in the Building for the additional insurance premiums thereafter paid by Landlord or by any of the other tenants and subtenants in the Building which shall have been charged because of the aforesaid reasons, such reimbursement to be made from time to time on Landlord's demand.

11.12 WAIVER OF SUBROGATION. To the fullest extent permitted by law, the parties hereto waive and release any and all rights of recovery against the other, and agree not to seek to recover from the other or to make any claim against the other, and in the case of Landlord, against all Tenant Parties, and in the case of Tenant, against all Landlord Parties, for any loss or damage incurred by the waiving/releasing party to the extent such loss or damage is insured under any insurance policy required by this Lease or which would have been so insured had the party carried the insurance it was required to carry hereunder. Tenant shall obtain from its subtenants and other occupants of the Premises a similar waiver and release of claims against any or all of the Tenant Parties and the Landlord Parties. In addition, the parties hereto (and in the case of Tenant, its subtenants and other occupants of the Premises) shall procure an appropriate clause in, or endorsement on, any insurance policy required by this Lease pursuant to which the insurance company waives subrogation. The insurance policies required by this Lease shall contain no provision that would invalidate or restrict the parties' waiver and release of the rights of recovery in this section. The parties hereto covenant that no insurer shall hold any right of subrogation against the parties hereto by virtue of such insurance policy.

11.13 ALTERATIONS. During such times as Tenant is performing Alterations or having work or services performed in or to the Premises, Tenant shall require its contractors, and their subcontractors of all tiers, to obtain and maintain commercial general liability, workers compensation, employer's liability, builder's risk, and equipment/property insurance in such amounts and on such terms as are customarily required of such contractors and subcontractors on similar projects. The amounts and terms of all such insurance are subject to Landlord's written approval, which approval shall not be unreasonably withheld. The commercial general liability carried by Tenant's contractors and their subcontractors of all tiers pursuant to this section shall name Landlord and the Additional Insureds as additional insureds with respect to liability arising out of or related to their work or services. Such insurance shall provide primary coverage without contribution from any other insurance carried by or for the benefit of Landlord or the Additional Insureds. Such insurance shall also waive any right of subrogation against each Additional Insured. Tenant shall obtain and submit to Landlord, prior to the earlier of (i) the entry onto the Premises by such contractors or subcontractors or (ii) commencement of the work or services, certificates of insurance evidencing compliance with the requirements of this Section.

11.14 LANDLORD INDEMNITY. Subject to Section 11.12 hereof, to the maximum extent permitted by law, Landlord shall indemnify, defend and hold harmless the Tenant Parties from and against any and all Claims against any of such parties arising from (i) the performance by Landlord or any of its employees, agents or contractors of any alterations, improvements, repairs or other work in the Building or the Premises and (ii) any negligent or otherwise wrongful act or omission of Landlord or any of its employees, agents or contractors whether resulting in injury or death to persons or damage to property or otherwise, except, in each case, to the extent that any such Claim results from the negligence or otherwise wrongful act or omission of any Tenant Party. Notwithstanding anything to the contrary contained herein, in no event shall Landlord be liable for any loss of business or other consequential or punitive damages under this Lease. The foregoing indemnity and hold harmless agreement shall include all reasonable out-of-pocket costs, expenses and liabilities (including, without limitation, reasonable attorneys' fees and disbursements) actually incurred by the Tenant Parties in connection with any such Claim or any action or proceeding brought thereon, and the defense thereof. In case any action or proceeding shall be brought against the Tenant Parties by reason of any such Claim, Tenant shall notify Landlord of any such action or proceeding and Landlord, upon notice from Tenant, shall resist and defend such action or proceeding on behalf of the applicable Tenant Parties by counsel for the insurer (if such Claim is covered by insurance) or otherwise by counsel reasonably satisfactory to Tenant. In no event shall Landlord be obligated' to indemnify or save harmless the Tenant Parties from or in respect of any Claim to the extent the same results from the negligence or otherwise wrongful act or omission of the Tenant Parties.

ARTICLE 12

FIRE, CASUALTY OR TAKING

12.1 RIGHT TO TERMINATE LEASE. Tenant shall give immediate notice to Landlord in case of fire or other casualty in the Premises. If (a) so much of the Building is damaged or rendered untenantable (whether or not the Premises or a portion thereof shall be damaged) by fire or other cause that Landlord shall determine not to restore the same or to demolish the remainder thereof; or (b) if the Premises shall suffer damage or be rendered untenantable by fire or other casualty and Landlord shall determine (i) that such portion of the Premises cannot be reasonably expected to be restored or rendered tenantable under a normal working schedule within a period of eighteen (18) months after the occurrence of such damage or destruction or (ii) that each Overlandlord and Mortgagee will not permit Landlord to apply the net proceeds of Landlord's insurance to the restoration of the Building or the Premises, then and in any such event Landlord shall have the right to terminate this Lease by notice to Tenant given within ninety (90) days of the occurrence of such fire or other casualty. If either (y) the Premises shall be totally or substantially damaged or rendered wholly or substantially untenantable (whether or not any other portions of the Building shall be damaged) or (z) the Building shall be substantially damaged, so that Tenant's access to and use and enjoyment of the Premises shall be rendered substantially impossible, whether or not the Premises shall be damaged, and in case of either (y) or (z) Landlord determines that the same cannot reasonably be expected to be restored or rendered tenantable under a normal working schedule within a period of eighteen (18) months after the occurrence of such damage or destruction, then Landlord shall promptly notify Tenant of such fact, and within thirty (30) days thereafter either Landlord or Tenant may terminate this Lease by notice to the other party. If during the last year of the Lease Term the Building or the Premises shall be damaged by fire or casualty, and if such fire or casualty damage, whether to the Premises or the Building, cannot reasonably be expected to be repaired or restored within one hundred eighty (180) days from the time that repair or restoration work would commence or prior to the Expiration Date, whichever first occurs, then Landlord or Tenant shall have the right, by giving notice to the other not later than thirty (30) days after the occurrence of such damage, to terminate this Lease. If either Landlord or Tenant shall give notice of termination pursuant to this Section, the Lease Term shall expire by lapse of time upon the date which is thirty (30) days after such notice is given and Tenant shall vacate the Premises and surrender the same to Landlord. Upon the termination of this Lease under the conditions provided for in this Section, Tenant's liability for rent shall cease as of the date of such termination, subject, however, to abatement thereof between the date of such casualty and the date of such termination pursuant to Section 12.3 below. Tenant hereby expressly waives the provisions of Section 227 of the Real Property Law or any like law which may hereafter be enacted and agrees that the foregoing provisions of this Article shall govern and control in lieu thereof, this Article being an express agreement governing any case of damage or destruction of the Premises by fire or other casualty.

12.2 RESTORATION OF THE PREMISES. If the Building or any portion thereof is damaged by fire or other casualty and this Lease is not terminated pursuant to Section 12.1, then (a) Landlord, promptly after such damage and the determination of the net amount of insurance proceeds available, shall use due diligence to repair and restore the Premises (other than the Leasehold Improvements and Tenant's Property) and the Building as nearly as possible to their condition prior to such fire or other casualty, and (b) Tenant, promptly after the substantial completion of Landlord's restoration work, shall use due diligence to repair and restore the Leasehold Improvements and Tenant's Property as nearly as possible to their condition prior to such fire or other casualty. Notwithstanding the foregoing, Landlord shall not be obligated to expend for such repairs and restoration any amount in excess of the net insurance proceeds made available to Landlord after deduction therefrom of Landlord's expenses in obtaining such proceeds and any amounts applied by any Overlandlord or Mortgagee to obligations other than restoration of the Building. If Landlord is not obligated to and elects not to complete such restoration pursuant to the previous sentence, Landlord shall promptly notify Tenant of such fact, and within thirty (30) days thereafter, Tenant may terminate this Lease by notice to Landlord and the Lease shall terminate as of a date specified by Tenant in such notice to Landlord, which date shall not be earlier than thirty (30) and not later than ninety (90) days after the date of Tenant's notice, with the same force and effect as if such date were the date originally established as the Expiration Date hereof. In no event shall Landlord be obligated to repair or restore the Leasehold Improvements or Tenant's Property.

Where Landlord is obligated or otherwise elects to effect the repair and restoration of the Premises (other than the Leasehold Improvements and Tenant's Property), unless such repair and restoration is completed within eighteen (18) months from the date of the casualty, Tenant shall have the right to terminate this Lease at any time after the expiration of such 18-month period but prior to the time that the repair and restoration is substantially completed, such termination to take effect as of the thirtieth (30^{th}) day after such notice is given, with the same force and effect as if such date were the date originally established as the Expiration Date hereof unless, within such thirty (30) day period such restoration is substantially completed, in which case Tenant's notice of termination shall be of no force and effect and this Lease and the Lease Term shall continue in full force and effect.

12.3 PAYMENT OF RENT FOLLOWING CASUALTY. Until this Lease is terminated pursuant to Section 12.1 or, if this Lease is not so terminated, until Landlord notifies Tenant that Landlord's repair and restoration work has been substantially completed pursuant to Section 12.2, the Annual Fixed Rent, Tenant's Tax Payment and Tenant's Share of Operating Expenses shall be abated on a pro rata basis according to the part of the Premises that is usable by Tenant. No damages, compensation or claims shall be payable by Landlord for inconvenience, loss of business or annoyance arising from any repair or restoration of any portion of the Premises or of the Building. If rent abates in respect of all or any portion of the Premises and Tenant reoccupies the Premises or such portion thereof, or any part thereof, for the conduct of Tenant's business operations during the period in which Landlord's restoration work is taking place and prior to the date that the same is made completely tenantable, the Annual Fixed Rent, Tenant's Tax Payment and Tenant's Share of Operating Expenses allocable to the space so reoccupied shall be payable from the date of such reoccupancy. Notwithstanding anything in this Section to the contrary, if Landlord shall be unable to collect all of the insurance proceeds (including rent insurance proceeds) payable by reason of any damage to the Building or the Premises under Landlord's insurance policies by reason of the failure by Tenant to comply with any of the provisions of this Lease (including, without limitation, Sections 9.2 and 11.10 hereof) or Tenant's negligence or willful misconduct, then without prejudice to any other remedy which may be available against Tenant, the abatement of rent provided for in this Section 12.3 shall not be effective to the extent of the uncollected insurance proceeds, and the amount of any abatement theretofore taken by Tenant shall be immediately payable to Landlord on demand.

12.4 UNINSURED CASUALTY. Notwithstanding anything to the contrary contained in this Lease, if the Building or the Premises shall be substantially damaged by fire or casualty as the result of a risk not covered by the forms of casualty insurance at the time maintained by Landlord and such fire or casualty damage cannot, in the ordinary course, reasonably be expected to be repaired within thirty (30) days from the time that repair work would commence, either Landlord or Tenant may terminate the Lease Term by giving notice to the other not later than thirty (30) days after the occurrence of such damage, to terminate this Lease. If Tenant shall give notice of termination pursuant to this Section, the Lease Term shall expire by lapse of time upon the date which is thirty (30) days after such notice is given and Tenant shall vacate the Premises and surrender the same to Landlord. If Landlord shall give such notice, then this Lease shall terminate as of the date of such notice with the same force and effect as if such date were the date originally established as the Expiration Date hereof. Upon the termination of this Lease under the conditions provided for in this Section, Tenant's liability for rent shall cease as of the date of such termination, subject, however, to abatement thereof between the date of such casualty and the date of such termination pursuant to Section 12.3 below. Tenant hereby expressly waives the provisions of Section 227 of the Real Property Law or any like law which may hereafter be enacted and agrees that the foregoing provisions of this Article shall govern and control in lieu thereof, this Article being an express agreement governing any case of damage or destruction of the Premises by fire or other casualty.

12.5 LANDLORD NOT TO INSURE LEASEHOLD IMPROVEMENTS OR TENANT'S PROPERTY. Landlord is not required to carry insurance of any kind on the Leasehold Improvements or Tenant's Property or any telephone, computer or communications systems, cabinet work or special decorative effects and shall not be obligated to repair any damage thereto or to replace the same.

12.6 EMINENT DOMAIN – COMPLETE OR SUBSTANTIAL TAKING. If all or substantially all of the Building or of the Premises shall be taken by condemnation or in any other manner for any public or quasi-public use or purpose (other than for temporary use or occupancy), the Lease Term shall forthwith cease and terminate as of the date of vesting of title by reason of such taking (which date is hereinafter referred to as the "date of the taking"), and the rent shall be apportioned as of such date. If such portion of the Building shall be so taken so that substantial structural alterations or reconstruction of the Building shall be necessary as a result of such taking (whether or not the Premises be affected), which alterations or reconstruction Landlord determines will take at least 180 days to complete, Landlord may, at its option, terminate this Lease and the Lease Term and estate hereby granted as of the date of such vesting of title by notifying Tenant in writing of such termination within sixty (60) days following the date of the taking.

12.7 EMINENT DOMAIN – PARTIAL TAKING. If any part, but less than all or substantially all, of the Premises shall be so taken and this Lease shall not be terminated pursuant to Section 12.6, then the part so taken shall no longer constitute part of the Premises but this Lease shall otherwise remain unaffected by such taking; provided, however, that Tenant may elect to terminate the Lease Term in the event of:

(i) a taking of more than twenty-five percent (25%) of the total rentable area of the Premises, or

(ii) a taking that has a material adverse effect on Tenant's access to the Building or the Premises, if Landlord determines that it will be unable to provide or in fact fails to provide adequate alternative access to the Premises within one hundred eighty (180) days thereafter,

by giving notice of such election to Landlord not later than sixty (60) days after Tenant's receipt from Landlord of notice of such taking or the date of such taking, whichever first occurs, or not later than thirty (30) days after such one hundred eightieth (180^{th}) day, as the case may be. If notice of termination of this Lease shall be given pursuant to this Section, then upon such date as may be specified by Tenant by notice to Landlord, which date shall be not earlier than thirty (30) and not later than sixty (60) days after the date of Tenant's notice, the Lease Term shall terminate as of the date specified in such notice and the rent shall be apportioned as of such date of termination. Upon a partial taking and this Lease continuing in force as to any part of the Premises,

(a) the Annual Fixed Rent, Tenant's Tax Payment and Tenant's Share of Operating Expenses shall be appropriately reduced to reflect the part that no longer constitutes part of the Premises for the remainder of the Lease Term; and

(b) Landlord shall, at its expense, restore with reasonable diligence the remaining portions of the Premises as nearly as practicable to the same condition as it was in prior to such condemnation or taking; provided, however, that Landlord shall not be obligated to expend for such restoration and for restoration of the remainder of the Building any amount in excess of the net condemnation proceeds actually received by Landlord. Tenant, promptly after the substantial completion of Landlord's restoration work, shall use due diligence to repair and restore the Leasehold Improvements and Tenant's Property as nearly as possible to their condition prior to such fire or other casualty. Proceeds of any award applied by the holder of any mortgage to reduction of the indebtedness secured thereby or retained by any Overlandlord as compensation for the taking shall not be deemed to have been received by Landlord.

12.8 LANDLORD TO RECEIVE ENTIRE AWARD. In the event of any condemnation or taking hereinabove mentioned of all or a part of the Building (whether or not the Premises be affected) Landlord shall be entitled to receive the entire award in the condemnation proceeding, including any award made for the value of the estate vested by this Lease in Tenant, and Tenant hereby expressly assigns to Landlord any and all right, title and interest of Tenant now or hereafter arising in or to any such award or any part thereof, and Tenant shall be entitled to receive no part of such award. The foregoing, however, shall not be deemed to preclude Tenant from recovering a separate award for Tenant's moving expenses and Tenant's Property, but only provided that such award does not reduce and is not payable out of the amount for the Land and the Building.

ARTICLE 13

ASSIGNMENT, SUBLETTING, MORTGAGING

13.1 LANDLORD'S CONSENT REQUIRED.

(a) Except as specifically permitted by this Article, Tenant shall not, by operation of law or otherwise, assign, mortgage or encumber this Lease, or sublet or permit the Premises or any part thereof to be used by others. If and so long as Tenant is a corporation with fewer than five hundred (500) shareholders or a limited liability company or a partnership, an assignment, within the meaning of this Article 13, shall be deemed to include one or more sales or transfers of stock or membership or partnership interests, by operation of law or otherwise, or the issuance of new stock or membership or partnership interests, by which an aggregate of more than fifty percent (50%) of Tenant's stock or membership or partnership interests shall be vested in a party or parties who are not stockholders or members or partners as of the date hereof (a "Change in Control"); provided, however, the transfer of the outstanding capital stock of Tenant for purposes of this Section 13.1 shall not be deemed to include the sale of such stock by persons or parties through the "over-the-counter market" or through any recognized stock exchange, other than by those deemed to be a "control person"' within the meaning of the Securities Exchange Act of 1934, as amended. For the purpose of this Section 13.1, ownership of stock or membership or partnership interests shall be determined in accordance with the principles set forth in Section 544 of the Internal Revenue Code of 1986, as amended from time to time, or the corresponding provisions of any subsequent law. In addition, the merger or consolidation of Tenant into or with any other entity, or the sale of all or substantially all of its assets, shall be deemed to be an assignment within the meaning of this Article 13. The limitations set forth in this Section 13.1(a) shall be deemed to apply to subtenant(s), assignee(s) and guarantor(s) of this Lease.

(b) Anything in the foregoing Section 13.1(a) to the contrary notwithstanding, an assignment of this Lease or a subletting of the Premises to an entity which controls or is controlled by Tenant or is under common control with Tenant (an "Affiliate") which does not result in a physical demise of separate space, shall not require Landlord's consent under this Article 13; provided that: (i) a copy of any applicable instrument of assignment or sublease shall have been delivered to Landlord at least ten (10) days prior to the effective date of any such transaction, (ii) in case of an assignment the successor to Tenant agrees directly with Landlord, by written instrument in form reasonably satisfactory to Landlord, to be bound by all the obligations of Tenant hereunder, (iii) in no event shall Tenant be released from its obligations under this Lease, (iv) any such transfer or transaction is for a legitimate, regular business purpose of Tenant including, without limitation, for the purposes of transferring Tenant's interest in this Lease to a special purpose entity (as long as Tenant remains obligated under this Lease), (v) the Affiliate of Tenant shall be of good reputation and engaged in a business or activity which is in keeping with the standards of the Building and (vi) the provisions of Section 13.5(b), (c), (h), (i), (k), (l), (m) and (n) and Section 13.7 hereof shall be satisfied. If any Affiliate to whom Tenant shall have assigned this Lease or sublet all or any portion of the Premises shall thereafter cease to be an Affiliate of Tenant, then the continuation of such entity's tenancy or occupancy shall be subject to Landlord's consent pursuant to this Article 13. For the avoidance of doubt, the terms and conditions of Section 13.3, 13.4 and 13.10 shall not apply to an assignment of this Lease or a subletting of the Premises permitted without Landlord's consent under this Section 13.1(b).

