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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-36327

Neoleukin Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

98-0542593
(I.R.S. Employer
Identification No.)

**360-1616 Eastlake Avenue East,
Seattle, Washington, 98102**
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (206) 732-2133

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 \$0.000001	NLTX	The Nasdaq Stock Market LLC

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

None

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$24.2 million as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price on The Nasdaq Global Market reported for such date. Excludes an aggregate of 13,276,120 shares of the registrant's common stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

There were 38,373,160 shares of the registrant's Common Stock issued and outstanding as of March 12, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the registrant's 2020 Annual Meeting of Stockholders (the "**2020 Proxy Statement**").

NEOLEUKIN THERAPEUTICS, Inc.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2019

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Except as otherwise indicated herein or as the context otherwise requires, references in this report to, “the Company,” “we,” “us,” “our” and similar references refer to Neoleukin Therapeutics, Inc. (formerly Aquinox Pharmaceuticals, Inc.), a Delaware corporation. The name “Neoleukin” is a registered trademark of the Company in the United States. This report also contains references to registered marks, trademarks and trade names of other companies that are property of their respective holders. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are “forward-looking statements” for purposes of these provisions, including those relating to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict,” “potential,” “intend” or “continue,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading “Item 1A—Risk Factors.” We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Item 1. Business.

Overview

We are a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. We use sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Existing protein engineering treatments generally involve the modification of native proteins. With our proprietary platform we design completely new protein structures from the ground up, capable of demonstrating specifically desired biological properties. Through this method we are able to produce proteins that, while resembling native proteins, can be designed around the structural issues of native proteins while delivering therapeutic benefit. *De novo* proteins have the capacity to be cytokine receptor agonists, antagonists, or result in conditional activation of specific cytokine receptors such that they may regulate inflammation or the immune response to cancer. We are initially focused on key cytokine mimetics, which we refer to as Neoleukin *de novo* cytokine mimetics. Neoleukin *de novo* cytokine mimetics can be modified to adjust affinity, thermodynamic stability, resistance to biochemical modification, pharmacokinetic characteristics, and targeting to tumor or inflamed tissues.

Our lead product candidate, NL-201, is a *de novo* protein designed to mimic the therapeutic activity of the cytokines interleukin-2, or IL-2, and interleukin-15, or IL-15, for the potential treatment of various types of cancer, including renal cell carcinoma, or RCC, and melanoma, while limiting the toxicity caused by the preferential binding of native IL-2 and IL-15 to non-target cells. In preclinical studies, a closely-related precursor to NL-201 demonstrated higher levels of activity and lower toxicity in multiple murine solid tumor syngeneic models as compared to recombinant, native IL-2.

Neoleukin/Aquinox Merger

On August 8, 2019, Neoleukin Therapeutics, Inc., or Former Neoleukin, completed its merger with Aquinox Pharmaceuticals, Inc., or Aquinox, in accordance with the terms of the Agreement and Plan of Merger dated August 5, 2019, or the Merger Agreement by and among Aquinox, Former Neoleukin and Apollo Sub, Inc., a wholly-owned subsidiary of Aquinox. Pursuant to the Merger Agreement, Apollo Sub, Inc. merged with and into Former Neoleukin, with Former Neoleukin surviving the Merger as a wholly-owned subsidiary of Aquinox, referred to herein as the Merger. Upon completion of the Merger, Aquinox was renamed Neoleukin Therapeutics, Inc. and our common stock trades under the new ticker symbol “NLTX” on the Nasdaq Global Market.

De Novo Protein Design Technology

Our proprietary technology, which we refer to as our Neoleukin platform, uses a set of advanced computational algorithms and methods to design functional *de novo* proteins. A protein is generally defined as one or more chains of covalently-linked amino acids – totaling at least 50 amino acids – that assemble into a 3-dimensional structure. Human cells contain tens of thousands of different proteins; however, this is still only a small subset of all possible amino acid sequences that can be assembled to form a protein. While protein engineering to date has largely been conducted through the modification of native proteins, with our platform we are able to explore the full sequence space, guided by the physical principles that underlie protein folding, and design functional proteins from the ground up. Our *de novo* proteins fit the above definition of a protein, but, unlike native proteins, are designed using our proprietary computational algorithms and methods. Successful *de novo* protein design is a cutting-edge process that requires both the advanced computational tools of our proprietary platform and deep insight into how a sequence of amino acids will fold into a stable 3-dimensional protein.

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To design a Neoleukin *de novo* cytokine mimetic using the Neoleukin platform, we begin with an accurate model of the biological target. This is typically a high-resolution crystal structure but may instead be a computationally-modeled structure. Then, critical points of contact between molecular interfaces are identified so that essential interactions can be maintained or strengthened, and undesirable interactions can be avoided. Next, we use a computational algorithm to build idealized 3-dimensional topologies. Finally, we use a separate computational algorithm to select amino acids for each position within the idealized 3-dimensional topologies that maximizes interactions at the desired interface and the thermodynamic stability of the resulting protein. The resulting amino acid sequences are then expressed in bacteria, tested in the laboratory, and further modified to optimize the final sequence. The resulting protein is unlike anything that exists in nature and can be fine-tuned to improve on the desired biological activity.

While we are currently focused on the design of Neoleukin *de novo* cytokine mimetics, we believe this approach could be used broadly to widen the therapeutic window and improve drug-like characteristics of therapeutic proteins, including chemical stability, pharmacokinetic properties, or novel routes of administration. Furthermore, we believe that the Neoleukin platform can also be used to generate *de novo* proteins that inhibit activation of specific receptors, a property that could be valuable for treatment of inflammatory or autoimmune conditions. Computational design of therapeutic proteins is in a very early stage. The potential is vast, and we are focused on continuing to improve the technology and realizing the tremendous potential of *de novo* protein design to improve human health.

Our Strategy

Our business model is focused on three primary goals:

- Develop proprietary *de novo* protein immunotherapies for the treatment of cancer and inflammatory conditions;
- Become the leader in *de novo* protein design for therapeutic applications by strengthening our intellectual property and know-how; and
- Collaborate with leading biotechnology, pharmaceutical, and academic partners to expand the scope of our platform.