(c) Anything in the foregoing Section 13.1(a) to the contrary notwithstanding, (i) transactions with an entity into or with which Tenant is merged or consolidated, (ii) transactions with an entity to which all or substantially all of Tenant's assets (including this Lease) or stock are transferred as a going concern or (iii) transfers resulting in a Change in Control shall not require Landlord's consent under this Article 13; provided that: (A) the successor to Tenant has a tangible net worth computed in accordance with GAAP at least equal to the tangible net worth of Tenant immediately prior to such merger, consolidation or transfer, (B) the creditworthiness, earnings and earnings forecast of the successor to Tenant shall be comparable to that of Tenant immediately prior to the date of such merger, consolidation or sale of Tenant's stock or assets, as the case may be and (C) proof satisfactory to Landlord of such tangible net worth, creditworthiness and earnings shall have been delivered to Landlord at least ten (10) days prior to the effective date of any such transaction, (D) a copy of any applicable instrument of assignment or sublease shall have been delivered to Landlord at least ten (10) days prior to the effective date of any such transaction (or, where such pre-transfer notice is prohibited by contradictory restrictions, Tenant shall provide such notice within five (5) days thereafter), (E) the successor to Tenant agrees directly with Landlord, by written instrument in form reasonably satisfactory to Landlord, to be bound by all the obligations of Tenant hereunder, (F) in no event shall Tenant be released from its obligations under this Lease, (G) any such transfer or transaction is for a legitimate, regular business purpose of Tenant other than a transfer of Tenant's interest in this Lease, (H) the successor to Tenant shall be of good reputation and engaged in a business or activity which is in keeping with the standards of comparable first-class office, laboratory and research buildings and (I) the provisions of Section 13.5(b), (c), (h), (i), (k), (l), (m) and (n) and Section 13.7 hereof shall be satisfied. Notwithstanding the foregoing, a sale of all or substantially all of Tenant's assets that does not include this Lease or Tenant's operations in the Premises, or an assignment of all of Tenant's leases other than this Lease, shall be an assignment for purposes of this Article 13 (it being intended that a transaction that would result in Tenant's only substantial asset or lease being this Lease or Tenant's operation in the Premises would not be permitted hereunder). For the avoidance of doubt, the terms and conditions of Section 13.3, 13.4 and 13.10 shall not apply to transfers that are permitted without Landlord's consent under this Section 13.1(c).

(d) The Tenant originally named in this Lease together with any permitted successors and assigns under Section 13.1(c) is sometimes referred to herein as "Original Tenant".

(e) Anything in the foregoing Section 13.1(a) to the contrary notwithstanding, Landlord's consent shall not be required for the occupancy of offices within the Premises by any individual or business entity who or which is a client, service provider or otherwise has a bona fide material business relationship with Tenant (a "Space Occupant"), provided that (i) each Space Occupant shall be of good reputation, and engaged in a business or activity which is in keeping with the standards of the Building and which is a permitted use in accordance with the provisions of Article 10 hereof, (ii) the Space Occupants shall not occupy, in the aggregate, more than twenty percent (20%) of the rentable area of the Premises, (iii) the portions of the Premises occupied by the Space Occupants shall be physically part of, and not separately demised from, the remainder of the Premises occupied by Tenant, (iv) no Space Occupant shall have a separate entrance, (v) no Space Occupant shall have any signage outside of the Premises, nor any listing on the Building's lobby directory, (vi) the proposed Space Occupant shall not then be a tenant, subtenant or occupant of any space in the Building, nor an affiliate of any tenant, subtenant or occupant of any space in the Building, (vii) the proposed Space Occupant shall not then be a person or entity, nor an affiliate of a person or entity, with whom Landlord is then actively negotiating to lease space in the Building, (viii) the consideration paid by the Space Occupant to Tenant shall not exceed the rent allocable to such space for the period of such occupancy under this Lease and (ix) Tenant shall give Landlord a Space Occupant Notice (as hereinafter defined) with respect to each such Space Occupant at least thirty (30) days prior to the commencement of such Space Occupant's occupancy in the Premises. Each such occupancy shall be subject and subordinate to this Lease and to the matters to which this Lease is or shall be subordinate, shall be terminable on not more than thirty (30) days' notice, and in the event of the termination of this Lease, such occupancy shall immediately terminate. Occupancy by a Space Occupant shall not be deemed to vest in such Space Occupant any right or interest in this Lease nor shall it relieve, release, impair or discharge any of Tenant's obligations hereunder. Each "Space Occupant Notice" given by Tenant to Landlord pursuant to this Section 13.1 shall include (A) the name and the nature of the business or occupation of such Space Occupant, (B) a description of the relationship between Tenant and such Space Occupant and (C) the material terms of such Space Occupant's occupancy. For the avoidance of doubt, the terms and conditions of Section 13.3, 13.4 and 13.10 shall not apply with respect to the occupancy of Space Occupants permitted without Landlord's consent under this Section 13.1(e).

13.2 OFFER NOTICE. If Tenant shall have received and negotiated a bona fide written offer from an independent third party which it desires to accept to sublet all or any part of the Premises or to assign this Lease, Tenant shall submit to Landlord a notice (any such notice being hereinafter called an "Offer Notice") containing the following:

(i) the name and address of the proposed subtenant or assignee and a brief description of such person's or entity's business, current financial information in respect of such person or entity (including, without limitation, its most recent balance sheet and income statements certified by its chief financial officer or a certified public accountant), the identity of any broker entitled to a commission in respect of such subletting or assignment and the commission, if any, payable to such broker, and any other information reasonably requested by Landlord; and

(ii) a duplicate original of the offer setting forth the material economic terms of the proposed assignment or sublease, together with an executed copy of the proposed instrument of assignment or sublease (both containing, in the case of an assignment, a provision for assumption by the assignee of all of the terms, covenants, conditions and agreements herein contained on the Tenant's part to be performed for the Lease Term), the effective date of which shall be at least thirty (30) days but not more than ninety (90) Operating Days after the date of the giving of such notice, which shall be conditioned on Landlord's consent thereto and which shall comply with the provisions of Section 13.5 (provided, however, that in the event Landlord shall have consented to the assignment or sublease proposed in the Offer Notice and Landlord shall not have exercised its rights under Section 13.3 or 13.4 hereof, the effective date of any such assignment or sublease may occur on the date of consent; and

(iii) executed copies of all other agreements, if any, relating to the proposed assignment or sublease and, if not fully disclosed by such agreements, a statement of all consideration to be received by Tenant for or in connection with such assignment or sublease (including, without limitation, any payment to be made for Tenant's Property or Leasehold Improvements) and the terms of payment therefor.

13.3 LANDLORD'S RIGHT TO UNDERLET. Upon receipt of any Offer Notice in which Tenant proposes to sublet all or any part of the Premises, Landlord shall have the option with respect to each such Offer Notice, exercisable by Landlord in writing within thirty (30) days after receipt of such Offer Notice, to underlet from Tenant the space which Tenant so desires to sublet, for the term for which Tenant desires to sublet it and for a rent equal to the lower of:

(i) the net effective rent for which Tenant proposes to sublet such space taking into consideration all economic terms and transaction costs set forth in the Offer Notice and otherwise in connection with such proposed sublease such as, but not limited to, free rent, work allowances and brokerage commissions; or

(ii) the rent which Tenant by the terms of this Lease is required to pay for the rentable area of the space so to be sublet,

such underlease to be upon the covenants, agreements, terms, provisions and conditions contained in this Lease except as hereinafter provided and except for such thereof which are irrelevant or inapplicable and, without limiting the generality of the foregoing, it is hereby expressly agreed that:

(a) such underlease to Landlord shall give the undertenant the unqualified and unrestricted right, without Tenant's permission, (x) to assign such underlease or any interest therein and/or to underlet from time to time the space covered by such underlease or any parts of such space for any purpose, or purposes that the undertenant, in the undertenant's uncontrolled discretion, shall deem suitable or appropriate, except that Landlord agrees that any such underlease will not be assigned except simultaneously with an assignment of Landlord's interest under this Lease so that at all times the Landlord under this Lease and the undertenant under said underlease shall be the same person, corporation or other entity, and each assignor of such underlease shall thereafter be released of all obligations under such underlease, and (y) to make any and all changes, alterations and improvements in the space covered by such underlease deemed desirable by the undertenant;

(b) such underlease shall provide that (x) any assignee or subtenant of the undertenant may, at the election of the undertenant, be permitted to make alterations, decorations and installations in such space or any part thereof, and (y) any such alterations, decorations and installations therein made by any assignee or subtenant of the undertenant may be removed, or left, in whole or in part, by such assignee or subtenant, at its option, prior to or upon the expiration or other termination of such underlease provided that such assignee or subtenant, at its expense, shall repair the damage and injury to such space so underlet caused by such removal;

(c) such underlease shall also provide that the parties to such underlease expressly negate any intention that any estate created under such underlease be merged with any other estate held by either of said parties;

(d) Tenant shall and will at all times at its expense provide and permit an appropriate and lawful means of ingress and egress from such space so underlet by Tenant to Landlord, such means of ingress or egress to be specified by Tenant in the Offer Notice with respect to such space;

(e) Landlord, at Tenant's expense, may make such Alterations as may be required or deemed necessary by Landlord physically to separate the underleased space from the balance of the Premises and to comply with all laws and requirements of public authorities relating to such separation; provided, however, that any such Alterations shall be undertaken at Landlord's expense in the event that the Offer Notice provided that the proposed subtenant would be obligated to pay such expenses;

(f) the occupant or occupants of all or any part or parts of such space shall, in common with Tenant, have the use of toilet and other common facilities on the floor on which such space is located;

(g) at the expiration of such underlease, Tenant shall accept the space covered thereby in its then existing condition provided that Landlord shall have performed Landlord's obligations to keep and maintain such space in good order and condition except for ordinary wear and tear (and further provided that in the event of Landlord's failure to perform any of such obligations Tenant shall have no right to terminate this Lease either in whole or as to such part of the space covered by the underlease); and

(h) no default by Landlord under such underlease or by anyone claiming through such underlease shall be deemed to constitute a default under this Lease, nor shall Tenant be liable for any default under this Lease or be deemed to be in default hereunder if such default is occasioned or arises from any act or omission by anyone claiming through such underlease.

If Landlord fails to respond within thirty (30) days after Tenant's submittal of Tenant's Offer Notice, Tenant may provide Landlord with an additional notice which shall set forth in bold capital letters the following statement: "**IF LANDLORD FAILS TO RESPOND WITHIN FIVE (5) BUSINESS DAYS AFTER RECEIPT OF THIS NOTICE, THEN TENANT SHALL BE ENTITLED TO SUBLET THE PREMISES OR ASSIGN THE LEASE IN ACCORDANCE WITH THE TERMS OF THAT CERTAIN OFFER SUBMITTED TO LANDLORD ON [ENTER DATE]**". If Landlord fails to respond to such notice within five (5) Business Days after receipt by Landlord, then Landlord shall be deemed to have waived its rights under this Section 13.3 with respect to such Offer Notice.

13.4 LANDLORD'S RIGHT TO TERMINATE. Upon receipt of any Offer Notice in which Tenant proposes to assign this Lease (which shall include, for purposes of this Section 13.4, a proposed subletting of all or substantially all of the Premises for the entire or substantially the entire remaining Lease Term), or in which Tenant proposes to sublet less than substantially all of the Premises for the entire or substantially the entire remaining Lease Term, then and in such event Landlord shall have the right, exercisable by notice to Tenant given within thirty (30) days after Landlord receives Tenant's Offer Notice, and in addition to the other rights granted Landlord under this Article 13, (i) in the case of an assignment, to terminate this Lease, in which event this Lease shall terminate on the date fixed in Landlord's notice, which shall not be less than thirty (30) nor more than ninety (90) days after the giving of such notice, with the same force and effect as if the termination date fixed in Landlord's notice were the date originally fixed in this Lease as the Expiration Date, or (ii) in the case of a subletting of less than substantially all of the Premises, to terminate this Lease with respect to the space proposed by Tenant to be sublet, in which event on the date fixed in Landlord's notice, which shall not be less than thirty (30) nor more than ninety (90) days after the giving of such notice, such space shall no longer be part of the Premises or covered by this Lease and the rentable area of the Premises, the Annual Fixed Rent, Tenant's Tax Payment and Tenant's Share of Operating Expenses shall be appropriately reduced. If Landlord fails to respond within thirty (30) days after Tenant's submittal of Tenant's Offer Notice, Tenant may provide Landlord with an additional notice which shall set forth in bold capital letters the following statement: "**IF LANDLORD FAILS TO RESPOND WITHIN FIVE (5) BUSINESS DAYS AFTER RECEIPT OF THIS NOTICE, THEN TENANT SHALL BE ENTITLED TO SUBLET THE PREMISES OR ASSIGN THE LEASE IN ACCORDANCE WITH THE TERMS OF THAT CERTAIN OFFER SUBMITTED TO LANDLORD ON [ENTER DATE]**". If Landlord fails to respond to such notice within five (5) Business Days after receipt by Landlord, then Landlord shall be deemed to have waived its rights under this Section 13.4 with respect to such Offer Notice. For the avoidance of doubt, the time periods in which Landlord may exercise its rights under Section 13.3 or this Section 13.4 shall run concurrently with respect to any Offer Notice delivered to Landlord.

13.5 ADDITIONAL CONDITIONS. If Landlord does not exercise any option granted to Landlord by Sections 13.3 and 13.4 with respect to a proposed sublease or assignment which is the subject of an Offer Notice, Landlord agrees that, after Landlord's receipt of an executed copy of the proposed instrument of sublease or assignment and all other agreements, if any, related to the proposed sublease or assignment, and any other information reasonably requested by Landlord, Landlord will not unreasonably withhold, condition or delay its consent to such proposed sublease or assignment provided that the terms of the instrument of sublease or assignment conform to the Offer Notice and the following further conditions shall be satisfied:

(a) the Premises or any part thereof shall not, without Landlord's prior consent, have been listed or otherwise publicly advertised for subletting at a rental rate less than the rental rate being sought by Landlord for space in the Building provided that Landlord shall, within ten (10) days after Tenant so requests, have informed Tenant of the rental rate being sought by Landlord for such space, and all advertisements of the Premises or any portion thereof for subletting shall have been approved by Landlord. The foregoing, however, shall not be deemed to prohibit Tenant from negotiating or consummating a sublease at a lower rental rate;

(b) Tenant shall not then be in default under this Lease with respect to any monetary obligations and shall not otherwise be in default under this Lease beyond the time herein provided, if any, to cure such default;

(c) the proposed subtenant or assignee is engaged in a business or activity, and the Premises, or the relevant part thereof, will be used in a manner, which (A) is in keeping with the then standards of the Building, (B) is limited to the Permitted Use and such incidental ancillary uses reasonably approved by Landlord in connection therewith and (C) is not prohibited under Section 10.4;

(d) the proposed subtenant or assignee shall not then be a tenant, subtenant or occupant of any space in the Building, nor an affiliate of any tenant, subtenant or occupant of any space in the Building, and Landlord then has (or reasonably expects to have) comparable space in the Building available for leasing;

(e) the proposed subtenant or assignee shall not then be a person or entity, nor an affiliate of a person or entity, with whom Landlord is then actively negotiating to lease comparable space in the Building;

(f) the proposed subtenant or assignee is of good reputation with sufficient financial worth considering the responsibility involved, and Landlord has been furnished with reasonable evidence of such financial worth and any sublease shall provide that, upon Landlord's request from time to time, subtenant shall deliver to Landlord a copy of subtenant's most recent financial statements certified by an officer of subtenant (provided, with respect to such financial statements, that Landlord has executed a non-disclosure agreement provided by such proposed subtenant or assignee on a customary form reasonably acceptable to Landlord);

(g) the character of the business to be conducted or the proposed use of the Premises by the proposed subtenant or assignee shall not (i) be likely to increase Landlord's operating expenses beyond that which Landlord now incurs for use by Tenant; (ii) increase the burden on elevators or other Building systems over the burden prior to such proposed subletting; or (iii) violate or be likely to violate any provisions or restrictions contained herein relating to the use or occupancy of the Premises;

(h) any proposed sublease shall state that it is expressly subject to all of the obligations of Tenant under this Lease and shall contain the further condition and restriction that the sublease shall not be assigned, encumbered or otherwise transferred or the subleased premises further sublet by the sublessee in whole or in part, or any part thereof suffered or permitted by the sublessee to be used or occupied by others, without the prior written consent of Landlord in each instance;

(i) any proposed sublease shall provide that it is subject and subordinate to this Lease and to the matters to which this Lease is or shall be subordinate, and that in the event of the termination of this Lease, or the re-entry or dispossession of Tenant by Landlord under this Lease, such subtenant shall, at Landlord's option, attorn to Landlord as its sublessor pursuant to the then applicable terms of such sublease for the remaining term thereof, except that such subtenant shall have no right to use any portion of the Premises (or other space in the Building occupied or controlled by Tenant) which is not part of the subleased premises, and Landlord shall not be (i) liable for any previous act or omission of Tenant; (ii) subject to any offset or defense which theretofore accrued to such subtenant (including, without limitation, any rights under 11 U.S.C. §365(h)); (iii) bound by any rent or other sums paid by such subtenant more than one month in advance; (iv) liable for any security deposit not actually received by Landlord; (v) liable for any work or payments on account of improvements to the subleased premises or (vi) bound by any amendment of such sublease not consented to in writing by Landlord;

(j) no subletting shall be for a term of less than two (2) years (provided, however, that if less than two (2) years remains in the Lease Term, such sublease may be for a term of no less than one (1) year);

(k) in no event shall there be more than one (1) occupant (including Tenant) in the Premises and all Alterations made to create a separately demised unit on any floor of the Premises shall be deemed Specialty Alterations;

(l) Tenant shall reimburse Landlord on demand for any reasonable, out-of-pocket costs that may be incurred by Landlord in connection with said sublease or assignment, including, without limitation, the costs of making investigations as to the acceptability of the proposed subtenant or assignee and reasonable legal costs incurred in connection with the granting of any consent;

(m) no part of the rent payable under the proposed assignment or sublease shall be based in whole or in part on the income or profits derived from the Premises nor shall any proposed assignment or sublease potentially have any adverse effect on the REIT qualification requirements applicable to Landlord and its affiliates; and

(n) any proposed sublease shall comply with the requirements of Section 11.9 hereof.

Tenant agrees to furnish Landlord such information in addition to the information set forth in the Offer Notice as Landlord may reasonably request in connection with the proposed sublease or assignment.

13.6 LANDLORD MAY COLLECT RENT FROM SUBTENANT OR ASSIGNEE. If this Lease shall be assigned, or if the Premises or any part thereof be sublet or occupied by any person or persons other than Tenant, Landlord may, after default by Tenant, collect rent from the assignee, subtenant or occupant and apply the net amount collected to the rent herein reserved, but no such assignment, subletting, occupancy or collection of rent shall be deemed a waiver of the covenants in this Article, nor shall it be deemed acceptance by Landlord of the assignee, subtenant or occupant as a tenant, or a release of Tenant from the full performance by Tenant of all the terms, conditions and covenants of this Lease.

13.7 ASSUMPTION OF LEASE. Each permitted assignee or transferee shall assume and be deemed to have assumed the obligations of Tenant under this Lease to be performed, or arising or accruing, on and after the effective date of such assignment or transfer and shall be and remain liable jointly and severally with Tenant for the payment of Annual Fixed Rent and Additional Rent, and for the due performance of all the terms, covenants, conditions and agreements herein contained on Tenant's part to be performed for the Lease Term. No assignment shall be binding on Landlord unless such assignee or Tenant shall deliver to Landlord a duplicate original of the instrument of assignment which contains a covenant of assumption by the assignee of all of the obligations aforesaid and shall obtain from Landlord the aforesaid written consent, prior thereto. No assignment in whole or in part of this Lease shall release Tenant or any assignee of Tenant of its continuing liability under this Lease.