The key elements of our strategy are:

- **Rapidly advance NL-201 to clinical proof-of-concept.** NL-201 is our lead product candidate and we believe it will be the first entirely *de novo* therapeutic protein to be evaluated in a clinical setting. NL-201 is currently in preclinical development and manufacturing and we expect to present preclinical and scientific data in the first half of 2020. We expect to conduct Investigational New Drug, or IND, enabling toxicology studies and anticipate submitting an IND by the end of 2020.
- **Generate preclinical data for additional product candidates.** Our research activities are currently focused on the development of novel *de novo* interleukin receptor agonists and antagonists to expand our oncology pipeline. We are currently optimizing and evaluating several early research projects as potential clinical candidates. Beyond oncology targets, we also intend to develop *de novo* protein therapeutics to address significant unmet medical needs in inflammation and autoimmunity indications.
- **Expand the capabilities of the Neoleukin platform.** *De novo* protein design is in the earliest stages of development and has the potential to generate therapeutics to treat a wide range of human diseases. We believe that there will be a rapid evolution in the enabling technology, such that it will be feasible to design more complex and dynamic proteins in the future. We intend to devote a significant amount of resources to building our computational talent and infrastructure in order to position Neoleukin as a leader in the design and development of *de novo* protein therapeutics.
- **Build partnerships to leverage the Neoleukin platform.** There is substantial interest in the field of *de novo* protein design for therapeutic applications. We intend to seek potential partners that can provide additional resources and expertise to further advance our pipeline and broaden our potential targets. We may also strategically pursue one or more collaborations to design, out-license, or co-develop *de novo* proteins.

NL-201

Our lead program, NL-201, is an IL-2/IL-15 immunotherapy designed to eliminate binding to the alpha subunit of the IL-2 receptor (also known as CD25) while maintaining high-affinity binding to the beta and gamma subunits. In multiple preclinical animal models, a precursor to NL-201 demonstrated substantial anti-tumor activity without detectable binding to CD25, as compared to native IL-2 and to competitor engineered IL-2 variants in development. Following these preclinical studies, we further refined our precursor to extend its half-life, resulting in our NL-201 product candidate. We have since completed multi-dose, non-GLP and GLP toxicology studies of NL-201 in rats and non-human primates. This included completion of GLP in-life dosing with no unexpected toxicities observed. NL-201 is intended to be used as either a single-agent or in combination with complementary therapeutic modalities, including checkpoint inhibitors. In addition, we believe NL-201 holds promise in combination with allogeneic cell therapy to expand and maintain populations of transplanted CAR-T and natural killer, or NK, cells.

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IL-2 is one of the few immunology drugs proven to work as a single agent. IL-2 has a demonstrated mechanism of action for treating tumors; however, it has encountered issues as a therapeutic due to the biased activation of cells that contain CD25. CD25 induces conformational changes in IL-2 that enable high-affinity binding to the beta and gamma subunits of the IL-2 receptor. Preferential binding to endothelial cells expressing CD25 is believed to exacerbate vascular leak syndrome, while preferential activation of CD25-expressing regulatory T cells can inhibit anti-cancer immune responses. Due to IL-2's potential for high toxicity, with vascular leak syndrome and cytokine storm being frequent side effects, and reduced efficacy over time, its use as a therapeutic has been limited. Further, low-dose treatments have generally been insufficient to demonstrate activity.

While the problem posed by IL-2 is well understood, it has been difficult to modify native IL-2 to retain potent activation of IL-2 receptor signaling while eliminating binding to CD25. Instead of modifying native IL-2, we used the Neoleukin platform to design a new sequence with the proper intermolecular interactions to efficiently bind the beta and gamma subunits while eliminating CD25 binding in preclinical models. As opposed to traditional recombinant human, or humanized, protein therapeutics, *de novo* proteins are entirely novel sequences with no homology to native proteins. While there is a potential that patients may mount an anti-drug immune response against NL-201, we believe that this risk is mitigated by several factors, including the stability of the protein and its resistance to proteolytic degradation.

Immunotherapy Market Overview

Over the past several decades, the potential of the immune system to control and/or eliminate cancer has been better understood and appreciated. Immunotherapies, including allogenic stem cell transplantation, checkpoint inhibitors, and cellular therapies have led to impressive improvements in patient outcomes. Immunotherapy is one of the fastest growing segments of the oncology market. Immune checkpoint inhibitors are one of the most widely used classes of cancer immunotherapy. Checkpoint inhibitors promote an anti-cancer immune response by blocking inhibitory signals between cancer cells and the immune microenvironment. Patients with metastatic cancers, who previously had uniformly poor prognoses, now have the opportunity to achieve durable responses with checkpoint inhibitors. The initial drug in this class, ipilimumab, was approved in 2011. Since that time, at least five additional checkpoint inhibitors have been approved. In addition to checkpoint inhibitors, other notable cancer immunotherapies expected to improve cancer outcomes over the next decade include bi-specific T-cell engagers, such as blinatumomab, and more recent CAR-T therapies, such as tisagenlecleucel and axicabtagene ciloleucel.

Limitations of Current Treatments

Despite achieving success in a subset of patients, checkpoint inhibitors often fail to control tumor growth. In addition, some patients do not tolerate checkpoint inhibitors. While checkpoint inhibitors work to block the mechanisms by which malignant cells evade immunological surveillance by anti-cancer T cells, they are less effective in patients who lack a favorable tumor microenvironment, expression of the inhibitory ligand, or sufficient tumor-specific antigens. For these patients, novel approaches to immunotherapy are needed that complement and/or enhance checkpoint inhibition. What is needed is a new class of agents that activate immune cells in the tumor microenvironment.

We believe that stimulation of the IL-2 and IL-15 pathways is an attractive approach to generate an anti-cancer immune response because it promotes the proliferation and activation of both CD8⁺ effector T cells and NK cells. Recombinant human IL-2, or aldesleukin, is a proven therapy and is approved for the treatment of adults with metastatic RCC or metastatic melanoma. However, significant toxicity has resulted in multiple boxed warnings in the labeling, including a requirement that administration occur in the hospital under supervision of an experienced physician. As a result of these toxicities, aldesleukin is not frequently used in the clinic. In addition, aldesleukin has a relatively modest rate of durable remissions, potentially because it preferentially stimulates the proliferation of regulatory T cells, which can inhibit the antitumor response. We believe there is a clear clinical need for an agent that stimulates an immunological response to cancer with greater selectivity and less toxicity than aldesleukin.

Initial Clinical Development Plan

We expect to administer NL-201 as monotherapy by intravenous injection and, during dose escalation, it will be tested in patients with a variety of relapsed and refractory solid tumors. Dosage and escalation schedules will be determined by evaluation of safety, tolerability, pharmacokinetics, and pharmacodynamic measures to achieve the optimal regimen for outpatient administration. Multiple schedules may be tested during Phase 1. Subsequently, we expect that expansion cohorts will be enrolled using tumor-specific inclusion/exclusion criteria to evaluate both safety and antitumor activity in uniform patient populations. If the clinical data are considered promising, additional trials will be initiated, which may include combination regimens and trials with registrational intent.

UW License Agreement

On July 8, 2019, Former Neoleukin entered into an Exclusive License Agreement with the University of Washington, or UW, under which UW (on behalf of itself and Stanford University) granted us an exclusive worldwide license under certain patent rights, to make, have made, use, offer to sell, sell, offer to lease or lease, import, export or otherwise offer to dispose of licensed products in all fields of use, and a nonexclusive worldwide license to use certain know-how. The foregoing licenses are able to sublicense by us without UW's consent, subject to certain limited conditions. We assumed the benefits and obligations of the Exclusive License Agreement in connection with the completion of the Merger.

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As consideration for the licensed rights, Former Neoleukin issued shares of common stock to UW, representing five percent of its fully-diluted capitalization on the date on which the Exclusive License Agreement was executed. In addition, we agreed to issue additional shares of common stock to UW sufficient to ensure UW maintains its ownership percentage of our fully-diluted capitalization, until we raised a certain amount of equity capital. Pursuant to the agreement, we also granted to UW an assignable right to participate in any future sale of equity securities by us, subject to certain exclusions. Additionally, we are required to pay UW: (i) an annual maintenance fee starting in January 2022 (but excluding any year in which minimum annual royalties are paid); (ii) up to \$875,000 in combined development and regulatory milestone payments with respect to each distinct class of licensed product; (iii) up to \$10.0 million in combined commercial milestone payments based on cumulative net sales of licensed products within each distinct class of licensed product; (iv) a low single digit royalty on net sales of licensed products sold by us and our sublicensees, which may be subject to reductions, and subject to minimum annual royalty payments following the first commercial sale of a licensed product; (v) a certain percentage of any sublicense consideration (other than royalties) we receive from sublicensees, ranging from 50% to low single digit percentages based on the stage of development at the time the sublicense is executed; and (vi) a certain percentage of consideration we receive from an acquisition of us or our assets, ranging from 50% to zero based on the stage of development at the relevant time. We are obligated to pay royalties on a country-by-country basis until the expiration of the last valid claim within the licensed patent rights in such country.

The agreement will expire upon the expiration of the last valid claim within the licensed patent rights. We may terminate the agreement upon prior written notice to UW. UW may terminate the agreement by giving a specified number of days' notice if we permanently cease operations, become insolvent or similar, or if we challenge the validity of the licensed patent rights. In addition, UW may terminate the agreement for material breach that is not cured within a specified number of days, which cure period is to be at least doubled if we are proceeding diligently to cure the default.

Research Programs

Beyond our initial focus on NL-201, our research team is working on further applying *de novo* protein design principles to develop therapeutics to address significant unmet medical needs in immuno-oncology, inflammation, and autoimmunity. Our research is powered by the Neoleukin platform, our computational framework for developing highly selective, hyper-stable *de novo* immunomodulatory proteins. Beyond NL-201, we are developing targeted and conditionally active IL-2/IL-15 mimetics, as well as cytokine mimetic programs for other oncology targets. Our research team is also actively applying the Neoleukin platform to generate *de novo* receptor agonist and antagonist candidates against multiple targets of interest for inflammatory and autoimmune indications. As we validate additional candidates, they will enter our preclinical pipeline.

Intellectual Property

Our intellectual property strategy is centered around robust protection of our pipeline molecules and enabling technologies. We have licensed rights to two pending international patent applications filed under the Patent Cooperation Treaty, or the PCT, and one pending U.S. non-provisional patent application stemming from provisional patent applications that our scientific co-founders authored while they were employees at the University of Washington, or UW. These patent applications include disclosure and claims encompassing our NL-201 product candidate, the composition of matter of key molecule families, as well as methods of using the computational algorithms that form the basis of the Neoleukin platform. We have secured an exclusive license from UW to develop and commercialize products covered by these patent applications. Any patents that may issue from these patent applications in-licensed from UW are expected to expire in 2039, absent any patent term adjustments or extensions. As our product candidate advances through research and development, we expect to seek to identify and protect new inventions, such as methods of administration and combination therapies.

Also, through our research efforts, we anticipate generating intellectual property covering novel compounds and significant improvements on existing molecules. We expect that patents that result from this new research will remain Neoleukin's exclusive property, except to the extent jointly developed with third parties. In addition, our research team is extending and enhancing our computational technology and capabilities. We intend to protect improvements to the Neoleukin platform through a combination of new patent filings as well as the maintenance of trade secrets. We file U.S. non-provisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when appropriate. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 153 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of 2 1/2 years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first 2 1/2 years of filing.

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We intend to pursue patent issuance and protection in key commercial markets where we expect significant product sales may occur.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our Neoleukin platform and our knowledge, experience and scientific resources provide us with competitive advantages going forward, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

The development of next-generation IL-2 or IL-15 agonists for cancer immunotherapy is an area of intense interest within the biotechnology industry. We are aware of several IL-2 or IL-15 agonists in various stages of clinical development. Noted in the table below are engineered variants of IL-2 that each attempt to improve on aldesleukin's narrow therapeutic window by inhibiting IL-2's natural high-affinity interaction with CD25 using traditional protein engineering approaches including steric inhibition and mutagenesis. While these strategies partially mitigate IL-2's interaction with CD25, to our knowledge, none have successfully eliminated CD25 binding.

<u>Developer</u>	<u>Name</u>	<u>Stage</u>
Nektar Therapeutics	NKTR-214	Phase 3
Roche	RG7461	Phase 2
Alopexx	DI-Leu16-IL2	Phase 2
Philogen	Darleukin	Phase 2
Apeiron	Hu14.18-IL2	Phase 1
Alkermes	ALKS 4230	Phase 1/2
Novartis	NIZ985	Phase 1
Cue Biopharma	CUE-101	Phase 1
Sanofi (formerly Synthorx)	THOR-707	Phase 1
Medicenna Therapeutics	MDNA109	Preclinical
Pivotal Biosciences	PB101	Preclinical
BioNTech	BNT151	Preclinical
Xencor	XmAb24306	Preclinical
Ascendis Pharma	Transcon IL-2	Preclinical

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. We believe the factors determining the success of our programs will be the efficacy, safety and convenience of our product candidates.