13.8 TENANT'S INDEMNIFICATION. If Landlord shall fail or refuse to give its consent to any proposed assignment or sublease, or if Landlord shall exercise any of its options set forth in Sections 13.3 and 13.4, Tenant shall indemnify and hold harmless Landlord from and against any and all loss, liability, costs and expenses (including, without limitation, reasonable attorneys' fees) asserted against, imposed upon or incurred by Landlord by reason of any claims made against Landlord by the proposed assignee or sublessee or by any brokers, finders or other persons for commissions or other compensation in connection with the proposed assignment or sublease. Notwithstanding the foregoing, if, after Landlord exercises any of its options under Section 13.3 with respect to a particular proposed assignment or sublease, Landlord subsequently leases the Premises (or a portion thereof) to Tenant's proposed assignee or subtenant (if same was previously identified by Tenant to Landlord), the indemnity in the immediately preceding sentence shall not apply to any claim made against Landlord by (i) such proposed assignee or subtenant or (ii) any broker finders or other persons that represented such proposed assignee or subtenant, in each case in connection with Tenant's proposed assignment or sublease or such proposed assignee's or subtenant's lease from Landlord.

13.9 TIME LIMITATION; AMENDMENTS. If Landlord grants its consent to an assignment or sublease and such assignment or sublease does not become effective for any reason within one hundred fifty (150) days after the granting of such consent, or if such assignment or sublease is modified or amended prior to its becoming effective, then and in either such event Landlord's consent shall be deemed to have been withdrawn and Tenant shall not have the right to assign this Lease or to sublease all or any portion of the Premises without once again complying with all of the provisions and conditions of Sections 13.1, 13.2, 13.3, 13.4, 13.5 and 13.6. In no event shall Tenant agree to modify or amend any sublease to which Landlord has consented without Landlord's prior written consent.

13.10 ADDITIONAL RENT DUE UPON ASSIGNMENT OR SUBLETTING. If Landlord shall not exercise any of its options set forth in Sections 13.3 and 13.4 and shall give its consent to any assignment of this Lease or to any sublease, Tenant shall, as consideration therefor, pay to Landlord as Additional Rent the following amounts:

(a) in the case of any assignment, an amount equal to fifty percent (50%) of all sums and other considerations paid to or for the benefit of Tenant by the assignee for or by reason of such assignment (including, but not limited to, sums paid for the sale of any of Tenant's Property, fixtures or Leasehold Improvements); or

(b) in the case of a sublease, fifty percent (50%) of the excess, if any, of (i) any rents, additional charges or other consideration payable under the sublease or any agreement relating thereto to or for the benefit of Tenant by the subtenant (including, but not limited to, sums paid for the sale of any of Tenant's Property, fixtures or Leasehold Improvements) over (ii) the rents accruing during the term of the sublease in respect of and allocable to the subleased space pursuant to the terms of this Lease.

Amounts due to Landlord pursuant to this Section 13.10 shall be paid to Landlord as Additional Rent at the time such payments are payable by the assignee or subtenant to Tenant and whether or not such payments are made. Reasonable attorneys' fees and brokerage or leasing commissions to an independent third-party broker actually incurred by Tenant in connection with the assignment or subletting, which amounts, in the case of a sublease, shall be amortized on a straight line basis over the term of the sublease without interest, may be deducted from the rents, charges and other consideration payable by the assignee or subtenant to Tenant in connection with the assignment or subletting prior to the computation of amounts due to Landlord pursuant to subsection (a) or (b) above.

13.11 LIABILITY NOT DISCHARGED. The joint and several liability of Tenant and any assignee or successor of Tenant under this Lease, or any guarantor of Tenant's obligations under this Lease, shall not be discharged, released or impaired in any respect by any agreement or stipulation made by Landlord modifying any of the obligations contained in this Lease, or by any waiver or failure by Landlord to enforce any of the obligations of this Lease, but in no event shall Tenant's continued liability exceed what its continuing liability would have been had the Lease not been modified except for those modifications, if any, which were consented to by Tenant.

13.12 EFFECT OF LISTING OF NAMES. The listing of any name other than Tenant on the door of the Premises, on the Building directory or otherwise shall not operate to vest any right or interest in this Lease or in the Premises in any other person or entity, nor shall such listing be deemed to be the consent of Landlord to any assignment or transfer of this Lease or to any sublease of the Premises or any portion thereof or to the use or occupancy of the Premises or any portion thereof by others.

13.13 GOOD REPUTATION. For purposes of this Article 13, "good reputation" shall refer to the business reputation of Tenant or any assignee, subtenant or Space Occupant, and not to how any particular laboratory or life science testing is performed within the Premises.

ARTICLE 14

NO LIABILITY OR REPRESENTATIONS BY LANDLORD; FORCE MAJEURE

14.1 NO LIABILITY.

(a) Neither Landlord nor any other Landlord Parties shall be liable for (i) any damage to property of Tenant or of others entrusted to employees of the Building, nor for the loss of or damage to any property of Tenant by theft; (ii) any injury or damage to persons or property resulting from fire, explosion, falling plaster, steam, gas, electricity, water, rain or snow or leaks in or from any part of the Building or the Property or from the pipes, vents, risers, appliances or plumbing or from the roof, street or subsurface or from any other place or by dampness or by any other cause of whatsoever nature; nor shall Landlord and its agents or employees be liable for any such damage caused by other tenants or persons in the Building or caused by operations in construction of any private, public or quasi-public work; (iii) any latent defect in the Premises, the Building or other improvements on the Property (except as expressly set forth in Section 7.1); or (iv) any injury or damages for which Tenant is reimbursed under its insurance policies; except, in each case, to the extent that any such claim results from the gross negligence or willful misconduct of Landlord or any other Landlord Party.

(b) If at any time any windows of the Premises are temporarily or permanently closed, darkened or bricked up as a result of causes beyond Landlord's control, or are temporarily closed or darkened by Landlord, Landlord shall not be liable for any damage Tenant may sustain thereby and Tenant shall not be entitled to any compensation therefor nor abatement of rent nor shall the same release Tenant from its obligations hereunder nor constitute an eviction.

(c) Landlord shall have no responsibility or liability for the ventilating conditions and/or temperature of the Premises during the hours or days Landlord is not required to furnish heat, ventilation or air-conditioning pursuant to Exhibit D or pursuant to Sections 14.3 or 20.12, Landlord having informed Tenant that the windows of the Premises and the Building may be sealed, and that the Premises may become uninhabitable and the air therein may become unbreathable during such times. Insofar as air temperature and ventilation are concerned, any use or occupancy of the Premises during the hours or days Landlord is not so required to, or pursuant to Section 14.3 or 20.12 does not furnish heat, ventilation or air-conditioning to the Premises shall be at the sole risk, responsibility and hazard of Tenant. Such condition of the Premises shall not constitute nor be deemed to be a breach or a violation of this Lease or of any provision hereof, nor shall it be deemed an eviction, nor shall Tenant claim or be entitled to claim any abatement of rent nor make any claim for any damages or compensation by reason of such condition of the Premises.

(d) Tenant shall neither assert nor seek to enforce any claim against any of Landlord's assets other than Landlord's interest in the Land and the Building, and Tenant agrees to look solely to such interest for the satisfaction of any liability of Landlord under this Lease, it being specifically agreed that neither Landlord, nor any successor holder of Landlord's interest hereunder, nor any general or limited partner of Landlord or any such successor (if Landlord or such successor is a partnership) nor any shareholder of Landlord or any such successor (if Landlord or such successor is a corporation) shall ever be personally liable for any such claim or liability. Landlord shall in no event be liable for any loss of business or any indirect or consequential damages under this Lease.

14.2 NO REPRESENTATIONS BY LANDLORD. Tenant expressly acknowledges and agrees that Landlord has not made and is not making, and Tenant, in executing and delivering this Lease, is not relying upon, any warranties, representations, promises or statements, except for those expressly set forth in this Lease and the Exhibits annexed hereto or in any other written agreement which may be made between the parties hereto concurrently with the execution and delivery of this Lease and which shall expressly refer to this Lease. No rights, easements or licenses are acquired by Tenant by implication or otherwise except as expressly set forth in the provisions of this Lease.

14.3 FORCE MAJEURE. This Lease and the obligation of Tenant to pay rent hereunder and perform and comply with all of the other covenants and agreements hereunder on the part of Tenant to be performed and complied with shall in no way be affected, impaired or excused because of Landlord's delay or failure to perform or comply with any of the covenants or provisions hereunder on the part of Landlord to be performed or complied with, or because Landlord is unable to fulfill any of its obligations under this Lease or is unable to supply or is delayed in supplying any service expressly or impliedly to be supplied or is unable to make or is delayed in making any repair, additions, alterations or decorations or is unable to supply or is delayed in supplying any equipment or fixtures, if Landlord is prevented or delayed from so doing by reason of Force Majeure. Except as expressly provided herein to the contrary, this Lease and the obligation of Landlord to perform and comply with all of the other covenants on the part of Landlord to be performed and complied with shall in no way be affected, impaired or excused because of Tenant's delay or failure to perform or comply with any of the covenants or provisions hereunder on the part of Tenant to be performed or complied with (other than Tenant's obligation to pay rent hereunder), or because Tenant is unable to fulfill any of its obligations under this Lease (other than Tenant's obligation to pay rent hereunder) or is unable to make or is delayed in making any repair, additions, alterations or decorations, if Tenant is prevented or delayed from so doing by reason of Force Majeure. For purposes hereof, the term "Force Majeure" shall mean, collectively, (i) strikes or labor troubles, (ii) governmental preemption in connection with a national emergency, (iii) any rule, order or regulation of any government agency or any department or subdivision thereof, whether in connection with a drought, energy shortage or other like event or otherwise, (iv) any fact, condition or circumstance related to war, terrorism, virus, global pandemic or other emergency, (v) except as otherwise set forth in Article 12, fire, casualty or other acts of God (including the time necessary to repair any damage caused thereby) or (vi) any other cause (other than causes delaying the payment of money due and payable hereunder) whatsoever beyond Landlord's or Tenant's reasonable control. Landlord and Tenant shall, in each instance, exercise reasonable diligence to effect performance when and as soon as possible or practicable. For the avoidance of doubt, Tenant's obligation to pay Annual Fixed Rent and Additional Rent hereunder shall not be affected hereby unless specifically provided for in this Lease.

ARTICLE 15

ENTRY, RIGHT TO CHANGE PUBLIC PORTIONS OF THE BUILDING

15.1 LANDLORD'S RIGHT OF ENTRY. Landlord shall have the right, without being deemed thereby to evict Tenant from the Premises or any part thereof or otherwise to violate any of the terms of this Lease or any of Tenant's rights hereunder,

(a) to enter and pass through the Premises or any part or parts thereof,

(i) to examine the Premises and to show them to the fee owners, Overlandlord or Mortgagee (both as hereafter defined) and to prospective purchasers, mortgagees or lessees of the Building as an entirety;

(ii) for the purpose of performing such maintenance and making such repairs or changes in or to the Premises or in or to the Building or its facilities as may be provided for or permitted by this Lease or as may be mutually agreed upon by the parties or as Landlord may be required to make by laws and requirements of public authorities; provided, however, that any such maintenance, repairs or changes in or to the Premises shall not cause a reduction of the usable floor space of the Premises (other than to a de minimis extent);

(iii) at such times as such entry shall be required by circumstances of emergency affecting the Premises or the Building, provided that in such event, if practicable, Landlord or its agents shall be accompanied by a designated representative of Tenant or a member of the police, fire, water or other municipal department concerned or of a recognized protection company or of a public utility which is concerned;

(iv) to exhibit the Premises or any portion thereof to prospective tenants or occupants (A) during the last twelve (12) months of the Lease Term, (B) at any time during the Lease Term while there exists a default of Tenant hereunder beyond the expiration of all applicable notice and cure periods or (C) during any period in which Landlord may exercise a right to underlease the space in question or to terminate this Lease (provided, however, that in the case of the foregoing clause (A), Landlord shall provide Tenant reasonable prior notice and the opportunity to designate a representative of Tenant to be present at such exhibiting of the Premises); and

(v) for the purpose of photographing the Premises for use by Landlord and/or Landlord's affiliates in connection with promotional and marketing materials (provided, however, that (A) Landlord shall provide Tenant reasonable prior notice and the opportunity to designate a representative of Tenant to be present during such photographing of the Premises and (B) Landlord shall in no event photograph and transmit images disclosing any proprietary information of Tenant).

(b) to take all materials into and upon the Premises that may be required for any repairs, changes or maintenance and to store the same therein for a reasonable time as reasonably required in connection with the completion of such repairs, changes or maintenance; provided, however, that Landlord shall use reasonable efforts (but not including the use of overtime or premium labor) to perform such work in such a manner so as to minimize interference that might be occasioned to Tenant's business operations.

Landlord's rights under this Section shall be exercised in such manner as to create the least practicable interference with Tenant's use of the Premises; provided, however, that the foregoing shall not obligate Landlord to perform any work outside of Operating Hours (as defined in Exhibit D). Except in the case of an emergency which makes notice to Tenant impractical, any entry on the Premises by Landlord pursuant to this Section 15.1 shall be made after reasonable notice to Tenant.

15.2 LANDLORD'S RIGHT TO CHANGE ENTRIES, ETC. Landlord shall have the right at any time without thereby creating any actual or constructive eviction or incurring any liability to Tenant therefor, and without abatement in rent, to change the arrangement or location of lobbies, entrances, passageways, doors, doorways, stairways, elevators, corridors and other like portions of the Building outside of the Premises, provided that such change does not interfere with Tenant's access to the Premises.

15.3 EXCAVATION. In the event that an excavation or any construction should be made for building or other purposes upon land adjacent to the Building, or should be authorized to be made, Tenant shall, if necessary, afford to the person or persons causing or authorized to cause such excavation or construction, license to enter upon the Premises for the purpose of doing such work as shall reasonably be necessary to protect or preserve the wall or walls of the Building, or the Building, from injury or damage and to support them by proper foundations, pinning and/or underpinning, or otherwise.

ARTICLE 16

ELECTRICITY

16.1 TENANT TO PURCHASE ELECTRICITY.

(a) Landlord shall make electricity available to the Premises at the service level set forth in Exhibit D attached hereto, and otherwise subject to and in accordance with the provisions of this Article.

(b) Tenant acknowledges that electricity shall be furnished to the Premises on a "submetering" basis, which may be effectuated by Landlord through one (1) or more submeters installed by Landlord at Landlord's sole cost and expense. In the event more than one (1) submeter measures the electric service to Tenant in the Premises, the electric service rendered through each submeter shall be computed and billed as if one (1) submeter measured such electric service.

(c) In the event that there is located in the Premises a data center containing high density computing equipment, as defined in the U.S. EPA's Energy Star® rating system, Landlord may require the installation in accordance with Energy Star of separate metering or sub-metering equipment (Tenant being responsible for the costs of any such meter or sub-meter and the installation and connectivity thereof). Tenant shall pay to Landlord, as Additional Rent, an amount equal to (i) the Average Rate (as hereinafter defined) multiplied by the number of kilowatt-hours of electricity used in the Premises during the period for which such payment is being made plus five percent (5%) within thirty (30) days after being billed thereof by Landlord; in either case in addition to other electric charges payable by Tenant under the Lease. For purposes hereof, the term "Average Rate" shall mean the average cost to Landlord of supplying one (1) kilowatt-hour of electricity to the Building, and such rate shall be determined by dividing (A) the electric bill for the Building for the period(s) covered by Tenant's payment by (B) the number of kilowatt-hours of electricity supplied to the Building during such period. In addition, electrical consumption for any common areas on the floor on which the Premises is located shall be determined by a meter(s) installed by Landlord at Landlord's expense and, Tenant shall pay to Landlord, as Additional Rent, for electricity supplied to such common areas, including electricity supplied to the Building HVAC System serving the Premises, an amount equal to Tenant's pro rata share (based upon the ratio of the rentable square feet of the Premises to the rentable square feet of the entire floor and adjusted equitably according to estimated usage) of the actual cost of the entire supply of electric current to the common area of such floor, based upon the bill received by Landlord from the utility company for electricity rendered through the meter for such floor. Tenant's payments shall be made within thirty (30) days after receipt of a statement setting forth the actual cost of electricity and the computation of Tenant's payment shall be adjusted from time to time in accordance with the provisions of this Section 16.1.

16.2 LANDLORD NOT LIABLE. Subject to Section 20.12, Landlord shall not in any way be liable or responsible to Tenant for any loss or damage or expense which Tenant may sustain or incur if either the quantity or character of electric service is changed or interrupted or is no longer available or suitable for Tenant's requirements unless due to the negligence of Landlord, its agents, employees or contractors.

16.3 TENANT NOT TO OVERLOAD CIRCUITS. In no event shall Tenant use or install any fixtures, equipment or machines the use of which in conjunction with other fixtures, equipment and machines in the Premises would result in an overload of the electrical circuits servicing the Premises.

16.4 TENANT NOT TO EXCEED CAPACITY; LIGHT BULBS. Tenant covenants and agrees that at all times its use of electric current shall never exceed the capacity of the then existing feeders to the Building or the risers or wiring installation. Landlord shall furnish, install and replace, as required, all lighting tubes, lamps, bulbs and ballasts required in the Premises at Tenant's sole cost and expense. All lighting tubes, lamps, bulbs and ballasts so installed shall become Landlord's property upon the expiration or sooner termination of this Lease.

ARTICLE 17

SUBORDINATION; ASSIGNMENT OF RENTS

17.1 SUBORDINATION TO MORTGAGES, ETC.

(a) This Lease is and shall be subject and subordinate to any ground or underlying lease (collectively called "Underlying Lease") which may now or hereafter affect the Building and/or the Land and to any amendment, modification, renewal or extension of any such Underlying Lease. This Lease also is and shall be subject and subordinate to all mortgages which may now or hereafter affect any Underlying Lease, the Land and/or the Building, to each and every advance made thereunder and to all renewals, modifications, amendments, consolidations, replacements or extensions thereof. The landlord or lessor under any Underlying Lease is referred to herein as a "Overlandlord" and the secured party under any such mortgage is referred to herein as a "Mortgagee". This clause shall be self-operative and no further instrument of subordination shall be required by any Overlandlord or Mortgagee. In confirmation of such subordination, Tenant, without cost or charge to Landlord, shall execute promptly any certificate or instrument of subordination that Landlord may reasonably request, provided that the same shall not increase Tenant's obligations or decrease Tenant's rights under this Lease (other than to a *de minimis* extent). Tenant hereby, irrevocably constitutes and appoints Landlord as Tenant's attorney-in-fact, coupled with an interest, to execute any such certificate or certificates or any such instrument or instruments for and on behalf of Tenant if Tenant shall fail or refuse to execute the same for ten (10) days after demand.

(b) Tenant agrees that if any Overlandlord or Mortgagee shall succeed to interest of Landlord under this Lease by foreclosure or otherwise, and the Overlandlord or Mortgagee elects in its sole discretion not to cause this Lease to be terminated in connection therewith, this Lease shall not be terminated or affected thereby but shall continue in full force and effect as a direct lease between Overlandlord or Mortgagee and Tenant upon all of the terms, covenants and conditions set forth in this Lease (it being understood that Tenant shall, if requested, enter into a new lease on terms identical to those in this Lease) and, in such event, Tenant shall attorn to Overlandlord or Mortgagee provided, however, that the provisions of such Underlying Lease or such mortgage shall govern with respect to the disposition of any casualty insurance proceeds or condemnation awards and Overlandlord or Mortgagee shall not be (i) bound by any prepayment of rent which Tenant might have paid for more than the current month to any prior landlord (including Landlord), (ii) bound by any waiver or forbearance under, or any amendment, modification, cancellation or surrender (in whole or in part) of this Lease made without the consent of such Overlandlord or Mortgagee, (iii) liable for any act, omission or default of any prior landlord (including Landlord) under this Lease (it being understood that the foregoing is not intended to relieve any such Overlandlord or Mortgagee of any liability arising by reason of its acts or omissions (x) from and after the date it succeeds to the interests of Landlord or (y) prior to the date it succeeds to the interests of Landlord if such default is continuing after such date of succession but then only to the extent such default occurred after the date of succession), (iv) bound by or subject to any (A) credits, offsets or abatements the rights to which first accrued prior to the date upon which Successor Landlord succeeded to the interest of Landlord under the Lease or (B) defenses or claims (except defenses or claims against Successor Landlord based on acts, omissions or other matters first occurring after Successor Landlord succeeded to the interest of Landlord under the Lease) that Tenant might have against any prior Landlord (including, without limitation, the then defaulting Landlord), (v) liable for performance of any work or installations or payment of any sums which are required to be made by Landlord under this Lease, or (vi) liable for any security deposit, in whatever form, provided by Tenant, unless such security deposit shall have been received in hand by such Overlandlord or Mortgagee. The provisions of this Section 17.1(b) shall be self-operative and no further instrument shall be required to give effect to these provisions.