Manufacturing

We conduct manufacturing activities for the clinical development of our product candidates under individual purchase orders with third-party contract manufacturing organizations as we do not have a manufacturing facility and currently do not intend to develop one.

The FDA and other health authorities worldwide regulate and inspect equipment, facilities and processes used in manufacturing pharmaceutical products prior to approval. If we or our partners fail to comply with applicable requirements and conditions of product approval, the FDA and/or other global health authorities may seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA and/or other global health authorities' approval, seizure or recall of products and criminal prosecution.

Commercial Operations

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that NL-201 will be approved.

Government Regulation

As a biopharmaceutical company that operates and anticipates seeking approval for pharmaceutical product candidates in the United States, we are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Our pharmaceutical product candidates must be approved by the FDA before we can commence clinical trials or market those products in the United States.

Although the discussion below focuses on regulation in the United States, we conduct research activities and anticipate seeking approval for, and marketing of, our products in other countries and regions, such as Europe. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

FDA Approval Process

The FDA is the main regulatory body that controls pharmaceuticals in the United States, and its regulatory authority is based in the FDC Act. Pharmaceutical products are also subject to other federal and state statutes and regulations. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of New Drug Applications, or NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a Biologics License Application, or BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs. A failure to comply with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an institutional review board, or IRB, of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The steps required before a new biological product may be marketed in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with federal regulations and with current good clinical practices, or GCPs, to establish the safety and efficacy of the investigational drug product for each targeted indication;
- submission of BLA to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the BLA.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after licensure date of the reference product licensed under a BLA.

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Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as tests of reproductive toxicity and carcinogenicity in animals, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to patients under the supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. Clinical trials must be conducted: (1) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions if it believes that the patients are subject to unacceptable risk. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, for example, the data safety monitoring board, or DSMB. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk.

The clinical investigation of an investigational drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are generally described as follows:

- *Phase 1* — Phase 1 includes the initial introduction of an investigational drug into humans. Phase 1 clinical trials may be conducted in patients with the target disease or condition or healthy volunteers. These trials are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase 2 clinical trials.
- *Phase 2* — Phase 2 includes controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.
- *Phase 3* — Phase 3 clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide an adequate basis for product approval. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and 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, the manufacturer must develop methods for testing the identity, strength, quality, purity and potency of the final product. 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.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, a BLA is submitted to the FDA to request market approval for the product in specified indications. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacturing, and controls. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial user fee; there may be some instances in which the user fee is waived.

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The FDA will initially review the BLA for completeness before it accepts the BLA for filing. The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the Agency's threshold determination that it is sufficiently complete to permit substantive review. After the BLA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. For a new molecular entity, or NME, that is classified as a standard review product, FDA's goal is to review the BLA within ten months of the date the FDA files the BLA; an application for an NME that is classified as a priority review product has a goal for review of six months from the date the FDA files the BLA. A BLA can be classified for priority review when the FDA determines the biologic product has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The FDA can extend the review process by three or more additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

The FDA does not always achieve its performance goal and its review of BLAs can take significantly longer. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect the sponsor and one or more clinical sites to assure compliance with GCP. After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, time or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The approval process is lengthy and difficult and notwithstanding the submission of any requested additional information, the FDA ultimately may refuse to approve an BLA if applicable regulatory criteria are not satisfied or if the FDA believes additional clinical data or other data and information are required. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than a company interprets the same data.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. FDA's approval of a product may be significantly limited to specific disease and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, restricted distribution, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, or modification to a REMS, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses—that is, uses not approved by the FDA and therefore not described in the drug's labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the U.S. Department of Justice (DOJ), or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA or BLA submitted on or after August 18, 2020.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Post-Approval Regulations

After regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of a BLA, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved BLA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the drug or biological product. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. 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.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning or untitled letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

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Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Enforcement

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Comparable European and Other International Government Regulation

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

Some countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application, or MAA. The MAA is similar to the NDA, with the exception of, among other things, country-specific document requirements and environmental impact assessments.

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

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to additional regulation and oversight under other healthcare laws by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. These laws include the federal Anti-Kickback Statute, which 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 either the referral of an individual, or purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable, in whole or part, under Medicare, Medicaid or another federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, 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. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor from federal Anti-Kickback Statute liability. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, 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. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, further strengthened these laws by amending the intent standard under the federal Anti-Kickback Statute and the criminal health care fraud statutes (discussed below), 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 civil False Claims Act (discussed below).

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Federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalties laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, including the Medicare and Medicaid programs. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Recently, several 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 off-label, and thus, non-covered, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes certain HIPAA 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 the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in some 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 local, state and foreign governments have enacted legislation requiring pharmaceutical companies to, among other things, establish compliance programs, file periodic reports with the state or foreign government, 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 specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices. In addition, our future commercial activities may also be subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicaid and Medicare, integrity obligations, injunctions, as well as reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage, Reimbursement and Pricing

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent that third-party payors provide coverage, and establish adequate reimbursement levels for such drug products. In the United States, third-party payors include federal healthcare programs, state healthcare programs, managed care providers, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services, in addition to questioning their safety and efficacy. 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. NL-201 or our future product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug 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 a drug product is reimbursed under a governmental healthcare program, such as Medicare, Medicaid or TRICARE, additional laws and program requirements will apply.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare 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 upon. 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 drugs, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. The European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical 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 products 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, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In March 2010, President Obama signed the Affordable Care Act, which substantially changed healthcare financing and the delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The Affordable Care Act impacts existing government healthcare programs and requires the development of new programs. For example, the Affordable Care Act provides for Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Among the Affordable Care Act's provisions of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biological products apportioned among these entities according to their market share in some government healthcare programs, that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of AMP;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts, now 7% 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;

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- 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 Public Health Service pharmaceutical pricing program;
- a requirement to report annually specified financial arrangements with physicians and teaching hospitals, as defined in the Affordable Care Act and its implementing regulations, including reporting information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members;
- a requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners, pharmacies of hospitals and other healthcare entities; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will stay in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Furthermore, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act, or ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the ACA.

We cannot predict what healthcare reform initiatives may be adopted in the future. However, we anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system. We also expect ongoing initiatives to increase pressure on drug pricing. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Anti-Corruption Legislation

The Foreign Corrupt Practices Act, or 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.

The Corruption of Foreign Public Officials Act, or CFPOA, prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Under the CFPOA, companies may be liable for the actions of their employees or third-party agents, even if such persons operate outside of Canada.

Employees

As of December 31, 2019, we had 36 employees, of whom 13 hold Ph.D. degrees or M.D. degrees and all of which are full time employees. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We believe that relations with our employees are good.

Corporate Information

We commenced operations in May 2007 as Aquinox Pharmaceuticals, Inc., a corporation under the laws of the State of Delaware. Following the merger with Neoleukin Therapeutics in August 2019, we changed our name to Neoleukin Therapeutics, Inc. Our principal executive offices are located at 360-1616 Eastlake Avenue East, Seattle, Washington 98102, and our telephone number is (206) 732-2133. Our website address is www.neoleukin.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report.

We make available free of charge on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. The reports are also available at www.sec.gov.

Neoleukin and our other registered or common law trademarks, service marks, or trade names appearing in this Annual Report on Form 10-K are the property of Neoleukin Therapeutics, Inc. Other trademarks, service marks, or trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K and the information incorporated by reference herein. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed.

This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Capital Needs

We will require substantial additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of our product candidates.

The development of biopharmaceutical product candidates is capital-intensive. If our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing, and sales capabilities. We have used substantial funds to develop our technology and product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect to continue incurring costs associated with operating as a public company.

Preclinical studies and clinical trials for our product candidates will require substantial funds to complete. As of December 31, 2019, we had approximately \$143.1 million in cash and cash equivalents. We expect to incur substantial expenditures in the foreseeable future as we seek to advance NL-201 and any future product candidates through preclinical and clinical development, the regulatory approval process and, if approved, commercial launch activities. Based on our current operating plan, we believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through 2022. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund expansion, develop new or enhanced products, or otherwise respond to competitive pressures, may vary significantly from what we expect and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we may receive or make under our collaboration agreements;
- our ability to maintain our current licenses and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory submissions and timing of regulatory approvals;
- the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before our product candidates are clinically tested, approved for commercialization and successfully marketed.

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We will be required to seek additional funding in the future and currently intend to do so through additional collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our future debt financings, if available, are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We have incurred significant losses in every quarter since our inception and anticipate that we will continue to incur significant losses in the future.

We are a biotechnology company with a limited operating history. Investment in biotechnology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities for marketing or commercial sale, we have not generated any revenue from product sales to date, and all of our product candidates are in preclinical development. We continue to incur significant expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2003. For the years ended December 31, 2019, 2018 and 2017, we reported a net loss of \$69.4 million, \$31.6 million and \$50.2 million, respectively. As of December 31, 2019, we had an accumulated deficit since inception of \$299.5 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we seek to identify, acquire and conduct research and development of future product candidates, and potentially begin to commercialize any future products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our financial condition. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our financial condition. If any of our future product candidate fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been primarily limited to organizing and staffing our company, acquiring product and technology rights, discovering and developing novel small molecule drug candidates and undertaking preclinical studies and, prior to the Merger, clinical trials of rosiptor. We have not yet obtained regulatory approval for any product candidate. Consequently, evaluating our performance, viability or possibility of future success will be more difficult than if we had a longer operating history or approved products on the market.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales, or otherwise. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize any products that we may develop, in-license or acquire in the future. Even if we can successfully achieve regulatory approval for any future product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. Our ability to generate revenue from any of our future product candidates also depends on several additional factors, including our or any future collaborators' ability to:

- complete development activities, including the necessary clinical trials;
- complete and submit BLAs to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;

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- achieve market acceptance for our products, if any;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biological product development, any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials. Therefore, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we can complete the development and regulatory process for any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we can generate revenues from the sale of any future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

We will require additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of develop future product candidates.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. Our operations have consumed substantial amounts of cash since inception. If we identify and advance any current or future product candidates into clinical trials and launch and commercialize any product candidates for which we receive regulatory approval, we expect research and clinical development expenses, and our selling, general and administrative expenses to increase substantially. In connection with our ongoing activities, we believe that our existing cash and cash equivalents will be sufficient to fund our operating requirements for at least the next 12 months. However, circumstances may cause us to consume capital more rapidly than we anticipate. We will likely require additional capital for the further development and potential commercialization of future product candidates and may also need to raise additional funds sooner to pursue a more accelerated development of future product candidates.

If we need to secure additional financing, fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- significantly delay, scale back or discontinue clinical trials related to the development or commercialization of any of our future product candidates or cease operations altogether;
- seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- our ability to identify additional product candidates for development;
- if we in-license or acquire product candidates from third parties, the cost of in-licensing or acquisition;
- the initiation, progress, timing, costs and results of clinical trials for any future product candidates;
- the clinical development plans we establish for any future product candidates;
- the achievement of milestones and our obligation to make milestone payments under our present or any future in-licensing agreements;
- the number and characteristics of product candidates that we discover, or in-license and develop;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;

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- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- the effect of competing technological and market developments;
- the costs and timing of the implementation of commercial-scale outsourced manufacturing activities; and
- the costs and timing of establishing sales, marketing, distribution and pharmacovigilance capabilities for any product candidates for which we may receive regulatory approval in territories where we choose to commercialize products on our own.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our business, results of operations, financial condition and cash flows and future prospects could be materially adversely affected.

Risks Related to Discovery, Development and Commercialization

Our product candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of, or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts. We have no products on the market and all of our product candidates, including NL-201, are still in the preclinical or drug discovery stages, and we may not ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. We currently expect to submit an Investigational New Drug application, or IND, with respect to NL-201 by the end of 2020. However, it is possible that the FDA may deny our IND or require additional testing before allowing clinical testing in humans. Alternatively, we may obtain data while preparing for an IND that causes us to delay or even abandon clinical testing of NL-201. Additionally, we have a portfolio of targets and programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. If we do not receive regulatory approvals for clinical testing and commercialization of our product candidates, we may not be able to continue our operations.