(c) Tenant shall not do nor suffer nor permit any action which would constitute a default under any Underlying Lease or any mortgage which may now or hereafter affect any Underlying Lease, the Land and/or the Building, or cause any Underlying Lease to be terminated or forfeited by virtue of any right of termination or forfeiture granted to the Overlandlord by such Underlying Lease.

(d) In the event that (i) any Overlandlord or Mortgagee shall succeed to the interest of Landlord under this Lease by foreclosure or otherwise, (ii) as of the date of such succession, Landlord has not Substantially Completed the Base Work and (iii) such Overlandlord or Mortgagee succeeding to Landlord’s interest does not agree to Substantially Complete the Base Work, then Tenant, in Tenant’s sole discretion, shall have the right to terminate this Lease upon written notice delivered to Landlord and such Overlandlord and Mortgagee within thirty (30) days after such succession, time being of the essence.

17.2 RIGHTS OF MORTGAGEES, ETC. In the event of any act or omission by Landlord which would or may give Tenant the right to terminate this Lease or to claim a partial or total eviction (other than under Article 12 or with respect to Tenant's termination rights if the Commencement Date does not occur by the outside date set forth herein), Tenant will not exercise any such right until:

(a) it has given written notice of any such act or omission to Landlord, and to any Overlandlord or Mortgagee whose names and addresses have previously been furnished to Tenant, and

(b) a reasonable period of time for remedying such act or omission shall have elapsed following such giving of notice during which the parties to whom such notice has been given, or any of them, have not commenced with reasonable diligence the remedying of such act or omission.

17.3 MODIFICATIONS REQUIRED BY LENDERS. If, in connection with obtaining temporary or permanent financing for the Land and/or Building, or any Underlying Lease, any lender shall request reasonable modifications of this Lease as a condition to such financing, Tenant will not unreasonably withhold, delay or defer the execution of an agreement of modification of this Lease provided such modifications do not increase the monetary obligations of Tenant hereunder, or materially adversely affect the leasehold interest hereby created, or Tenant's rights hereunder.

17.4 ASSIGNMENT OF LEASE TO MORTGAGEE, ETC. With reference to any assignment by Landlord of Landlord's interest in this Lease, or the rents payable hereunder, conditional in nature or otherwise, which assignment is made to an Overlandlord or Mortgagee, Tenant agrees:

(a) that the execution thereof by Landlord, and the acceptance thereof by such Overlandlord or Mortgagee, shall never be treated as an assumption by such Overlandlord or Mortgagee of any of the obligations of Landlord hereunder, unless such Overlandlord or Mortgagee shall, by notice sent to Tenant, specifically otherwise elect; and

(b) that, except as aforesaid, such Overlandlord, or Mortgagee shall be treated as having assumed Landlord's obligations hereunder only, in the case of a Mortgagee, upon foreclosure by such Mortgagee and the taking of possession of the Premises, or, in the case of an Underlying Lease, the assumption of Landlord's position hereunder by such Overlandlord, any such assumption in each such case to be limited as set forth in Section 14.1(d). In no event shall the acquisition of title to the Building and/or the Land by a purchaser which, simultaneously therewith, leases the entire Building and/or the Land back to the seller thereof be treated as an assumption, by operation of law or otherwise, of Landlord's obligations hereunder, but Tenant shall look solely to such seller-lessee, and its successors from time to time in title, for performance of Landlord's obligations hereunder. For all purposes, such seller-lessee, and its successors in title, shall be the landlord hereunder unless and until Landlord's position shall have been assumed by such purchaser-lessor.

17.5 SUBORDINATION OF MORTGAGE, ETC., TO LEASE. Notwithstanding anything to the contrary set forth in this Article 17, if any Overlandlord or Mortgagee shall file in the office of the Register of the City of New York, New York County, an instrument in which such Overlandlord or Mortgagee shall subordinate its Underlying Lease or mortgage to this Lease, then and in such event such Underlying Lease or mortgage shall be subordinate to this Lease and the provisions of this Article 17, insofar as they would subordinate this Lease to that particular Underlying Lease or mortgage, shall be of no further force or effect.

ARTICLE 18

CERTAIN ADDITIONAL TENANT COVENANTS

In addition to the covenants contained elsewhere in this Lease, Tenant covenants, during the Lease Term and for such further time as Tenant occupies any part of the Premises:

(a) to pay when due all Annual Fixed Rent and Additional Rent and all charges for utility services rendered to the Premises and service inspections therefor and, as further Additional Rent, all charges for additional and special services rendered pursuant to Exhibit D;

(b) to keep the Premises equipped with all safety appliances (including without limitation fire extinguishers) required by law or ordinance or any other regulation of any public authority, to procure all licenses and permits so required because of any use made of the Premises or any portion thereof by Tenant, and, if requested by Landlord, to do any work so required because of such use, it being understood that the foregoing provisions shall not be construed to broaden in any way the uses to which Tenant is permitted to make of the Premises under the terms of this Lease;

(c) not to place a load upon any floor in the Premises exceeding the floor load per square foot of area which such floor was designed to carry and which is allowed by law; and not to move any safe, vault or other heavy equipment in, about or out of the Premises except in such manner and at such time as Landlord shall in each instance expressly authorize. Tenant’s business machines and mechanical equipment shall be placed and maintained by Tenant at Tenant’s expense in settings sufficient to absorb and prevent vibration or noise that may be transmitted to the Building structure or to any other space in the Building;

(d) to pay promptly when due all taxes which may be imposed upon personal property (including, without limitation, fixtures and equipment) in the Premises by whomever assessed;

(e) to pay on demand as Additional Rent, regardless of whether any default or Event of Default has occurred or whether any proceeding to enforce the Lease has been commenced, all costs and expenses, attorneys' fees and disbursements and other fees incurred by Landlord in connection with (i) the enforcement by Landlord of any obligation of Tenant under this Lease; (ii) the preservation and enforcement of Landlord's rights and remedies in connection with the Lease; (iii) any unsuccessful attempt by Tenant to enforce any obligation or purported obligation of Landlord under this Lease; (iv) any unsuccessful action or proceeding brought by Tenant against Landlord related to this Lease; and (v) any voluntary or involuntary bankruptcy case, proceeding or action by or on behalf of Tenant, including, without limiting the generality of the foregoing, any and all expenses and attorneys' fees incurred by Landlord related to (A) the assumption or rejection of this Lease, including attempts by Tenant to extend any deadlines related to such assumptions or rejections; (B) the filing of proof(s) of claim by Landlord, and any defense of such proof(s) of claim; (C) the assignment of this Lease; and (D) the reorganization or liquidation of Tenant. This provision shall survive the termination of this Lease;

(f) to observe and comply with, and to cause its servants, employees, agents, visitors, licensees and sublessees to comply with, the Rules and Regulations set forth in Exhibit E and the Lab Rules and Regulations (as each of such rules and regulations may, from time to time, be adopted or amended in accordance with Section 20.13 hereof);

(g) to cause all of the windows in the Premises to be kept closed; to keep entirely unobstructed at all times all of the vents, intakes, outlets and grills; and to comply with and observe all reasonable regulations and requirements prescribed by Landlord for the proper functioning of the heating, ventilating and air-conditioning system;

(h) not to, either directly or indirectly (i) conduct business in the Premises in such a manner that would or may create or (ii) use any contractors and/or labor and/or materials if the use thereof, would or may create, any difficulty with other contractors and/or labor and/or materials engaged or used by Tenant or Landlord or others in the construction, maintenance and/or operation of the Building or any part thereof. Without limiting any other provision of this Lease, all contractors, vendors and service providers requiring access to the Premises or the Building shall be subject to Landlord's prior and continuing review and approval with respect to insurance, security and operational matters. This provision shall apply prior to, as well as during, the Lease Term; and

(i) to comply with all the terms covenants, covenants and conditions of the HireNYC requirements set forth on Exhibit J hereto.

ARTICLE 19

TENANT'S DEFAULT; LANDLORD'S REMEDIES

19.1 TENANT'S DEFAULT. This Lease and the Lease Term are subject to the limitation that Tenant shall be in default if, at any time during the Lease Term, any one or more of the following events (herein called an "Event of Default") shall occur:

(a) if Tenant shall fail to pay any installment of the Annual Fixed Rent, or any Additional Rent, or any other charges for which provision is herein made, or any part thereof, when the same shall become due and payable and such failure shall continue for five (5) days after notice thereof from Landlord to Tenant (provided that if Tenant shall have failed to pay any such installment or other charge or portion thereof when the same becomes due and payable two (2) times during any Lease Year and Landlord shall in each case have given Tenant notice of such failure, then after such second time it shall be an Event of Default in the event Tenant thereafter during such Lease Year fails to pay any such installment or other charge or portion thereof on the date the same becomes due and payable, without notice (or, in the case of other charges which are payable on or subsequent to demand, further notice) from Landlord); or

(b) if the Premises shall become abandoned and such abandonment continues for more than thirty (30) days after notice from Landlord; or

(c) if an assignment or subletting shall occur or if Tenant's interest in this Lease shall devolve upon or pass to any person or entity, whether by operation of law or otherwise, and whether directly or indirectly, except as expressly permitted by Article 13 hereof, or

(d) if Tenant fails to maintain any of the insurance required to be maintained by Tenant hereunder or to deliver certificates thereof when required hereunder and Tenant fails to remedy such default within five (5) days after notice by Landlord to Tenant specifying such default; or

(e) Tenant shall fail to perform or observe some term or condition of this Lease which, because of its character, would immediately jeopardize Landlord's interest in the Property, the health or safety of any person, the operation of the Building or any Building system, or the business operations of any occupant (including, without limitation, Tenant's failure to perform any Alterations during non-Operating Hours when required to do so by the terms of this Lease), and such failure continues for two (2) days after notice from Landlord to Tenant specifying such default; or

(f) if Tenant shall fail to perform or observe any other term, covenant, or condition of this Lease on the part of Tenant to be performed or observed and such failure shall continue for thirty (30) days after notice thereof from Landlord to Tenant, or, if said default is curable but shall reasonably require longer than thirty (30) days to cure, if Tenant shall fail to commence to cure said default within thirty (30) days after receipt of notice thereof and/or fail continuously to prosecute the curing of the same to completion with due diligence, and in any event within such period of time as will prevent Landlord from being subjected to the risk of criminal liability or termination of any Underlying Lease or foreclosure of any mortgage; or

(g) if the estate hereby created shall be taken on execution or by other process of law; or

(h) (i) if Tenant shall generally not, or shall be unable to, or shall admit in writing its inability to, pay its debts as they become due; or

(ii) if Tenant shall commence or institute any case, proceeding or other action (x) seeking relief on its behalf as debtor, or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization or relief of debtors, or (y) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any substantial part of its property; or

(iii) if Tenant shall make a general assignment for the benefit of creditors; or

(iv) if any case, proceeding or other action shall be commenced or instituted against Tenant (x) seeking to have an order for relief entered against it as debtor or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization or relief of debtors, or (y) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any substantial part of its property, which either (1) results in any such entry of an order for relief, adjudication of bankruptcy or insolvency or such an appointment or the issuance or entry of any other order having a similar effect or (2) remains undismissed for a period of sixty (60) days; or

(v) if any case, proceeding or other action shall be commenced or instituted against Tenant seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial part of its property which results in the entry of an order for any such relief which shall not have been vacated, discharged, or stayed or bonded pending appeal within sixty (60) days from the entry thereof; or

(vi) if Tenant shall take any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clauses (ii), (iii), (iv) or (v) above; or

(vii) if a trustee, receiver or other custodian is appointed for any substantial part of the assets of Tenant which appointment is not vacated or effectively stayed within seven (7) Operating Days; or

(i) if Tenant fails to (A) deliver any Security Deposit, Letter of Credit, pre-paid rent, financial information, guaranty or other item required but not delivered upon the execution and delivery of this Lease within three (3) days after notice from Landlord to Tenant demanding same, provided, however, that Tenant's failure to timely provide the initial Letter of Credit as replacement for the Cash Deposit pursuant to Section 20.22 shall constitute an immediate Event of Default hereunder for which Tenant shall not be entitled to such three (3) day notice and cure period or (B) timely deliver a Replacement Letter in accordance with the terms of Section 20.22(a), 20.22(b) or 20.22(d) hereof or (C) timely restore the Letter to the face amount then required under Section 20.22(b) hereof after Landlord has drawn upon the Letter; or

(j) if any representation or warranty made by Tenant herein or in any report, certificate, financial statement or other instrument, agreement or document furnished to Landlord shall have been materially false or misleading as of the date the representation or warranty was made.

19.2 TERMINATION.

(a) (i) If an Event of Default described in Section 19.1(h) hereof shall occur, or

(ii) if an Event of Default described in Sections 19.1(a),(b),(c),(d), (e), (f), (g), (i) or (j) shall occur and Landlord, at any time thereafter, at its option gives written notice to Tenant stating that this Lease and the Lease Term shall expire and terminate on the date specified in such notice, which date shall not be less than three (3) days after the giving of such notice, then this Lease and the Lease Term and all rights of Tenant under this Lease shall expire and terminate, as if the date on which the Event of Default described in clause (i) above occurred, or the date specified in the notice given pursuant to this clause (ii) above, as the case may be, were the date herein definitely fixed for the expiration of the Lease Term (except that Tenant shall continue liable as hereinafter provided) and Tenant immediately shall quit and surrender the Premises.

(b) Anything contained herein to the contrary notwithstanding, if such termination shall be stayed by order of any court having jurisdiction over any proceeding described in Section 19.1(h) hereof, or by federal or state statute, then, following the expiration of any such stay, or if Tenant, or Tenant as debtor-in-possession or the trustee appointed in any such proceeding (being collectively referred to as "Tenant" only for the purposes of paragraph (b) of this Section 19.2) shall fail to assume Tenant's obligations under this Lease within the period prescribed therefor by law or within one hundred twenty (120) days after entry of the order for relief or as may be allowed by the court, or, if Tenant shall fail to provide adequate protection of Landlord's right, title and interest in and to the Premises or adequate assurance of the complete and continuous future performance of Tenant's obligations under this Lease, Landlord, to the extent permitted by law or by leave of the court having jurisdiction over such proceeding, shall have the right, at its election, to terminate this Lease on three (3) days' notice to Tenant and upon the expiration of said three (3) day period this Lease shall cease and expire as aforesaid and Tenant shall immediately quit and surrender the Premises as aforesaid. Upon the termination of this Lease provided above, Landlord, without notice, may re-enter and repossess the Premises using such force for that purpose as may be necessary without being liable to indictment, prosecution or damages therefor and may dispossess Tenant by summary proceedings or otherwise.

(c) If, at any time, (i) Tenant shall comprise two (2) or more persons, or (ii) Tenant's obligations under this Lease shall have been guaranteed by any person other than Tenant, or (iii) Tenant's interest in this Lease shall have been assigned, the word "Tenant", as used in clause (h) of Section 19.1, shall be deemed to mean any one or more of the persons primarily or secondarily liable for Tenant's obligations under the Lease. Any monies received by Landlord from or on behalf of Tenant during the pendency of any proceeding of the types referred to in said clause (h) shall be deemed paid as compensation for the use and occupation of the Premises and the acceptance of any such compensation by Landlord shall not be deemed an acceptance of rent or a waiver on the part of Landlord of any rights under this Section.

(d) The provisions of subdivisions (b) and (c) of this Section 19.2 apply only in respect of the circumstances described in subsection 19.1(h) and as such are not intended to constitute modifications of any of the provisions of Article 13 except in such circumstances.

19.3 RE-ENTRY; CONTINUED LIABILITY; RELETTING.

(a) If Tenant shall default in the payment of any installment of Annual Fixed Rent or any Additional Rent on any date on which the same becomes due and payable, and if such default shall continue for five (5) days after Landlord shall have given Tenant notice of such default, or if this Lease shall be terminated pursuant to or as provided in Section 19.2, Landlord and Landlord's agents and employees may immediately or at any time thereafter re-enter the Premises, or any part thereof in the name of the whole, either by summary dispossess proceedings or by any suitable action or proceeding at law or otherwise, without being liable to indictment, prosecution or damages therefor, and may repossess the same, and may remove any persons therefrom, to the end that Landlord may have, hold, possess and enjoy the Premises again.

(b) If this Lease is terminated or if Landlord shall re-enter the Premises as aforesaid, or in the event of the termination of this Lease, or of re-entry, by or under any proceeding or action or any provision of law by reason of an Event of Default hereunder on the part of Tenant, Tenant covenants and agrees forthwith that,

(i) the Annual Fixed Rent (including, without limitation, an amount equal to the amount of Annual Fixed Rent which would have been payable during the Rent Concession Period) and Additional Rent shall become due thereupon and be paid by Tenant up to the time of such re-entry, dispossession and/or termination, together with such expenses as Landlord may incur for legal expenses, attorneys' fees and disbursements, brokerage, and/or putting the Premises in good order, or for preparing the same for reletting;

(ii) Landlord may relet the Premises or any part or parts thereof, either in the name of Landlord or otherwise (but shall have no obligation to do so), for a term or terms, which may at Landlord's option be less than or exceed the period which would otherwise have constituted the balance of the Term of this Lease and may grant concessions or free rent;

(iii) Tenant or the legal representatives of Tenant shall also pay Landlord, as liquidated damages for the failure of Tenant to observe and perform Tenant's covenants herein contained, amounts equal to the Annual Fixed Rent and Additional Rent which would have been payable by Tenant had this Lease not been so terminated, or had Landlord not so reentered the Premises, such payments to be made upon the due dates therefor specified herein following such termination or re-entry and continuing until the Expiration Date; provided, however, that if Landlord shall relet the Premises, Landlord shall credit Tenant, up to the amount due from Tenant, with the net rent received by Landlord for such reletting after deducting from the first installments of such rent received the expenses incurred or paid by Landlord in terminating this Lease or in re-entering the Premises and in securing possession thereof, as well as the expenses of reletting, including legal expenses, attorneys' fees and disbursements, brokerage commissions, alteration costs and other expenses incurred for keeping the Premises in good order or for preparing the same for reletting. Any suit brought to collect the amount of the aforesaid damages for any month or months shall not prejudice in any way the rights of Landlord to collect the damages for any subsequent month or months by a similar proceeding. Nothing contained herein shall be deemed to require Landlord to postpone suit until the date when the Lease Term would have expired if it had not been so terminated under or pursuant to Section 19.2, or under any provision of law, or had Landlord not re-entered the Premises.

(c) The terms “re-enter” and “re-entry,” as used herein, are not limited to their technical legal meanings.

19.4 LIQUIDATED DAMAGES. Landlord may elect, as an alternative to the damages and charges provided for in Section 19.3(b)(iii), and in lieu of all other such damages thereafter accruing, to have Tenant pay the liquidated damages provided for below, which election may be made by notice given to Tenant at any time after the termination of this Lease under or pursuant to Section 19.2, above, and whether or not Landlord shall have collected any damages as hereinabove provided in Section 19.3. Upon such notice, Tenant shall promptly pay to Landlord, as liquidated damages, in addition to any damages collected or due from Tenant from any period prior to such notice, such a sum as at the time of such notice represents the amount of the excess, if any, of (i) the discounted present value, at a discount rate of [***], of the Annual Fixed Rent, Additional Rent and other charges which would have been payable by Tenant under this Lease for the remainder of the Lease Term if Tenant had fulfilled all of its obligations hereunder, over and above (ii) the discounted present value, at a discount rate of [***], of the Annual Fixed Rent, Additional Rent and other charges that would be received by Landlord (after deducting all reasonably estimated costs of reletting, including, without limitation, brokerage fees, advertising, required tenant improvements and concessions and attorneys’ fees) if the Premises were relet at the time of such notice for the remainder of the Lease Term at the fair rental value thereof at the time of such notice.

For the purposes of this Article, if Landlord elects to require Tenant to pay liquidated damages in accordance with this Section 19.4, (a) the total rent shall be computed by assuming Tenant’s Tax Payment and Tenant’s Share of Operating Expenses under Article 6 to be the same as were payable for the twelve (12) calendar months (or if fewer than twelve calendar months shall have elapsed since the date hereof, for the partial year, but annualized) immediately preceding such termination or re-entry, and (b) if the Premises or any part thereof shall have been relet by Landlord for the unexpired portion of the Lease Term, or any part thereof, before presentation of proof of such damages to any court, commission or tribunal, the amount of rent received upon such reletting shall be prima facie evidence of the fair rental value of the Premises, or part thereof, so relet during the term of such reletting.

19.5 RIGHTS IN THE EVENT OF TENANT’S BANKRUPTCY. Nothing contained in this Lease shall limit or prejudice the right of Landlord to prove for and obtain, in proceedings for the termination of this Lease by reason of bankruptcy or insolvency, an amount equal to the maximum allowed by any statute or rule of law in effect at the time when, and governing the proceedings in which, the damages are to be proved, whether or not the amount be greater, equal to, or less than the amount of the loss or damages referred to above.

19.6 WAIVER OF REDEMPTION, ETC.

(a) Tenant, for itself and any and all persons claiming through or under Tenant, including its creditors, upon the termination of this Lease or expiration of the Lease Term in accordance with the terms hereof, or in the event of entry of judgment for the recovery of the possession of the Premises in any action or proceeding, or if Landlord shall reenter the Premises by process of law or otherwise, hereby waives any right of redemption provided or permitted by any statute, law or decision now or hereafter in force, and does hereby waive, surrender and give up all rights or privileges which it or they may or might have under and by reason of any present or future law or decision, to redeem the Premises or for a continuation of this Lease for the Term of this Lease after having been dispossessed or ejected therefrom by process of law, or otherwise.

(b) If Tenant is in arrears in the payment of Annual Fixed Rent or Additional Rent, Tenant waives its right, if any, to designate the item against which any payments made by Tenant are to be credited and Tenant agrees that Landlord may apply any payment made by Tenant to any items as Landlord may see fit, irrespective of and notwithstanding any designation or request by Tenant as to the items against which any such payment shall be credited.

(c) Landlord, Tenant and all of Tenant's successors, subtenants, and assignees (Tenant and all of Tenant's successors, subtenants, and assignees are collectively for the purposes of this Section 19.6(c) referred to as "Tenant"), each hereby waive trial by jury in any action, proceeding or counterclaim brought by either against the other on any matter whatsoever arising out of or in any way connected with the Lease, the relationship of Landlord and Tenant and Tenant's use or occupancy of the Premises or any other claim (other than claim for personal injuries or property damage). It is further mutually agreed that if Landlord commences any summary proceedings for non-payment of rent, Tenant will not interpose and does hereby waive the right to interpose any counterclaim of whatever nature or description in such proceeding (unless failure to impose such counterclaim would preclude or otherwise prejudice Tenant from asserting in a separate action the claim that is the subject of such counterclaim).

19.7 ADDITIONAL RIGHTS OF LANDLORD.

(a) In the event of a breach or threatened breach by Tenant of any of its obligations under this Lease, Landlord shall also have the right to obtain an injunction. The remedies to which Landlord may resort under this Lease are cumulative and are not intended to be exclusive of any other remedies to which Landlord may be lawfully entitled at any time and Landlord may invoke any remedies allowed at law or in equity as if specific remedies were not provided for herein.

(b) If this Lease shall terminate under or pursuant to Section 19.2, or if Landlord shall re-enter the Premises under the provisions of this Article, or in the event of the termination of this Lease, or of re-entry by or under any summary dispossess or other proceeding or action or any provision of law by reason of Tenant's default hereunder, Landlord shall be entitled to retain all moneys, if any, paid by Tenant to Landlord, whether as advance rent, security or otherwise, but such moneys shall be credited by Landlord against any Annual Fixed Rent or Additional Rent due from Tenant at the time of such termination or re-entry or, at Landlord's option, against any damages payable by Tenant under this Article or pursuant to law.

19.8 LANDLORD'S DEFAULT. Landlord shall in no event be in default in the performance of any of Landlord's obligations hereunder unless and until (i) Landlord shall have failed to perform such obligations within thirty (30) days (or, if an obligation is such that it cannot be performed within thirty (30) days, Landlord shall have failed to commence with reasonable diligence performance of the same within such thirty (30) day period) after notice by Tenant to Landlord properly specifying wherein Landlord has failed to perform any such obligation, and (ii) Tenant has given notice to all parties as required under Section 17.2 hereof and such parties have not commenced the performance of such obligations within the time provided in Section 17.2.

19.9 FEES AND EXPENSES. If for any reason, any suit is initiated between Landlord and Tenant to interpret or enforce any provision of this Lease, the prevailing party in such suit shall be entitled to recover from the other party its legal costs, expert witness expenses, and reasonable attorneys' fees, as fixed by the court. Subject to the immediately preceding sentence, Landlord shall be entitled to recover all reasonable costs and expenses, attorneys' fees and disbursements and other fees incurred by Landlord in connection with (i) the enforcement by Landlord of any obligation of Tenant under this Lease; (ii) the preservation and enforcement of Landlord's rights and remedies in connection with this Lease; (iii) any unsuccessful attempt by Tenant to enforce any obligation or purported obligation of Landlord under this Lease; (iv) any unsuccessful action or proceeding brought by Tenant against Landlord related to this Lease; and (v) any voluntary or involuntary bankruptcy case, proceeding or action by or on behalf of Tenant, including, without limiting the generality of the foregoing, any and all expenses and attorneys' fees incurred by Landlord related to (A) the assumption or rejection of this Lease, including attempts by Tenant to extend any deadlines related to such assumptions or rejections; (B) the filing of proof(s) of claim by Landlord, and any defense of such proof(s) of claim; (C) the assignment of this Lease; and (D) the reorganization or liquidation of Tenant.

ARTICLE 20

MISCELLANEOUS

20.1 WAIVER. Failure on the part of Landlord or Tenant to complain of any action or non-action on the part of the other, no matter how long the same may continue, shall never be a waiver by Tenant or Landlord, respectively, of any of the other's rights hereunder.

No waiver by Landlord of any condition precedent to the execution or effectiveness of this Lease, nor any failure by Tenant to deliver any security deposit, letter of credit, pre-paid rent, financial information, guaranty or other item required upon the execution and delivery of this Lease, shall be construed as excusing satisfaction of any such condition or the delivery of any such item by Tenant, and Landlord reserves the right to declare the failure of Tenant to satisfy any such condition or deliver any such item a default under this Lease. Without limiting the foregoing, in no event shall Tenant be permitted to move into the Premises for the conduct of its business unless Tenant has delivered any security deposit, letter of credit, pre-paid rent, and/or guaranty required under this Lease. Further, no waiver at any time of any of the provisions hereof by Landlord or Tenant shall be construed as a waiver of any of the other provisions hereof, and a waiver at any time of any of the provisions hereof shall not be construed as a waiver at any subsequent time of the same provisions. The consent or approval of Landlord or Tenant to or of any action by the other requiring such consent or approval shall not be construed to waive or render unnecessary Landlord's or Tenant's consent or approval to or of any subsequent similar act by the other.

No payment by Tenant, or acceptance by Landlord, of a lesser amount than shall be due from Tenant to Landlord shall be treated otherwise than as a payment on account. The acceptance by Landlord of a check for a lesser amount with an endorsement or statement thereon, or upon any letter accompanying such check, that such lesser amount is payment in full, shall be given no effect, and Landlord may accept such check without prejudice to any other rights or remedies which Landlord may have against Tenant. Further, the acceptance by Landlord of Annual Fixed Rent, Additional Rent or any other charges paid by Tenant under this Lease shall not be or be deemed to be a waiver by Landlord of any default by Tenant, whether or not Landlord knows of such default, except for such defaults as to which such payment relates and then only to the extent of the amount of such payment. If Landlord and Tenant shall now or hereafter enter into any agreement for the renewal of this Lease at the expiration of the Lease Term, the execution of such renewal agreement between Landlord and Tenant prior to the expiration of the Lease Term shall not be considered a vested right in Tenant to such further term so as to prevent Landlord from terminating this Lease and any such extension or renewal thereof if Landlord became entitled so to do during the remainder of the original Lease Term; and if Landlord shall so terminate this Lease, any such renewal or extension previously entered into between Landlord and Tenant or the right of Tenant to any such renewal or extension shall also be terminated thereby. Any right herein contained on the part of Landlord to terminate this Lease shall continue during any extension or renewal hereof and any default or Event of Default which occurs and is not cured prior to the commencement of a renewal term or extension of the Lease Term shall continue as such in and during such renewal term or extension of the Lease Term.

20.2 CONSENTS. Wherever in this Lease Landlord's consent or approval is required and Landlord has expressly agreed in writing that such consent or approval shall not be unreasonably withheld, if Landlord shall refuse such consent or approval Tenant in no event shall be entitled to and shall not make any claim, and Tenant hereby waives any claim, for money damages (nor shall Tenant claim any money damages by way of set-off, counterclaim or defense) based upon any assertion by Tenant that Landlord unreasonably withheld or unreasonably delayed its consent or approval. Tenant's sole remedy in such circumstance shall be an action or proceeding to enforce any such provision by way of specific performance, injunction or declaratory judgment. Where Landlord has not so expressly agreed in writing, it is the express intent of the parties that any such consent shall be given or required only in the sole, absolute and unfettered discretion of Landlord, and may be withheld for any reason whatsoever.

20.3 QUIET ENJOYMENT. Landlord agrees that, upon Tenant's paying the Annual Fixed Rent, Additional Rent and other charges herein reserved, and performing and observing the covenants, conditions and agreements hereof upon the part of Tenant to be performed and observed, Tenant shall and may peaceably hold and enjoy the Premises during the term of this Lease, without interruption or disturbance from Landlord or persons claiming through or under Landlord, subject, however, to the terms of this Lease and to the terms and conditions of all Underlying Leases and all mortgages which now or hereafter affect the Premises. This covenant shall be construed as running with the Land to and against subsequent owners and successors in interest, and is not, nor shall it operate or be construed as, a personal covenant of Landlord, except to the extent of Landlord's interest in the Land and Building, and this covenant and any and all other covenants of Landlord contained in this Lease shall be binding upon Landlord and upon such subsequent owners and successors in interest of Landlord's interest under this Lease, to the extent of their respective interests in the Land and Building, as and when they shall acquire same and then only for so long as they shall retain such interest.

20.4 SURRENDER.

(a) No act or thing done by Landlord during the Lease Term shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept such surrender shall be valid, unless in writing signed by Landlord. No employee of Landlord or of Landlord's agents shall have any power to accept the keys of the Premises prior to the termination of this Lease; provided, however, that the foregoing shall not apply to the delivery of keys to Landlord or its agents in its (or their) capacity as managing agent or for purpose of emergency access. In any event, however, the delivery of keys to any employee of Landlord or of Landlord's agents shall not operate as a termination of this Lease or a surrender of the Premises.

(b) Upon the expiration or earlier termination of the Lease Term, or upon any re-entry by Landlord of the Premises, Tenant shall quit and surrender the Premises to Landlord vacant, broom clean and in good order, condition and repair, except for ordinary wear and tear, damage by fire or other casualty, if any, and other conditions requiring repair, if any, which are not the obligation of Tenant to repair under the terms of this Lease, and Tenant shall remove all of Tenant's Property therefrom and shall restore the Premises to the extent required under any of the other provisions of this Lease. Tenant shall repair any damage to the Premises occasioned by the removal by Tenant or any person claiming under Tenant of any of Tenant's Property and any Specialty Alterations required to be removed pursuant to this Lease. At Landlord's option, Tenant shall also remove all wiring and cabling located in the Premises including, without limitation, those located in the ceiling plenums. Tenant's obligations pursuant to this paragraph shall survive the expiration or sooner termination of the Lease Term. Tenant expressly waives, for itself and for anyone claiming through or under Tenant, any rights which Tenant may have under the provisions of Section 2201 of the New York Civil Practice Law and Rules and of any successor law of like import then in force in connection with any holdover summary proceedings which Landlord may institute to enforce the foregoing provisions of this paragraph.

20.5 BROKER.

(a) Tenant warrants and represents that Tenant has not dealt with any broker in connection with the consummation of this Lease other than the brokers, persons or firms designated in Section 1.2 hereof. In the event any claim is made against Landlord by any other broker or agent alleging dealings with Tenant, Tenant shall defend Landlord against such claim, using counsel approved by Landlord, such approval not to be unreasonably withheld, and save harmless and indemnify Landlord on account of any loss, cost, damage and expense (including, without limitation, reasonable attorneys' fees and disbursements) which may be suffered or incurred by Landlord by reason of such claim. Landlord agrees that it shall be solely responsible for the payment of brokerage commissions to the brokers, persons or firms designated in Section 1.2 hereof.

(b) Landlord warrants and represents that Landlord has not dealt with any broker in connection with the consummation of this Lease other than the brokers, persons or firms designated in Section 1.2 hereof. In the event any claim is made against Tenant by any broker or agent alleging dealings with Landlord, Landlord shall defend Tenant against such claim, using counsel approved by Tenant, such approval not to be unreasonably withheld, and save harmless and indemnify Tenant on account of any loss, cost, damage and expense (including, without limitation, reasonable attorneys' fees and disbursements) which may be suffered or incurred by Landlord by reason of such claim.

20.6 INVALIDITY OF PARTICULAR PROVISIONS. If any term or provision of this Lease, or the application thereof to any person or circumstance, shall to any extent be invalid or unenforceable, the remainder of this Lease, or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term and provision of this Lease shall be valid and be enforced to the fullest extent permitted by law.

20.7 PROVISIONS BINDING, ETC. The obligations of this Lease shall run with the Land, and except as herein otherwise provided, the terms hereof shall be binding upon and shall inure to the benefit of the successors and assigns, respectively, of Landlord and Tenant and, if Tenant shall be an individual, upon and to his heirs, executors, administrators, successors and assigns. The reference contained herein to successors and assigns of Tenant is not intended to constitute a consent to assignment by Tenant, but has reference only to those instances in which Landlord may hereafter give consent to a particular assignment as required by the provisions of Article 13 hereof. This Lease shall be construed as though the covenants herein between Landlord and Tenant are independent and not dependent and Tenant hereby expressly waives the benefit of any law to the contrary. Except as otherwise set forth in this Lease, the obligations of Landlord and Tenant under this Lease shall not survive the expiration or sooner termination of this Lease.

20.8 NO RECORDING. Tenant agrees not to record this Lease (whether directly or indirectly), or a memorandum or short form of this Lease or any other document related thereto.

20.9 NOTICES. Whenever, by the terms of this Lease, any notice, demand, request, approval, consent or other communication (each of which shall be referred to as a "notice") shall or may be given either to Landlord or to Tenant, such notice shall be in writing and shall be deemed sufficiently given or rendered if (i) hand delivered, or (ii) sent by certified or registered United States mail, postage prepaid, return receipt requested, or (iii) sent by reputable overnight delivery service, such as UPS or FedEx, as follows:

(i) If intended for Landlord, addressed to Landlord at the Present Mailing Address of Landlord set forth on the first page of this Lease (or to such other address or addresses as may from time to time hereafter be designated by Landlord by like notice), Attention: Karen Noy, with a copy to:

Vinson & Elkins LLP
The Grace Building
1114 Avenue of the Americas
New York, New York 10036
Attention: Adam M. Endick, Esq.

(ii) If intended for Tenant, addressed to Tenant at the Present Mailing Address of Tenant set forth on the first page of this Lease until the date that Tenant occupies the Premises for the conduct of its business, and thereafter at the Premises, Attention: Blaine Davis, CFO, with a copy to:

Cooley LLP
55 Hudson Yards
New York, New York 10001
Attention: Daniel A. Goldberger, Esq.

In no event shall the validity of any notice actually given to Landlord or Tenant be affected by any failure to deliver copies of such notices to counsel as hereinabove provided. Any notice to be given by any party may be given by such party's attorney. Notwithstanding anything to the contrary contained herein, rent bills and statements regarding Taxes and Operating Expenses shall be deemed sufficiently given or rendered if sent by regular United States mail.

20.10 WHEN LEASE BECOMES BINDING. Employees or agents of Landlord have no authority to make or agree to make a lease or any other agreement or undertaking in connection herewith. The submission of this document for examination and negotiation does not constitute an offer to lease, or a reservation of, or option for, the Premises, and this document shall become effective and binding only upon the execution and delivery hereof by both Landlord and Tenant.

20.11 HEADINGS. The Article and Section headings throughout this Lease and the Table of Contents hereof are for convenience and reference only, and the words contained therein shall in no way be held to explain, modify, amplify or aid in the interpretation, construction or meaning of the provisions of this Lease.

20.12 SUSPENSION OF SERVICES.

(a) Landlord reserves the right to interrupt, curtail or suspend the services required to be furnished by Landlord under Section 7.3 and Exhibit D when the necessity therefor arises by reason of accident, repairs, emergency, mechanical breakdown or governmental preemption or restriction, or when required by any law, order or regulation of any Federal, State, County or municipal authority, or as the result of the making by Landlord of any additions, improvements or installations in the Building or for any cause beyond the reasonable control of Landlord. Landlord shall use reasonable diligence to complete all required repairs or other necessary work as quickly as reasonably possible so that Tenant's inconvenience resulting therefrom may be for as short a period of time as circumstances will reasonably permit. No diminution or abatement of rent or other compensation shall or will be claimed by Tenant as a result of, nor shall this Lease or any of the obligations of Tenant be affected or reduced by reason of, any such interruption, curtailment or suspension.

(b) Provided no Event of Default exists, if for any reason other than (i) the negligence, willful misconduct, breach of the provisions of this Lease or violation of law by Tenant Parties or (ii) on account of Force Majeure, Landlord shall fail to supply services, perform repairs or maintenance, provide access or comply with Laws, in any case which Landlord is obligated under the terms of this Lease to supply, perform, provide or comply with, for more than ten (10) consecutive Operating Days after written notice thereof is delivered by Tenant to Landlord, and as a result of such failure the Premises is rendered Untenantable, then, as Tenant's sole and exclusive remedy, Tenant's obligation to pay Annual Fixed Rent shall be abated on a pro rata basis, from and after the eleventh (11th) Operating Day after such notice to Landlord until such until such condition is cured or Tenant recommences use or occupancy of such portion of the Premises. "Untenantable" means that Tenant shall be unable to occupy and use the Premises (including due to lack of access) for the ordinary conduct of Tenant's business, and that Tenant shall actually not be occupying or using the Premises or the applicable portion thereof for any use (other than emergency access).