We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- preclinical study results may show the product candidate to be less effective than desired or to have harmful or problematic side effects;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologicals similar to our product candidates;
- our third-party manufacturers' inability to successfully manufacture our products or to meet regulatory specifications;
- inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;
- delays in submitting INDs or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or other applicable regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- greater than anticipated costs of our clinical trials;
- manufacturing costs, formulation issues, pricing or reimbursement issues or other factors that no longer make a product candidate economically feasible;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- failure to demonstrate a benefit-risk profile acceptable to the FDA, EMA or other applicable regulatory authorities;

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- unfavorable inspection and review by the FDA, EMA or other applicable regulatory authorities of one or more clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our product candidates;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy, and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of our data by the FDA, EMA or other applicable regulatory authorities.

We or our future partners' inability to complete development of, or commercialize our product candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Further, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for advanced cancers, i.e. third-line or beyond. When cancer is detected early enough, first-line therapy, usually chemotherapy, surgery, radiation therapy, immunotherapy, hormone therapy, or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect our clinical trials for NL-201 will be with patients who have received one or more prior treatments. Subsequently, for those of our products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of therapy. Any product candidates we develop, even if approved, may not be successfully approved for earlier lines of therapy, and, prior to any such approvals, we will likely have to conduct additional clinical trials, which are often very lengthy, expensive, and have a significant risk of failure.

Our business is heavily dependent on the success of our Neoleukin platform and of our most advanced product candidate, NL-201. Existing and future preclinical studies and clinical trials of these product candidates may not be successful, and if we are unable to commercialize these product candidates or experience significant delays in doing so, our business will be materially harmed.

Our business is heavily dependent on our ability to obtain regulatory approval of and then successfully launch and commercialize our product candidates. We have invested a significant portion of our efforts and financial resources in the development of our proprietary system of advanced computational algorithms and methods for the design of functional *de novo* proteins, which we refer to as our Neoleukin platform, with an initial focus on key cytokine mimetics, which we refer to as Neoleukin *de novo* cytokine mimetics. Our lead product candidate, NL-201, is a Neoleukin *de novo* protein derived from our Neoleukin platform. However, NL-201 and our other product candidates are still in the preclinical or earlier stage. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our lead product candidates. Our product candidates may not be successful in clinical trials or receive regulatory approval. Even if they are successful in clinical trials, regulatory authorities may not complete their review in a timely manner, or additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. Regulatory authorities may approve a product candidate for targets, disease indications or patient populations that are not as broad as we intended or desired, approve more limited indications than requested, or require distribution restrictions or strong safety language, such as contraindications or boxed warnings. Regulatory authorities may also require Risk Evaluation and Mitigation Strategies, or REMS, or the performance of costly post-marketing clinical trials. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. In order to market and sell our product candidates in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may be required to expend significant resources to obtain regulatory approval, which may not be on a timely basis or successful at all, and to comply with ongoing regulations in these jurisdictions.

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The success of our Neoleukin platform, NL-201, and our other product candidates will depend on many factors, including the following:

- successful completion of necessary preclinical studies to enable the initiation of clinical trials;
- successful enrollment of patients in, and the completion of, our clinical trials;
- obtaining adequate financing to perform the expensive clinical development programs anticipated for approval;
- receiving required regulatory authorizations for the development and approvals for the commercialization of our product candidates;
- establishing and maintaining arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, including those that are currently in development; and
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval.

If we do not achieve any one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Our future clinical trials or those of any future collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, we may be required to pause, delay, or abandon the trials or our development efforts of one or more product candidates altogether, we may be required to have more restrictive labeling, or we may experience the delay or denial of regulatory approval by the FDA, EMA or other applicable regulatory authorities. We, the FDA, EMA or other applicable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. We designed NL-201 to mimic the therapeutic activity of the cytokine interleukin-2, or IL-2, and interleukin-15, or IL-15, while limiting the toxicity caused by the preferential binding of native IL-2 and native IL-15 to non-target cells. However, it is possible NL-201 will demonstrate significant adverse events similar to, or in addition to, those associated with IL-2 and IL-15, such as vascular leak syndrome, hypotension, impaired kidney and liver function, and mental status changes. Therapies involving cytokines have been known to cause side effects such neurotoxicity and cytokine release syndrome.

Further, de novo proteins are a new class of therapeutics that have not been previously tested in humans. De novo proteins can be substantially different from all known proteins and as a result, it is unknown to what extent, if any, these de novo proteins will produce immunologic reactions in patients. Immunologic reactions could substantially limit the effectiveness of the treatment, the duration of treatment, or represent safety risks.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by any of our products, several potentially significant negative consequences could result, including:

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

Any of these developments could materially harm our business, financial condition and prospects.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Our approach to the discovery and development of our therapeutic treatments is based on novel de novo protein design technology that are unproven and may not result in marketable products.

The success of our business depends primarily upon our ability to discover, develop, and commercialize a pipeline of product candidates using our Neoleukin platform. Unlike traditional protein-based therapeutics that modify native proteins, our Neoleukin platform designs new proteins from the ground up. Our platform uses advanced computational algorithms and methods to design functional de novo proteins that are hyper-stable, modifiable, and are designed to optimize desired intermolecular interactions and eliminate undesirable interactions. While we believe this approach will enable us to develop product candidates that may offer unique therapeutic benefits, the scientific basis of our efforts to develop product candidates using our Neoleukin platform is ongoing and may not result in viable product candidates.

While we have had favorable preclinical study results related to precursors to NL-201, we have not yet submitted an IND related to NL-201 or any other product candidate from our Neoleukin platform. Our approach may be unsuccessful in moving NL-201 from preclinical studies into clinical development, discovering additional product candidates, and any product candidates that we are currently developing may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the product candidates unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

To date, we have not tested any of our product candidates in any clinical trials. We may ultimately discover that our Neoleukin platform and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. Our product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue, or they may trigger immune responses that inhibit the activity of the product candidate or that cause adverse side effects in humans. We may spend substantial funds attempting to mitigate these properties and may never succeed in doing so. In addition, product candidates based on our Neoleukin platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Our Neoleukin platform and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective, or harmful ways.