20.13 RULES AND REGULATIONS.

(a) Landlord shall have the right, from time to time during the term of this Lease, to make reasonable and non-discriminatory changes in, and reasonable and non-discriminatory additions to, the rules and regulations set forth in Exhibit E, provided that such changes or additions:

(i) shall be similar to rules and regulations of comparable first-class office, laboratory and research buildings,

(ii) shall not apply to matters other than matters similar to those covered in the rules and regulations set forth in Exhibit E, and

(iii) do not unreasonably interfere with the use of the Premises by Tenant.

Said rules and regulations, as the same may be modified in accordance with this Section from time to time, are hereinafter called the "Rules and Regulations".

(b) Landlord shall have the right, from time to time during the term of this Lease, to promulgate reasonable and non-discriminatory rules and regulations with respect to the use and operation of the laboratories in the Building, provided that such rules and regulations shall be similar to laboratory rules and regulations of comparable first-class office, laboratory and research buildings, and

Said rules and regulations, as the same may be modified from time to time, are hereinafter called the "Lab Rules and Regulations".

(c) The right to dispute the reasonableness of any change in the Rules and Regulations or the Lab Rules and Regulations upon Tenant's part, or the non-discriminatory nature of any such change in the Rules and Regulations or the Lab Rules and Regulations or their enforcement, shall be deemed waived unless the same is asserted by service of a notice upon Landlord within thirty (30) days after notice is given to Tenant of the adoption of any such change.

(d) Nothing in this Lease shall be construed to impose upon Landlord any duty or obligation to enforce the Rules and Regulations or the Lab Rules and Regulations or terms, covenants or conditions in any other lease against any other tenant. Landlord shall not be liable to Tenant for violation of the Rules and Regulations or the Lab Rules and Regulations or of any other lease by other tenants or occupants of the Building, or their servants, agents, visitors or licensees.

(e) If any inconsistencies between this Lease and any Rules and Regulations (now existing or hereafter adopted) or Lab Rules and Regulations (now existing or hereafter adopted) shall be determined to exist, the provisions of this Lease shall prevail.

20.14 DEVELOPMENT RIGHTS. Tenant hereby expressly and irrevocably waives any and all right(s) it may have in connection with any zoning lot merger or transfer of development rights with respect to the Premises including, without limitation, any rights it may have to be a party to, to contest, or to execute, any Declaration of Restrictions (as such term is defined in Section 12-10 of the Zoning Resolution of the City of New York effective December 15, 1961 and as subsequently amended) with respect to the Premises, which would cause the Premises to be merged with or unmerged from any other zoning lot pursuant to such Zoning Resolution or to any document of a similar nature and purpose, and Tenant agrees that this Lease shall be subject and subordinate to any Declaration of Restrictions or any other document of similar nature and purpose now or hereafter affecting the Property. In confirmation of such subordination and waiver, Tenant shall execute and deliver promptly any certificate or instrument that Landlord reasonably may request and, in connection therewith, Tenant hereby irrevocably constitutes and appoints Landlord as Tenant's attorney-in-fact to execute any such certificate or instrument for and on behalf of Tenant, such power of attorney being coupled with an interest.

20.15 ESTOPPEL CERTIFICATES. Each party agrees, at any time and from time to time, as reasonably requested by the other party, upon not less than ten (10) days' prior notice, to execute and deliver to the other a written certified statement executed and acknowledged by an appropriate individual representing such party (a) stating that this Lease is then in full force and effect and has not been modified (or if modified, setting forth all modifications), (b) setting forth the then Annual Fixed Rent and Additional Rent, (c) setting forth the date to which the Annual Fixed Rent, Additional Rent and other charges, if any, have been paid, (d) stating whether or not, to the best knowledge of the signatory, the other party is in default under this Lease, and if so, setting forth the specific nature of all such defaults, (e) stating the amount of the security deposit, if any, held by Landlord under this Lease, (f) stating whether there are any subleases affecting the Premises, (g) stating the address of the person to which all notices and communication under this Lease shall be sent, (h) stating the Commencement Date, the Rent Commencement Date and the Expiration Date, (i) if applicable, stating whether or not there are any amounts of contribution by Landlord towards the cost of Tenant's work not yet advanced to Tenant, (j) stating what portion of the Premises Tenant is in possession and occupancy of pursuant to this Lease, (k) if applicable, all work required to be completed by Landlord in connection with preparing the Premises for Tenant's initial occupancy has been completed by Landlord, and (l) as to any other matters reasonably requested by the party requesting such certificate. The parties acknowledge that any statement delivered pursuant to this Section 20.15 may be relied upon by others with whom the party requesting such certificate may be dealing, which may, for Landlord, include, without limitation, any purchaser or owner of the Land or the Building, or of Landlord's interest (directly or indirectly) in the Land or the Building or any Underlying Lease, or by any Mortgagee or Overlandlord, or by any purchaser of the interest of any Mortgagee or Overlandlord (directly or indirectly) in the Land or the Building, or by any prospective or actual sublessee of the Premises or assignee of this Lease, or permitted transferee of or successor to Tenant. Together with its response to each such request hereunder, Tenant shall provide to Landlord a similar written statement certified to Landlord with respect to each sublease or other occupancy agreement from every subtenant and other occupant of the Premises.

20.16 SELF-HELP. Landlord may, but shall not be obligated to, cure, at any time, upon reasonable notice given to Tenant (except in any emergency where no such notice shall be required), any default by Tenant under this Lease without waiving or releasing Tenant from any obligations of Tenant in this Lease contained. All costs and expenses incurred by Landlord in curing a default, including, without limitation, attorneys' fees, together with interest on the amount of costs and expenses so incurred at the Lease Interest Rate, shall be paid by Tenant to Landlord on demand, and shall be recoverable as Additional Rent.

20.17 HOLDING OVER. If Tenant remains in possession of the Premises after the expiration or other termination of the Lease Term, then, at Landlord's option, Tenant shall be deemed to be occupying the Premises as a month-to-month tenant only, at a monthly rental equal to (i) for the first thirty (30) days of such holding over, the greater of (a) one hundred fifty percent (150%) of the Annual Fixed Rent and any Additional Rent payable hereunder during the last month of the Lease Term and (b) one hundred fifty percent (150%) of the then current market rent for the Premises and (ii) thereafter, the greater of (a) two hundred percent (200%) of the Annual Fixed Rent and any Additional Rent payable hereunder during the last month of the Lease Term and (b) two hundred percent (200%) of the then current market rent for the Premises, and otherwise on the terms and conditions set forth in this Lease, as far as applicable. Tenant shall also pay all Additional Rent payable under the terms of this Lease, prorated for each month during which Tenant remains in possession. Such month-to-month tenancy may be terminated by Landlord effective as of the last day of any calendar month by delivery to Tenant of notice of such termination prior to the first day of such calendar month. Landlord waives no rights against Tenant by reason of accepting any holding over by Tenant and Tenant shall defend, indemnify and hold Landlord harmless from and against any and all claims, losses and liabilities for damages resulting from failure to surrender possession within forty-five (45) days after the Expiration Date, including, without limitation, any claims made by any succeeding tenant and any lost profits, and such obligations shall survive the expiration or sooner termination of this Lease. The provisions of this Section 20.17 shall not in any way be deemed to (i) permit Tenant to remain in possession of the Premises after the Expiration Date or sooner termination of this Lease, or (ii) imply any right of Tenant to use or occupy the Premises upon expiration or termination of this Lease and the Lease Term, and no acceptance by Landlord of payments from Tenant after the Expiration Date or sooner termination of the Lease Term shall be deemed to be other than on account of the amount to be paid by Tenant in accordance with the provisions of this Section 20.17. Tenant's obligations under this Section 20.17 shall survive the expiration or earlier termination of this Lease.

20.18 RENT CONTROL. If any of the Annual Fixed Rent or Additional Rent payable under the terms and provisions of this Lease shall be or become uncollectible, reduced or required to be refunded because of the laws and requirements of any public authorities, Tenant shall enter into such agreement(s) and take such other steps (without additional expense to Tenant) as Landlord may request and as may be legally permissible to permit Landlord to collect the maximum rents which from time to time during the continuance of such legal rent restriction may be legally permissible (and not in excess of the amounts reserved therefor under this Lease). Upon the termination of such legal rent restriction, (a) the rent shall become and thereafter be payable in accordance with the amounts reserved herein for the periods following such termination and (b) Tenant shall pay to Landlord, to the maximum extent legally permissible, an amount equal to (i) the rent which would have been paid pursuant to this Lease but for such legal rent restriction, less (ii) the rent actually paid by Tenant during the period such legal rent restriction was in effect.

20.19 COUNTERPARTS. This Lease may be executed in several counterparts, each of which shall be deemed an original, and such counterparts together shall constitute but one and the same instrument.

20.20 ENTIRE AGREEMENT. This Lease (including the Exhibits attached hereto and all supplementary agreements provided for herein) constitutes the entire agreement between the parties hereto and supersedes all prior dealings between them, and all negotiations, considerations, representations and understandings between Landlord and Tenant are merged herein. There are no verbal or collateral understandings, agreements, representations or warranties not expressly set forth in this Lease. No act or omission of any employee or agent of Landlord shall alter, change or modify any of the provisions hereof, and no subsequent alteration, amendment, change or addition to this Lease shall be binding upon Landlord or Tenant, unless reduced to writing and signed by the party or parties to be charged therewith.

20.21 NO PARTNERSHIP. The relationship of the parties hereto is that of landlord and tenant and no partnership, joint venture or participation is hereby created.

20.22 SECURITY DEPOSIT.

(a) Upon execution by Tenant of this Lease, Tenant shall deposit (the "Cash Deposit") with Landlord, in cash, an amount equal to the Security Deposit as security for the performance by Tenant of all obligations on the part of Tenant hereunder. Within [***] days after the date hereof, Tenant shall furnish to Landlord, at Tenant's sole cost and expense, a clean, irrevocable and unconditional letter of credit (the "Letter of Credit") drawn in favor of Landlord substantially in the form attached hereto as Exhibit F, and Landlord, within [***] Operating Days after receipt of the Letter of Credit, shall return to Tenant any portion of the Cash Deposit then held by Landlord. The Letter of Credit shall have a face amount equal to the amount of the Security Deposit and shall be assignable, upon request, to any Overlandlord, Mortgagee or successor to Landlord at no additional charge to Landlord. Any Letter of Credit which replaces the initial Letter of Credit delivered hereunder is referred to as a "Replacement Letter". Any Replacement Letter shall be in a face amount at least equal to the Security Deposit then required hereunder. The initial Letter of Credit and any Replacement Letter are herein sometimes referred to simply as a "Letter". Each Letter shall be issued by and drawn on a commercial bank acceptable to Landlord in its reasonable discretion and at a minimum having a long-term issuer credit rating from Standard & Poor's Professional Rating Service of A or a comparable rating from Moody's Professional Rating Service. If the issuer's credit rating is reduced below A, or if the financial condition of such issuer changes in any other materially adverse way, then Landlord shall have the right to require that Tenant obtain from a different issuer a Replacement Letter that complies in all respects with the requirements of this Section within [***] days following Landlord's written demand. If the issuer of any Letter held by Landlord is placed into receivership or conservatorship by the Federal Deposit Insurance Corporation or any successor or similar entity then, effective as of the date such receivership or conservatorship occurs, said Letter shall be deemed not to meet the requirements of this Section, and Tenant shall obtain from a different issuer a Replacement Letter that complies in all respects with the requirements of this Section within [***] days following the date such receivership or conservatorship occurs. In any event, Tenant shall, not later than [***] days prior to the expiration of the term of the initial Letter of Credit or any Replacement Letter, deliver to Landlord a Replacement Letter such that a Letter shall be in effect at all times after the date of this Lease until [***] days beyond the end of the Lease Term, and any extensions or renewals thereof, and thereafter so long as Tenant is in occupancy of any part of the Premises. If Tenant fails to deliver to Landlord a Replacement Letter within the time limits set forth in this Section, Landlord may, without limiting Landlord's other rights or remedies on account of such failure, draw down the full amount of the existing Letter without notice or demand and retain and apply the proceeds thereof as substitute security subject to the provisions of this Section. Tenant shall be responsible for the payment of any and all costs incurred with the review of any Replacement Letter (including without limitation Landlord's reasonable attorneys' fees). Any and all fees or costs charged by the issuer in connection with the issuance, maintenance or transfer of the Letter shall be paid by Tenant. If a Letter is lost, mutilated, stolen, or destroyed, Tenant shall cooperate with Landlord to have the Letter replaced. The Security Deposit (whether a Letter, cash or other collateral) will not operate as a limitation on any recovery to which Landlord may be entitled.

(b) Landlord shall hold the Cash Deposit or Letter as security for the performance by Tenant of all obligations on the part of Tenant hereunder. If Tenant defaults in respect of any of Tenant's obligations hereunder, including but not limited to payment of Annual Fixed Rent or Additional Rent, or if Tenant remains in occupancy of any part of the Premises beyond the expiration of the Lease Term, Landlord shall have the right from time to time, without notice and without prejudice to any other remedy Landlord may have on account thereof, and upon presentation of a certificate of demand, to draw upon the Cash Deposit or any Letter and apply any funds so drawn to Landlord's damages arising from, or to cure, any default by Tenant, whether such damages accrue before or after summary proceedings or other reentry by Landlord. If Landlord shall so apply any funds, Tenant shall, within [***] days following Landlord's written demand, restore the Cash Deposit or Letter to the face amount required hereunder or obtain a Replacement Letter. Landlord shall have the right to hold and draw upon the Cash Deposit or Letter pursuant hereto until [***] days after (i) the expiration of the Lease Term (or the applicable extension or renewal period, if any) or (ii) the date Tenant has vacated the Premises, whichever is later. If there then exists no default by Tenant in any of the terms or conditions hereof, Landlord shall return the Letter, or, if applicable, the remaining proceeds thereof, to Tenant. If Landlord conveys Landlord's interest under this Lease, the Cash Deposit, any Letter or, if applicable, the proceeds thereof, shall be turned over and assigned by Landlord to Landlord's grantee (or, at Landlord's election, with respect to any Letter, Tenant shall furnish Landlord's successor with a new Replacement Letter showing such successor as payee, provided that the original Letter then outstanding shall be simultaneously returned to Tenant). From and after any such transfer, assignment or return, Tenant agrees to look solely to such grantee for proper application of the funds in accordance with the terms of this Section and the return thereof in accordance herewith. No Overlandlord or Mortgagee shall be responsible to Tenant for the return or application of the Cash Deposit, any Letter, or, if applicable, the proceeds thereof, whether or not it succeeds to the position of Landlord hereunder, unless such Cash Deposit or Letter shall have been received in hand by, and assigned to, such Overlandlord or Mortgagee.

(c) On the [***] anniversary of the Rent Commencement Date (the "Burn Down Date"), provided (i) no Event of Default shall then exist and (ii) Tenant shall then have liquid assets and a tangible net worth, determined in accordance with GAAP, no less than Tenant's liquid assets and tangible net worth so determined as of the date hereof (the foregoing conditions set forth in clauses (i) and (ii) being herein referred to as the "Burn Down Conditions"), Tenant shall have the right to reduce the amount of the Security Deposit (by delivery of a Replacement Letter or an amendment to the existing Letter) to an amount (the "Burn Down Amount") equal to [***] monthly installments of the then current Annual Fixed Rent (it being acknowledged and agreed that the foregoing amounts described apply with respect to the Premises prior to the exercise of the Expansion Option and shall be adjusted as applicable after any exercise of the same). Landlord shall cooperate reasonably with Tenant to effect such reductions of the amount of the Letter of Credit. If on any Burn Down Date Tenant shall not have the right to reduce the Security Deposit due to the Burn Down Conditions not being satisfied, if the Burn Down Conditions subsequently become satisfied, then upon such satisfaction (and provided no Event of Default shall then exist), Tenant shall have the right to reduce the Security Deposit to the Burn Down Amount.

20.23 FINANCIAL STATEMENTS.

(a) Tenant represents and warrants to Landlord that (i) the financial statements of Tenant heretofore delivered to Landlord are true and correct and fairly reflect the financial condition and results of operation of Tenant and (ii) as of the date of this Lease, there has been no material adverse change in the condition, financial or otherwise, of Tenant from the date of such financial statements which could affect Tenant's ability to perform its obligations hereunder.

(b) During the Lease Term, within ninety (90) days following the end of Tenant's fiscal year and, from time to time, within ten (10) days after request from Landlord, Tenant shall deliver to Landlord a copy of Tenant's financial statements for Tenant's fiscal year just ended, certified by an independent certified public accountant as presenting fairly, in all material respects, the financial condition of Tenant and the results of its operations in accordance with GAAP; provided, however, that the foregoing shall be deemed satisfied if Tenant instead delivers to Landlord, annually, at the time the same is sent to Tenant's stockholders, a copy of Tenant's Annual Report to Stockholders in the form filed with the Securities and Exchange Commission.

(c) Any financial statements delivered by Tenant to Landlord, whether before or after the date of this Lease, may be delivered to and relied upon by any Overlandlord or Mortgagee or by other parties with whom Landlord may be dealing.

20.24 GOVERNING LAW, ETC. This Lease shall be governed by the laws of the State of New York applicable to agreements made and to be wholly performed within the State, as the same may from time to time exist. Landlord and Tenant agree that any claim or action relating to this Lease shall be brought and maintained exclusively in a state or federal court located in the Borough of Manhattan, State of New York, United States of America, and Tenant hereby submits to the jurisdiction of all such state and federal courts and waives any right to assert that such courts constitute an inconvenient forum. Tenant represents that it is not entitled to immunity from judicial proceedings and agrees that, in the event Landlord brings any suit, action or proceeding in New York or any other jurisdiction to enforce any obligation or liability of Tenant arising, directly or indirectly, out of or relating to this Lease, no immunity from such suit, action or proceedings will be claimed by or on behalf of Tenant.

20.25 CONDOMINIUM CONVERSION. Landlord may elect, at any time during the Term, to convert the Building to condominium ownership (a "Conversion"), and Tenant, at Landlord's expense, shall cooperate with Landlord as reasonably requested by Landlord in connection with a Conversion, provided that:

(a) no Conversion shall have the effect of increasing any charges payable by Tenant under this Lease (including, without limitation, Tenant's payments with respect to Taxes or PILOT), in each case above the amounts as could reasonably have been anticipated to have been payable in the absence of such Conversion and if any such increase shall result from such Conversion, then the amount of such increase shall be borne by Landlord and not by Tenant;

(b) the obligations of Landlord under this Lease shall, at Landlord's option, either (i) continue to be performed and observed by Landlord as set forth herein, or (ii) shall have been assumed in writing by (A) the successor landlord with respect to obligations hereunder to be performed within the Premises, and (B) the board of managers or equivalent governing body of the condominium association, with respect to obligations hereunder affecting the Building and the Building systems outside of the Premises;

(c) no Conversion shall in any other manner have the effect of (i) increasing Tenant's obligations or decreasing Tenant's rights, or (ii) decreasing Landlord's obligations (subject to Section 25.25(b) hereof) or increasing Landlord's rights;

(d) the condominium declaration shall, if permitted by law, expressly provide that this Lease is superior thereto in all respects (or if not so permitted, Tenant shall be given a non-disturbance agreement reasonably satisfactory to Tenant); and

(e) no Conversion shall have any effect on the payment of brokerage commissions in connection with this Lease.

20.26 CONFIDENTIALITY OF LEASE. Tenant agrees that this Lease and the terms contained herein will be treated as strictly confidential and except as required by law or the requirements of any securities, bond or commodities exchange applicable to Tenant, Tenant shall not disclose the same to any third party except for Tenant's partners, lenders, accountants and attorneys who have been advised of the confidentiality provisions contained herein and agree to be bound by the same. Except as regularly required by any securities, bond or commodities exchange applicable to Tenant, in the event Tenant is required by law to provide this Lease or disclose any of its terms, Tenant shall give Landlord prompt notice of such requirement prior to making disclosure so that Landlord may seek an appropriate protective order. If failing the entry of a protective order Tenant is compelled to make disclosure, Tenant shall only disclose portions of the Lease which Tenant is required to disclose and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded to the information so disclosed.

20.27 OFAC.

(a) As an inducement to Landlord to enter into this Lease, Tenant hereby represents and warrants that: (i) Tenant is not, nor is it owned or controlled directly or indirectly by, any person, group, entity or nation named on the Specially Designated Nationals and Blocked Persons List maintained by the Office of Foreign Assets Control of the United States Treasury ("OFAC") (any such person, group, entity or nation being hereinafter referred to as a "Prohibited Person"); (ii) Tenant is not (nor is it owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) Tenant (and any person, group, or entity which Tenant controls, directly or indirectly) has not conducted nor will conduct business nor has engaged nor will engage in any transaction or dealing with any Prohibited Person that either may cause or causes Landlord to be in violation of any OFAC rule or regulation, including without limitation any assignment of this Lease or any subletting of all or any portion of the Premises. In connection with the foregoing, it is expressly understood and agreed that (x) any breach by Tenant of the foregoing representations and warranties shall be deemed a default by Tenant under Section 19.1(e) of this Lease and shall be covered by the indemnity provisions of Section 11.1 above, and (y) the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Lease.

(b) As an inducement to Tenant to enter into this Lease, Landlord hereby represents and warrants that: (i) Landlord is not, nor is it owned or controlled directly or indirectly by, any person, group, entity or nation named on the Specially Designated Nationals and Blocked Persons List maintained by OFAC; (ii) Landlord is not (nor is it owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) Landlord (and any person, group, or entity which Landlord controls, directly or indirectly) has not conducted nor will conduct business nor has engaged nor will engage in any transaction or dealing with any Prohibited Person that either may cause or causes Landlord to be in violation of any OFAC rule or regulation, including without limitation any assignment of this Lease or any subletting of all or any portion of the Premises. In connection with the foregoing, it is expressly understood and agreed that (x) any breach by Landlord of the foregoing representations and warranties shall be deemed a default by Landlord under Section 19.1(e) of this Lease and shall be covered by the indemnity provisions of Section 11.1 above, and (y) the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Lease.

20.28 ELECTRONIC SIGNATURES. The parties acknowledge and agree that, subject to the terms of this paragraph, this Lease may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. "Electronic signature" shall mean faxed versions of an original signature or electronically scanned and transmitted versions (i.e., email of a pdf) of an original signature and, absent contrary written instructions by the transmitting party, the transmission of such an electronic signature by fax or email by one party hereto to the other party(ies) hereto shall constitute execution and delivery of this Lease by the transmitting party. Any party hereto executing this Lease by electronic signature shall promptly thereafter deliver such transmitting party's original signature to this Lease to the recipient party(ies), but the failure to do so shall not affect the validity of this Lease.

20.29 BUILDING NAME AND SIGNAGE.

(a) The Building may be designated and known by any name Landlord may choose and such designated name may be changed from time to time in Landlord's sole discretion. Tenant shall have no right to require Landlord to change the name of the Building, whether in connection with an assignment of this Lease or otherwise.

(b) Tenant shall have the right, at Tenant's sole cost and expense and in accordance with the provisions of Article 8 hereof, to install Building standard signage on the entry doors to the Premises identifying the name of Tenant. Landlord shall provide directional signage identifying Tenant in the elevator vestibule on the floor on which the Premises are located.

20.30 IDA PILOT PROGRAM. Tenant acknowledges that each of Landlord and Tenant derive substantial benefit from the Agency Lease. As a material inducement to Landlord's entering into this Lease, Tenant hereby agrees to the following:

(a) On the date of this Lease, Tenant shall deliver to Landlord the following:

(i) A counterpart to the Rider to Tenant Lease Agreement (the "Rider") in the form attached hereto as Exhibit H; and,

(ii) A counterpart to the Living Wage Agreement (the "LW Agreement") in the form attached hereto as Exhibit I.

(b) Tenant shall indemnify, defend and hold harmless Landlord Parties from and against any and all claims, damages, losses, actions, causes of actions, proceedings, liens, fines, penalties, costs, expenses and liabilities, including, without limitation, additional tax liabilities, arising out of (i) any "Event of Default" under the Agency Lease or any (ii) any claims made against Landlord by the IDA, the New York City Economic Development Corporation, any successor thereof or any other agency of New York City, occasioned by or arising out of any act or omission of Tenant including, without limitation, any act or omission resulting in a breach of any terms or conditions of the Rider, the LW Agreement or this Lease (including, without limitation, Sections 10.1 or 18(i) hereof).

20.31 EMISSIONS. Tenant shall be responsible for its allocable share of the payment, within thirty (30) days after demand as Additional Rent, of any portion of the fines, penalties and/or excess emissions charges incurred by Landlord in connection with applicable laws and requirements of public authorities (including, without limitation, Local Law 97) attributable to the consumption of utilities serving the Building in excess of the carbon or other emissions limit allocable to the Building (including, without limitation, Local Law 97), based on the Building's emissions limit in the aggregate for such calendar year in question. In addition to the foregoing, in the event Landlord performs improvements to the Building required or designed to reduce emissions, the costs of such improvements shall be included in Operating Expenses, notwithstanding anything contained in Article 6 above to the contrary, as amortized over the useful life thereof in accordance with Section 6.2.1(x) hereof.

20.32 REGULATORY REQUIREMENTS.

(a) Tenant acknowledges that Landlord's affiliate, [***] [***], is subject to certain securities industry rules and regulations, including, but not limited to, regulatory obligations applicable to an investment adviser registered with the U.S. Securities and Exchange Commission. For the term of this Agreement, Tenant will comply with all rules, policies and procedures reasonably required, and will reasonably cooperate with the Landlord and its affiliates as Landlord and its affiliates deem necessary, to fulfill their regulatory obligations.

(b) Tenant acknowledges that [***] is subject to U.S. securities laws that make it unlawful for any person to (i) purchase or sell the securities of a company as to which such person possesses material nonpublic information of the company ("MNPI") or (ii) disclose MNPI to another person under circumstances in which it is reasonably foreseeable that another person may purchase or sell securities of a company on the basis of such MNPI. Tenant agrees to not convey any MNPI about an issuer to Landlord and its affiliates absent a non-disclosure agreement with Landlord and/or its affiliates.

20.33 LAB AREA AND LAB REQUIREMENTS.

(a) Tenant shall have the right, subject to and in accordance with the terms of this Lease, to use certain of Landlord's furniture, fixtures, personal property and systems designated by Landlord (collectively, the "Lab Systems"), from time to time located in the Lab Area; provided, however, that Tenant shall use the Lab Systems in a manner that will not interfere with the rights of any tenants or occupants in the Building or the providers of the services associated with the Lab Systems.

(b) Landlord's sole obligation for providing the Lab Systems shall be (i) to provide the Lab Systems determined by Landlord in the exercise of its sole and absolute discretion, and (ii) to contract with one or more third parties to maintain the Lab Systems that are deemed by Landlord in the exercise of its sole and absolute discretion to need periodic maintenance in accordance with the manufacturer's or supplier's standard guidelines or otherwise. During any period of replacement, repair or maintenance of the Lab Systems when they are not operational (including, but not limited to, any delays thereto due to the inability to obtain parts or replacements), Landlord shall have no obligation to provide Tenant with alternative, supplemental, temporary or back-up Lab Systems. Tenant acknowledges and agrees that Landlord, in its sole and absolute discretion, may (i) reduce the Lab Area or Lab Systems from time to time in response to a lack of usage by Tenant or obsolescence or similar reasons, (ii) increase, replace or otherwise modify the Lab Area or Lab Systems and/or resources therein from time to time in response to the needs of Tenant or (iii) reconfigure, relocate or otherwise modify the Lab Area and/or Lab Systems. Landlord shall have no liability for any such reduction, increase, replacement, reconfiguration, relocation or modification of the Lab Area or Lab Systems, and none of the foregoing shall reduce the Annual Fixed Rent payable by Tenant hereunder. Tenant acknowledges and agrees that any such increases, replacements, reconfigurations, relocations or modifications may result in an increase in Lab Costs, and Tenant agrees to pay for any increases in Lab Costs resulting from the same. The terms and provisions of this paragraph shall survive the expiration or earlier termination of this Lease.

(c) Landlord makes no representations or warranties of any kind, express or implied, with respect to the Lab Area or Lab Systems, and Landlord disclaims any such representations or warranties. Without limiting the foregoing, Tenant expressly acknowledges and agrees that Landlord does not guaranty or warrant that the Lab Systems will be operational at all times, will be of sufficient capacity to accommodate Tenant's use thereof, will be free of Hazardous Substances, or will function or perform adequately, and Landlord shall not be liable for any damages resulting from any failure of the Lab Systems.

(d) Landlord, for itself and its employees, agents and contractors, reserves the right to refuse to perform any repairs or services in any portion of the Premises which, pursuant to Tenant's routine safety guidelines, practices or custom, or prudent industry practices, require any form of protective clothing or equipment other than safety glasses. In any such case, Tenant shall contract with parties who are reasonably acceptable to Landlord for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Lab Costs in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

(e) If Tenant or any Tenant Party uses the Lab Area or the Lab Systems, Tenant shall comply with (or cause to be complied with) all applicable federal, state and local laws concerning any Regulated Medical Waste that Tenant or any subtenant or occupant of the Premises produces, brings on, keeps, uses, stores, disposes or treats in or about the Premises or transported from the Premises. Tenant shall also comply with all applicable federal, state and local laws related to the health and safety of its employees. "Regulated Medical Waste" means any substance, gas, material or chemical, or any part thereof, which is defined or included in the definition of "regulated medical waste" or words of similar import under any applicable laws and requirements of public authorities, including, but not limited to, Section 27-1502 of the New York Environmental Conservation Law, 42 U.S.C. Section 6901 et seq., the Medical Waste Tracking Act of 1988 and Track XIII of the New York State Public Health Law and the regulations promulgated thereunder. The terms and provisions of this paragraph shall survive the expiration or earlier termination of this Lease.

(f) If Tenant or any Tenant Party uses the Lab Area or the Lab Systems and Tenant defaults in its obligations under this Section 20.33 or Section 20.13(b) hereof, Landlord shall have the right, in addition to any other rights and remedies available to Landlord pursuant to the terms and conditions of this Lease, to terminate this Lease, in which event this Lease shall terminate on the date fixed in Landlord's notice.

20.34 RIGHT OF FIRST OFFER.

(a) Provided that at the time of such exercise and on the date the space is delivered to Tenant (1) there exists no Event of Default that has occurred and is then continuing, (2) this Lease is in full force and effect, and (3) Original Tenant is in actual occupancy of one hundred percent (100%) of the rentable square feet of the Premises (collectively, the "ROFO Conditions"), then if at any time balance of the 3rd floor of the Building becomes "available for leasing" or is anticipated to become "available for leasing", and Landlord desires to lease such space, Landlord shall (i) so notify Tenant (a "ROFO Notice"), (ii) identify the space available (the "Offered Space"), (iii) set forth the date (the "ROFO Delivery Date") on which Landlord anticipates that the Offered Space can be leased pursuant to the exercise by Tenant of its rights under this Section 20.34, which date shall be no sooner than thirty (30) days after the delivery of such ROFO Notice and (iv) set forth the Fair Market Rent for the Offered Space determined by Landlord as of the date of the ROFO Notice (the "ROFO Offer"). Original Tenant shall, within thirty (30) days after receipt of the ROFO Notice, by written notice (the "ROFO Election Notice"), either (I) accept the ROFO Offer (and state in Tenant's notice whether Tenant accepts the Fair Market Rent specified by Landlord in the ROFO Offer for the Offered Space or, if Tenant does not accept such Fair Market Rent, specify Tenant's determination of the Fair Market Rent of the Offered Space), or (II) reject the ROFO Offer, it being understood that Tenant's failure to respond to the ROFO Offer as aforesaid shall be deemed a rejection thereof. Any election by Tenant to accept or reject the ROFO Offer shall be irrevocable. If Tenant fails to timely elect to exercise any option to lease any such Offered Space in accordance with this Section 20.34(a), then Tenant shall no longer be entitled to exercise the ROFO Option. Original Tenant's option to lease Offered Space under this Section 20.34 shall be referred to herein as the "ROFO Option".

(b) If Tenant accepts a ROFO Offer, Tenant shall, within thirty (30) days, subject to the terms of clause (d) below, after such election enter into an amendment to this Lease adding the Offered Space to the Premises and otherwise incorporating the terms contained in the ROFO Notice (or if Tenant does not accept the Fair Market Rent specified by Landlord in the ROFO Offer, then such amendment shall be entered into by Tenant within thirty (30) days after the date of the determination of the Fair Market Rent for the Offered Space as provided in this Section 20.34); provided, however, that Landlord shall have no obligation to enter into such amendment of this Lease, or make any such ROFO Offer, if at the time of entering into such amendment of this Lease, or making of such ROFO Offer, the ROFO Conditions are not then met. If Tenant shall fail to enter into such an amendment to this Lease within such thirty (30) day period and Landlord is willing to enter into such an amendment, then Tenant shall have no further rights under this Section 20.34 with respect to the Offered Space (it being agreed that time is of the essence with respect to the giving of such notice and the execution of such amendment), and Landlord shall be free to lease any or all of the Offered Space to a third party or parties from time to time on such terms and conditions as it may deem appropriate. If Tenant accepts the ROFO Offer, the Offered Space shall be delivered broom clean in its then "AS IS" condition (but free of any furniture and other personal property of the prior tenant) without representation or warranty by Landlord. Landlord shall have no obligation to remove improvements made to the Offered Space prior to delivery to Tenant, whether or not made by Landlord, nor shall Landlord have any obligation to prepare the Offered Space for Tenant's occupancy.

(c) If, within sixty (60) days after receipt of the ROFO Notice, Landlord and Tenant fail to reach agreement on the determination of the Fair Market Rent to be paid by Tenant for the Offered Space, then either Landlord or Tenant shall initiate the arbitration proceedings for such determination by notice to the other, and by designating in such notice the name and address of a Qualified Arbitrator. Fair Market Rent for any Offered Space shall be determined in the same fashion as FMV for the Premises during a Renewal Term is determined pursuant to Section 3.4.3 and the provisions of the Section 3.4.3 for determining Fair Market Rent for the Premises during a Renewal Term shall apply, *mutatis mutandis*, in respect of a determination of Fair Market Rent for the Offered Space.

(d) Notwithstanding anything to the contrary contained herein, Annual Fixed Rent with respect to any Offered Space shall be equal to 100% of the Fair Market Rent for the Offered Space. If, pursuant to the preceding provisions of this Section 20.34, the Fair Market Rent for the Offered Space has not been determined as of the actual ROFO Delivery Date thereof, Tenant shall pay on account of Annual Fixed Rent for the Offered Space Landlord's determination thereof until such final determination is made, with necessary adjustments between Landlord and Tenant to be made retroactively, by credit against the next installment(s) of Annual Fixed Rent becoming due with respect to the Offered Space, after a final determination of the Fair Market Rent for the Offered Space as provided in this Section 20.34. Annual Fixed Rent with respect to the Offered Space shall commence to be payable on the actual ROFO Delivery Date.

(e) Notwithstanding anything to the contrary contained herein, Tenant may only exercise the ROFO Option if (A) Landlord then intends to market the Offered Space after the initial lease-up thereof, (B) Tenant exercises its option to lease all of the Offered Space under this Section 20.34 that Landlord so intends to market (unless Landlord specifies in the ROFO Notice that Landlord is marketing portions the Offered Space in separate segments) and (C) the Offered Space is contiguous to the Premises. The term of the leasing of the Offered Space shall be coterminous with the then current Term.

(f) In the event Landlord fails or is unable to deliver the entire Offered Space to Tenant on the estimated ROFO Delivery Date thereof as a result of the holding over of the prior tenant or for any other reason (other than Landlord’s willful refusal to deliver possession thereof to Tenant after such space has been vacated by the prior tenant thereof), Landlord shall not be subject to any liability whatsoever for such failure or inability to deliver possession, and the exercise of the ROFO Option shall remain effective, but the Annual Fixed Rent and Additional Rent shall not commence with respect to the Offered Space until the date on which the same is actually delivered to Tenant. The foregoing is intended to be “an express provision to the contrary” under Section 223-a of the New York Real Property Law or any successor statute of similar import.

(g) As used in this Sections 20.34, the term "available for leasing" shall mean that Landlord reasonably anticipates that such space shall be available for Tenant to lease in accordance with the terms of this Section 20.34 after the expiration or earlier termination of the initial lease with respect to such space. Notwithstanding the foregoing, Tenant's rights under this Sections 20.34 shall be subject and subordinate to (A) any option or commitment hereafter held by any existing or future tenant with respect to the Offered Space or any portion thereof and (B) the renewal or extension of an expiring lease with any such tenant with respect to the Offered Space.

(h) Notwithstanding anything to the contrary contained herein, Tenant shall not have any ROFO Option during the final five (5) years of the Term unless, simultaneously with the exercise of the ROFO Option, Tenant also exercises the Renewal Option, if then available.

Signatures on next page.

EXECUTED in one or more counterparts by persons or officers hereunto duly authorized on the date set forth in Section 1.2 above.

LANDLORD:

345 PAS HOLDING LLC,
a Delaware limited liability company

By: */s/ Karen Noy*
Name: Karen Noy
Title: Authorized Signatory

TENANT:

PROTARA THERAPEUTICS INC.

By:
Name:
Title:

EXECUTED in one or more counterparts by persons or officers hereunto duly authorized on the date set forth in Section 1.2 above.

LANDLORD:

345 PAS HOLDING LLC,
a Delaware limited liability company

By: _____
Name:
Title:

TENANT:

PROTARA THERAPEUTICS INC.

By: */s/ Blaine Davis*
Name: Blaine Davis
Title: CFO

EXHIBIT A

LAND

ALL that certain plot, piece or parcel of land. situate, lying and being in the Borough of Manhattan. City. County and State of New York. bounded and described as follows:

BEGINNING at the corner formed by the intersection of the easterly side of 4th Avenue with the southerly side of 26th Street:

RUNNING THENCE easterly along the southerly side of 26th Street. 120 feet:

THENCE southerly parallel with 4th Avenue. 98 feet 9 inches to the center line of the block between 25th and 26th Streets;

THENCE westerly along the said center line of the block. 30 feet:

THENCE southerly and parallel with the easterly side of 4th Avenue. 98 feet 9 inches to the northerly side of 25th Street:

THENCE westerly along the northerly side of 25th Street, 90 feet to the easterly side of 4th Avenue:

THENCE northerly along the easterly side of 4th Avenue, 197 feet 6 inches to the southerly side of 26th Street. at the point or place of BEGINNING.