The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. Because the FDA has no prior experience with de novo proteins as therapeutics, we anticipate that this may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We or any future partners may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the products resulting from our Neoleukin platform and research programs prove to be ineffective, unsafe or commercially unviable, our Neoleukin Platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Preclinical and clinical development involve a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All of our product candidates are in preclinical or earlier development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the success of later-stage clinical trials. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing and we have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials, and we could face similar setbacks. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support clinical development of our current or any of our future product candidates.

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We intend to advance NL-201, our lead development candidate from our Neoleukin platform, toward IND submissions by the end of 2020. Commencement of our future clinical trials is subject to finalizing the trial design and submitting an IND or similar submission to the FDA, EMA, or comparable foreign regulatory authorities. Even after we submit our IND or comparable submissions in other jurisdictions, the FDA, EMA, or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

We or any collaborators may experience delays in initiating or completing clinical trials or may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize NL-201 or any future product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to obtain regulatory authorizations to commence a clinical trial;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, or IRBs, ethics committees, FDA, EMA or other applicable regulatory authorities, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from trial protocol or drop out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial;
- we may be unable to obtain or manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates; and
- we may fail to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as our product candidate.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA, or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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Our product development costs will increase if we experience delays in clinical testing or obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed.

Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary or topline data and final data could significantly harm our reputation and business prospects.

Failure to obtain regulatory approval in international jurisdictions would prevent any future product candidates from being marketed outside the United States.

In order to market and sell our products in the European Union and other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our future product candidates by regulatory authorities in the European Union or another jurisdiction, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

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Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of, and commercialization of, our future product candidates and affect the prices we may obtain.

The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new drug products vary from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our future product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain marketing approval.

In the United States in recent years, Congress has considered reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare and Medicaid Services, or CMS, the agency that administers the Medicare program, also has the authority to revise reimbursement rates and to implement coverage restrictions for drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of, and reimbursement for, any approved products, which in turn could affect the price we can receive for those products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in establishing their own coverage policies and reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Affordable Care Act in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act, among other things, also expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation and regulation also revised the definition of AMP for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial provisions affecting compliance were enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Certain provisions of the Affordable Care Act have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". The Affordable Care Act has also been subject to judicial challenge. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Affordable Care Act unconstitutional in its entirety. Pending appeals, which could take some time, the Affordable Care Act is still operational in all respects. Congress may consider other legislation to repeal or replace elements of the Affordable Care Act. Because of the continued uncertainty about the implementation of Affordable Care Act, including the potential for further legal challenges or repeal of Affordable Care Act, we cannot quantify or predict with any certainty the likely impact of the Affordable Care Act or its repeal on our business, prospects, financial condition or results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President 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 did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 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 that went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Furthermore, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer's patient programs, and reform government program reimbursement methodologies for drug products. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our future product candidates, if any, may be.

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In the United States, the European Union and other potentially significant markets for our future product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional coverage, pricing and reimbursement controls in the European Union will put additional pressure on product coverage, pricing, reimbursement and utilization, which may adversely affect our business, results of operations, financial condition and cash flows and future prospects. These pressures can arise from various sources, including but not limited to, rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and Canada and require us to develop and implement costly compliance programs.

As we expand our operations outside of the United States and Canada, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We must also comply with U.S. laws applicable to the foreign operations of U.S. businesses and individuals, such as the Foreign Corrupt Practices Act, or FCPA, and Canadian laws applicable to the foreign operations of Canadian businesses and individuals, such as the Corruption of Foreign Public Officials Act, or CFPOA. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering 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 certain 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. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

The CFPOA prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Furthermore, a company may be found liable for violations by not only its employees, but also by its third-party agents. Any failure to comply with the CFPOA, as well as applicable laws and regulations in foreign jurisdictions, could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions, which may have a material adverse impact on us and our share price.

Even if we are able to commercialize our future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations and third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what that level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based in part on existing reimbursement amounts for lower cost drugs or may be bundled into the payments for other services. Net 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. Coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage and reimbursement determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We have never marketed a drug before. If we are able to identify and acquire a product candidate that is ultimately approved for sale, but are unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, we may be unable to generate any revenue.

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical drug products and the cost of establishing and maintaining such an infrastructure may exceed the cost-effectiveness of doing so. While we do not currently have any product candidates in clinical development, if we were able to identify and establish product candidates and advance them through clinical development, in order to market any products that may ultimately be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

We may not be successful in our efforts to use our Neoleukin platform to expand our pipeline of product candidates and develop marketable products.

The success of our business depends in part upon our ability to discover, develop, and commercialize products based on our Neoleukin platform, which may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial, and human resources.

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

Because we have limited financial and managerial resources, we focus our research and development efforts on our lead product candidate, NL-201, with initial indications in renal cell carcinoma and melanoma. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We face substantial competition, including companies developing novel treatments and technology platforms in oncology. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies, and emerging biotechnology companies, as well as with technologies and product candidates being developed at academic institutions, governmental agencies, and other public and private research institutions. Our competitors have developed, are developing, or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical, and interleukin and immunoregulatory therapeutics fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological, and therapeutics companies, including companies focused on oncology therapeutics, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our future partners. In addition, these companies compete with us in recruiting scientific and managerial talent.

Our success will depend partially on our ability to develop and commercialize therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we develop.

Our lead product candidate, NL-201, is under development for the treatment of advanced solid tumors, including melanoma and renal cell carcinoma. If approved, it would face competition from approved advanced melanoma and renal cell carcinoma treatments, including multiple checkpoint inhibitors, tyrosine kinase inhibitors, VEGF inhibitors, recombinant human IL-2, and several chemotherapy drugs or combinations. Further, we are aware of several of several IL-2 or IL-15 agonists in various stages of clinical and preclinical development. Nektar Therapeutics, Inc. and Altor BioScience Corporation have an IL-2 and IL-15 molecule, respectively, in Phase II clinical trials. Alkermes plc, Novartis International AG, Sanofi (formerly Synthorx), and Roche AG have disclosed Phase I clinical trials using IL-2 and IL-15 molecules, and we are aware of interleukin programs in preclinical studies at Medicenna Therapeutics Corp, Pivotal BioSciences Inc., BioNTech SE, Xencor Inc. and Ascendis Pharma A/S. Furthermore, several large pharmaceutical companies have disclosed preclinical investments in this field, including AstraZeneca plc, Bristol-Myers Squibb, Roche AG, and Celgene Corporation.