EXHIBIT B

PREMISES

The portion of the Building demised to Tenant pursuant to the Lease (the “Premises”) shall mean a portion of the rentable area on the third (3rd) floor of the Building substantially as shown on the floor plan(s) annexed to this Exhibit B and forming a part hereof within the outside walls of the Building, excluding the area occupied by Building stairs, fire towers, elevator shafts, flues, vents, stacks, pipe shafts and vertical ducts, with their enclosing walls (but including the area occupied by the shafts and machinery for any private elevators, pneumatic tubes, conveyors, mail chutes and the like installed by Tenant, and the interior walls and partitions enclosing such shafts and machinery).

EXHIBIT C

WORK LETTER

[***]

SCHEDULE C-1

Base Work

[see attached]

SCHEDULE C-2

Scheduled Tenant Changes

[***]

SCHEDULE C-3

Test Fit

[see attached]

EXHIBIT D

LANDLORD'S SERVICES

[***]

SCHEDULE 1 TO EXHIBIT D

CLEANING SPECIFICATIONS

[***]

EXHIBIT E

RULES AND REGULATIONS

1. Tenant shall not obstruct or encumber the sidewalks, entrances, passages, courts, elevators, vestibules, or corridors and halls outside of the Premises, nor shall such areas be used for any purpose other than ingress and egress to and from the Premises and for delivery of merchandise and equipment which delivery shall be completed in a prompt and efficient manner using elevators and passageways designated for such delivery by Landlord.

2. No awnings, air-conditioning units, fans or other projections shall be attached to or project through the outside walls or windows of the Building. Tenant shall not attach, hang or use any curtains, blinds, shades or screens, other than either mylar shades or other curtains, blinds, shades or screens that conform to Building standards or are otherwise approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing (but subject to the provisions of the Lease, including, but not limited to, Article 8 thereof), Tenant, at its sole cost and expense, shall be permitted to install so called "black-out" shades in its conference rooms; provided, however, if any of such shades are visible from the outside of the Building, then Landlord shall have the right to approve the same, which approval may be granted or withheld in Landlord's reasonable discretion. Tenant may not, under any circumstances apply mylar or other like films directly to Building glass. All electrical fixtures hung in offices or spaces along the perimeter of the Premises must be of a quality, type, design and bulb color approved by Landlord, such approval not to be unreasonably withheld, conditioned or delayed.

3. Except for signage required by applicable laws and requirements of public authorities or as otherwise provided in the Lease, Tenant shall not exhibit, inscribe, paint or affix any sign, advertisement, notice or other lettering (collectively, "Tenant Advertisement") on any part of the inside of the Premises if the same can be seen from the outside of the Premises. Except as otherwise expressly provided in the Lease, Tenant Advertisement may not be exhibited, inscribed, painted or affixed to any part of the outside of the Premises or the Building.

4. Tenant shall not permanently cover or obstruct the exterior windows that reflect or admit light into the Premises except as may be required by applicable laws and requirements of public authorities.

5. Tenant shall not, without Landlord's prior written consent, place any showcases or other articles in front of or affix such articles to any part of the exterior of the Building, nor place such articles in the halls, corridors or vestibules (other than within the Premises but in all events Tenant shall comply with applicable laws and requirements of public authorities), nor shall any article obstruct any air-conditioning supply or exhaust.

6. The water and wash closets and other plumbing fixtures shall not be used for any purposes other than those for which they were constructed, and no sweepings, rubbish, rags, acids or other substances shall be deposited therein. All damages resulting from any misuse of such fixtures in the Premises (or in the core bathrooms on the full floors of the Premises) shall be borne by Tenant unless caused by a Landlord Party.

7. Except as otherwise approved by Landlord or as otherwise permitted in accordance with the provisions of the Lease, Tenant shall not mark, paint, drill into, or in any way deface any part of the Premises or the Building, and no boring, cutting or stringing of wires shall be permitted, except with the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed.

8. Tenant, or any of Tenant's servants, employees, agents, sublessees, visitors or licensees, shall not at any time bring or keep upon the Premises any inflammable, combustible or explosive fluid, chemical or substance except such as are incidental to usual office occupancy and are properly safeguarded.

9. Tenant shall not install any additional locks or bolts of any kind upon any of the doors or windows, nor shall Tenant change existing locks or the mechanism thereof, unless Tenant promptly provides Landlord with the key or combination thereto. Tenant must, upon the termination of its tenancy, return to Landlord all keys to offices and toilet rooms and in the event of the loss of any keys furnished at Landlord's expense, pay the cost thereof. Notwithstanding the foregoing, subject to the applicable provisions of the Lease, Tenant, at its sole cost and expense, shall have the right to install a card key or other electronic or other entry system for the Premises; provided that at all times Tenant has provided Landlord with such master card keys or other "master" access rights for such card key or other electronic or other entry system.

10. Tenant shall not bring into or store any bicycles, vehicles or animals of any kind (except for animals to assist the handicapped) in or about the Premises or the Building; provided, however, (i) Tenant may bring bicycles into the Premises via the loading dock and freight elevator during Operating Hours in accordance with applicable laws and requirements of public authorities, including, without limitation, the New York City Bicycle Access to Office Buildings Law, and (ii) nothing set forth herein shall modify the rights of Tenant to bring bicycles into the Building or the Premises to the extent provided by applicable laws and requirements of public authorities.

11. Tenant shall remove and bring any safes, freight, furniture or bulky matter of any description into or out of the Premises in the manner and during the hours (which must be scheduled in advance) which are agreed to by Landlord and Tenant. Landlord reserves the right to inspect all safes, freight or other bulky articles to be brought into the Building and to exclude from the Building all safes, freight or other bulky articles which violate any of these Rules and Regulations or the Lease. Landlord shall have the right to prescribe the weight and position of safes and other objects of excessive weight, and no safe or other object whose weight exceeds the lawful load for the area, as the same may be reinforced as permitted under the Lease, upon which it would stand, shall be brought into or kept upon the Premises. If, in the reasonable judgment of Landlord, it is necessary to distribute the concentrated weight of any heavy object, Landlord shall so advise Tenant. Tenant shall be responsible for the payment of any and all costs incurred by Landlord as a result of any structural analysis, design or construction undertaken in response to Tenant's request to bring and keep any such safes, freight, furniture or other bulky matter in the Premises.

12. Landlord reserves the right to exclude from the Building all persons who do not present a pass signed or approved by Landlord or Tenant or who otherwise do not comply with Building security procedures. Landlord may require any person leaving the Building with any package or other object taken from the Premises to exhibit a pass from Tenant. Tenant shall comply with the security procedures implemented following the mutual agreement of Landlord and Tenant including provisions for approving companies delivering food and the manner of delivery.

13. No delivery persons or messengers shall be permitted to use the Building passenger elevators.

14. Tenant shall, at its expense, provide reasonable quantities of artificial light for the Landlord's employees doing janitor service or other cleaning, and making repairs or alterations in the Premises during such times as such parties are permitted to do so under the terms of the Lease.

15. Tenant's requirements for above standard services will be addressed only upon written notice delivered to Landlord's office at the Building. Building employees shall not perform any work or do anything outside of the regular duties unless under special instruction from the Landlord's office.

16. Canvassing, soliciting and peddling in the Building are prohibited and Tenant shall cooperate to prevent the same.

17. Tenant shall use commercially reasonable efforts to prevent the use in any space, or in the public halls of the Building, either by Tenant or by jobbers or others in the delivery or receipt of merchandise, of any hand trucks except those equipped with rubber tires and side guards.

18. Tenant shall control access to the Premises in accordance with reasonable security procedures implemented upon the mutual agreement of Landlord and Tenant.

19. Any person whose presence in the Building at any time shall, in the judgment of the Landlord, be prejudicial to the safety of the Building or of its tenants may be denied access to the Building or may be ejected therefrom. In case of invasion, riot, dangerous public excitement or other dangerous commotion, the Landlord may prevent all access to the Building during the continuance of the same, by closing the doors or otherwise, for the safety of the tenants and protection or property in the Building.

20. Smoking is prohibited at all times throughout any portion of the Building, including, but not limited to, the entrances thereto and the roof garden.

21. Tenant shall not make, or permit to be made within the Building, any unseemly or disturbing noises or unreasonably disturb or interfere with occupants of the Building (in any instance by more than a de minimis extent) by the use of any equipment, machinery, musical instrument, radio, television or in any other way.

22. Landlord shall have the right to prohibit any advertising which refers to the Building which, in Landlord's reasonable judgment, tends to impair the reputation of the Building and upon notice from Landlord, Tenant shall discontinue such advertising. The use of the Building address in the ordinary course of Tenant's business shall not constitute an advertisement.

23. Prior to Tenant's storing, placing, generating, manufacturing, refining, handling, or otherwise bringing on, in, under or around the Premises, the Building or Property any Hazardous Substances, Tenant shall notify Landlord of Tenant's intention to do any of the foregoing and shall register with Landlord any such Hazardous Substances, including, without limitation, the quantity, storage and use of the same.

In the event of any inconsistencies between the provisions of the Lease and the provisions of this Exhibit E (as opposed to additional detail or information in this Exhibit E that shall not be considered inconsistencies for purposes of this sentence), the provisions of the Lease shall prevail.

EXHIBIT F

FORM OF LETTER OF CREDIT

[***]

EXHIBIT G

FORM OF COMMENCEMENT DATE AGREEMENT

Agreement made this ___ day of _____, 20__, between _____, a _____ having an office c/o Deerfield Management Company, L.P., 780 Third Avenue, 37th Floor, New York, NY 10017, Attention: Jonathan Isler, hereinafter referred to as "Landlord," and _____ _____ a _____ having an office at _____ hereinafter referred to as "Tenant."

W I T N E S E T H:

1. The parties have heretofore entered into a written Indenture of Lease, dated as of _____, 20__, (hereinafter referred to as the "Lease") for the leasing by Landlord to Tenant of certain space on the ____ ( ) floor(s) in the building known as 345 Park Avenue South, New York, New York, all as in the Lease more particularly described.

2. Pursuant to Article 3 of the Lease, Landlord and Tenant agree that the Commencement Date of the term of the Lease is _____; the Rent Commencement Date is _____; and that the Expiration Date is _____.

IN WITNESS WHEREOF, Landlord and Tenant have respectively signed this Commencement Date Agreement as of the day and year first above written.

LANDLORD:

345 PAS HOLDING LLC,
a Delaware limited liability company

LANDLORD:

345 PAS HOLDING LLC,
a Delaware limited liability company

By: _____
Name:
Title:

TENANT:

_____

By: _____

EXHIBIT H

RIDER TO TENANT LEASE AGREEMENT DATED DECEMBER 1, 2020

RIDER TO TENANT LEASE AGREEMENT DATED DECEMBER 1, 2020

LANDLORD:	345 PAS Holding LLC
TENANT:	PROTARA THERAPEUTICS INC.
FLOOR(S)/ UNIT(S):	Suite located on the 3rd Floor
TENANT'S EIN #:	20-4580525
PREMISES:	10,252 rentable square feet on the 3rd floor of the Building
AGENCY:	New York City Industrial Development Agency
COMPANY LEASE:	Company Lease Agreement, dated as of August 1, 2019, between 345 PAS Holding LLC and the Agency
AGENCY LEASE:	Agency Lease Agreement, dated as of September 1, 2019, between the Agency and 345 PAS Holding LLC
LEASE AGREEMENT	Lease Agreement, dated December 1, 2020, between 345 PAS Holding LLC, as Landlord, and ProTara Therapeutics, Inc., as Tenant

1. Acknowledgment and Release. Tenant acknowledges that pursuant to the Company Lease, the Agency holds a leasehold estate in the entire Premises, and Tenant releases the Agency from any past, present or future claims that Tenant has or may have against the Agency.

2. Representation Regarding Relocation. Tenant represents that as a result of entering into the Lease Agreement and this Rider, and upon completion of the construction occupying the Premises, it has not and will not have relocated or abandoned any plant or facility from outside of New York City (but within the State of New York).

3. Representation Regarding Conduct. None of the Tenant, the Principals of the Tenant, or any Person that is an Affiliate of the Tenant:

a. is in default or in breach, beyond any applicable grace period, of its obligations under any written agreement with the Agency, NYCEDC or the City, unless such default or breach has been waived in writing by the Agency, NYCEDC or the City, as the case may be;

b. has been convicted of a misdemeanor related to truthfulness and/or business conduct in the past five (5) years;

c. has been convicted of a felony in the past ten (10) years;

d. has received formal written notice from a federal, state or local governmental agency or body that such Person is currently under investigation for a felony criminal offense; or

e. has received written notice of default in the payment to the City of any taxes, sewer rents or water charges, which have not been paid, unless such default is currently being contested with due diligence in proceedings in a court or other appropriate forum.

Capitalized terms used in this section have the meanings set forth below:

Affiliate means, with respect to a given Person, any other Person that directly or indirectly through one or more intermediaries Controls, is Controlled by, or is under common Control with such given Person.

City shall mean The City of New York.

Control or **Controls**, including the related terms "controlled by" and "under common control with", shall mean the power to direct the management and policies of a Person (x) through the ownership, directly or indirectly, of not less than a majority of its voting securities, (y) through the right to designate or elect not less than a majority of the members of its board of directors or trustees or other Governing Body, or (z) by contract or otherwise.

Entity shall mean any of a corporation, general partnership, limited liability company, limited liability partnership, joint stock company, trust, estate, unincorporated organization, business association, tribe, firm, joint venture, governmental authority or governmental instrumentality, but shall not include an individual.

Governing Body shall mean, when used with respect to any Person, its board of directors, board of trustees or individual or group of individuals by, or under the authority of which, the powers of such Person are exercised.

NYCEDC shall mean New York City Economic Development Corporation, and any successor thereof.

Person shall mean an individual or any Entity.

Principals shall mean, with respect to any Entity, the most senior three officers of such Entity, any Person with a ten percent (10%) or greater ownership interest in such Entity, and any Person as shall have the power to Control such Entity, and "principal" shall mean any of such Persons.

4. Subordination. Tenant acknowledges and agrees that the Lease, as modified by this Rider, is subject and subordinate to the Agency Lease, and that any conflict between the terms of the Agency Lease and the terms of the Lease, as modified by this Rider, shall be resolved in favor of the Agency Lease.

5. Indemnity. Tenant agrees to defend, indemnify and hold harmless the Agency, its officers, directors, employees and agents from and against any and all losses, claims, suits, damages, costs, expenses and liabilities arising from or attributable to any act or omission of Tenant, its employees or agents in the use or occupancy of the Premises.

6. Insurance. Notwithstanding anything to the contrary contained in the Lease, as modified by this Rider, Tenant agrees to obtain and maintain Commercial General Liability insurance ("CGL") on a per occurrence basis in the following amounts: minimum $[***] per occurrence and minimum $[***] in the aggregate per location. Tenant additionally agrees that:

(a) the CGL policy shall contain coverage for contractual liability, premises operations, and products and completed operations; and

(b) the CGL policy shall be written on Form CG-0001; and

(c) the CGL policy shall name the Agency as an additional insured; and

(d) Tenant shall provide to Landlord at least thirty (30) days before expiration of the CGL policy (and to the Agency upon the Agency's request), an ACORD certificate evidencing that Tenant has obtained CGL coverage as required herein; and that such ACORD certificate shall indicate the Agency as an additional insured as follows:

"New York City Industrial Development Agency is an additional insured on a primary and non-contributory basis for Commercial General Liability which is written on Form CG-0001 without modification to the contractual liability or waiver-of-subrogation provisions therein, and covering the following premises: 345 Park Avenue South, New York, New York 10010."

7. Employment Information. Tenant acknowledges that pursuant to the Agency Lease, Landlord is obligated to provide to the Agency employment information pertinent to all occupants of the building in which the Premises are located. Accordingly, Tenant agrees to provide to Landlord and, if requested by the Agency, to the Agency, information regarding Tenant's employment at the Premises, including, but not limited to, the then-current New York State Department of Labor's Form NYS-45, and the Agency's employment and benefits report form for Tenants (or any successor form as may be required by the Agency as a result of a change in law or as required by New York State agencies).

8. Living Wage. Tenant agrees to comply with all of the terms, covenants and provisions of the Living Wage requirements set forth in Appendix A hereto.

9. HireNYC. Tenant agrees to comply with all of the terms, covenants and provisions of the HireNYC requirements set forth in Appendix B hereto.

10. Intentionally Omitted.

11. Use of Premises. Tenant shall occupy 10,252 RSF of the Premises for use by Tenant in its operations as general and administrative use for a pharmaceutical development organization.

12. Non-discrimination. Tenant hall not discriminate nor permit any of its Affiliates (as defined in Section 3 above) to discriminate against any employee or applicant for employment because of race, color, creed, age, sex or national origin. Tenant shall ensure that employees and applicants for employment with Tenant are treated without regard to their race, color, creed, age, sex or national origin. As used herein, the term "treated" shall mean and include the following: recruited, whether by advertising or other means; compensated, whether in the form of rates of pay or other forms of compensation; selected for training, including apprenticeship; promoted; upgraded; downgraded; demoted; transferred; laid off; and terminated.

13. Incorporation in Sublease Agreement; Third-Party Beneficiary. Tenant agrees and acknowledges that this Rider is a part of and is incorporated into the Lease; and that the Agency is a third-party beneficiary of the foregoing provisions of this Rider. Except where modified by this Rider, the terms and conditions of the Lease, as modified by this Rider, remain unmodified and in full force and effect.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Rider as of the day and year first above written.

345 PAS HOLDING LLC,
(Landlord)

By: _____
Name:
Title:

PROTARA THERAPEUTICS INC.
(Tenant)

By: _____
Name:
Title:

EXHIBIT I

FORM OF LIVING WAGE AGREEMENT

[***]

EXHIBIT J

HireNYC

[***]

SCHEDULE 6.1.4(c)

Agency Lease PILOT Payment Schedule

[***]

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction
Proteon Securities Corp.	Massachusetts
Proteon International Holdings, Inc.	Delaware
Proteon Bermuda Limited	Bermuda
Proteon Ireland Limited	Ireland
ArTara Subsidiary, Inc.	Delaware

All subsidiaries are 100% owned.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Protara Therapeutics, Inc. on Form S-3 (File No. 333-251224) and Form S-8 (File Nos. 333-237497, 333-235918, 333-229123, 333-222415 and 333-200587) of our report dated March 11, 2021, with respect to our audits of the consolidated financial statements of Protara Therapeutics, Inc. as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019, which report is included in this Annual Report on Form 10-K of Protara Therapeutics, Inc. for the year ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 11, 2021

Exhibit 31.1

Certification of the Principal Executive Officer
Pursuant to
§240.13a−14 or §240.15d−14 of the Securities Exchange Act of 1934, as amended

I, Jesse Shefferman, certify that:

1. I have reviewed this annual report on Form 10−K of Protara Therapeutics, 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 registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, including its consolidated 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 11, 2021

/s/ Jesse Shefferman

Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of the Principal Financial Officer
Pursuant to
§240.13a−14 or §240.15d−14 of the Securities Exchange Act of 1934, as amended

I, Blaine Davis, certify that:

1. I have reviewed this annual report on Form 10−K of Protara Therapeutics, 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 registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, including its consolidated 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 11, 2021

/s/ Blaine Davis

Blaine Davis
Chief Financial 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 this annual report of Protara Therapeutics, Inc. (the "Company") on Form 10−K for the year ending December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Jesse Shefferman, Chief Executive Officer of the Company, and Blaine Davis, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes−Oxley Act of 2002, that, to our knowledge:

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 11, 2021

/s/ Jesse Shefferman
Jesse Shefferman
Chief Executive Officer

Date: March 11, 2021

/s/ Blaine Davis
Blaine Davis
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Protara Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.