Many of these competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

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

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar biological products (both highly similar and interchangeable biosimilar biological products). The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the first licensure date of the reference product licensed under a Biologics License Application, or BLA. The law is complex and some provisions are still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the BPCIA. There is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Most states have enacted substitution laws that permit substitution of only interchangeable biosimilars. The extent to which a highly similar biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. **Risks Related to Our Reliance on Third Parties**

We expect to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations, and prospects.

We intend to rely in the future on third-party clinical investigators, CROs, clinical data management organizations, and consultants to assist or provide the design, conduct, supervision, and monitoring of preclinical studies and clinical trials of our product candidates. Because we intend to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality, and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs, and consultants will not be our employees, and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful, or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with Good Laboratory Practices and clinical trials to be conducted in accordance with Good Clinical Practices, including for designing, conducting, recording, and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

We rely on third-party manufacturers and suppliers to supply components of our product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

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We do not own or operate facilities for drug manufacturing, storage, distribution, or quality testing. We currently rely, and expect to continue to rely, on third-party contract manufacturers to manufacture bulk drug substances, drug products, raw materials, samples, components, or other materials and reports, and conduct fill-finish services. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, available at acceptable prices. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to review by the FDA, EMA, or other applicable regulatory authorities. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other applicable regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates and approval may be delayed. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are responsible for ensuring that our products comply with regulatory requirements. If any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA, EMA, or other applicable regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance, and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs, or maintain a compliance status acceptable to the FDA, EMA, or other applicable regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. For example, in December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China, has since spread to several countries. To date, this outbreak has already resulted in extended shutdowns of certain businesses in the Wuhan region and has had ripple effects to businesses around the world. Global health concerns, such as coronavirus, could also result in adverse effects to our manufacturing operations. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

Our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.

Our product candidates are biopharmaceuticals, and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated, and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs, and guidelines for the bulk manufacturing, fill-finish services, packaging, and storage of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

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Manufacturing biopharmaceuticals 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. If microbial, viral, or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our third-party manufacturers' facilities are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny approval of our application until the deficiencies are corrected or we replace the manufacturer in our application 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 our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product, or provide fill-finish services, to specifications acceptable to the FDA, EMA, or other applicable 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 prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing, and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. Our de novo protein product candidates may not demonstrate sufficient long-term stability to support a BLA filing or obtain approval, or the product shelf life may be limited by stability results. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse development affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition, and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We may, in the future, seek to enter into collaborations with other third parties for the discovery, development and commercialization of our product candidates. If our collaborators cease development efforts under our collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.

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We expect a significant portion of our future revenue and cash resources to be derived from collaboration agreements or other similar agreements into which we may enter in the future for research, development, and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our likely future collaborators for any marketing, distribution, development, licensing, or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful, we may not be able to execute our strategy to develop certain targets, product candidates, or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services, and resulting options to acquire any licenses of successful product candidates, and the achievement of milestones, contingent payments, and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected.

With respect to future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates may pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, to the extent that any of our future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may have conflicts with our collaborators that could delay or prevent the development or commercialization of our product candidates.

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We may have conflicts with our collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses, and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, or other applicable regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing, and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty, and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership, and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations, and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

Risks Related to Our Business and Operations

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

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We have approximately 36 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers, and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel. We currently do not maintain key person insurance on any of these individuals. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations, and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and technologies related to our Neoleukin Platform, and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation, and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates will be limited which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors are and will be subject, directly and indirectly, to applicable anti-kickback, fraud and abuse, privacy, transparency and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal and administrative sanctions, civil penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, integrity obligations, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings and the curtailment or restructuring of our operations.

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our future arrangements with third-party payors and customers who are in a position to purchase, recommend and/or prescribe our product candidates for which we obtain marketing approval. These broadly applicable fraud and abuse and other healthcare laws and regulations may constrain our future business or financial arrangements and relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities, including our marketing practices, educational programs and pricing policies. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, among other things, prohibits individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g. public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters;

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- HIPAA, as amended by HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers;
- the federal Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS, information related to “payments or other transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other “transfers of value” to such physician owners and their immediate family members; and
- analogous local, state and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; local, state and foreign laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information and/or register their pharmaceutical sales representatives; and local, state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our internal operations and any business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Recent healthcare reform legislation has also strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute, such that a person or entity no longer needs to have actual knowledge of this 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 that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to penalties, including without limitation, significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity obligations, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, we expect there will continue to be federal, state, local and foreign laws and regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future drug candidates and programs because our research and development pipeline may be insufficient, our drug candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our drug candidates could also delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market.

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Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state data privacy and security, fraud and abuse and other healthcare laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations, financial condition and cash flows from future prospects, including the imposition of significant fines or other sanctions.

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

We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any product candidates that we may develop.

We currently maintain product liability insurance coverage of up to \$10 million, which may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our business, results of operations, financial condition and cash flows and future prospects.

We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our future product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;

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- increases to our expenses;
- the failure to discover undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition.

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

In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned 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 results 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 of our future product candidates could be delayed.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics such as the corona virus outbreak and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects.

Our business is subject to risks arising from epidemic diseases, such as the recent outbreak of the COVID-19 illness.

The recent outbreak in China of the Coronavirus Disease 2019, or COVID-19, which has been declared by the World Health Organization to be a pandemic has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing and clinical trials and adversely impact our business, financial condition or results of operations. The COVID-19 outbreak and mitigation measures may also have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Our ability to use our U.S. net operating losses to offset future taxable income will be subject to certain limitations.

As of December 31, 2019, we had U.S. net operating losses, or NOLs, of \$25.5 million, for which we have recorded a full valuation allowance. These NOLs and tax credit carryforwards expire in various years beginning in 2028, if not utilized. Utilization of the NOLs will be subject to significant annual limitations due to historical ownership changes pursuant to Sections 382 of the Internal Revenue Code, or the Code. If we experience further changes to our stock ownership in the future, some of which changes are outside our control, the tax benefits related to the NOLs may be further limited or lost. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition, cash flow and future prospects.

Recent tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, the Tax Cuts and Jobs Act, that significantly changes the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating losses created in 2018 and thereafter will be carried forward indefinitely pursuant to the Tax Cuts and Jobs Act. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of this Tax Cuts and Jobs Act on holders of our common stock is also uncertain and could be adverse. We urge investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Risks Related to Intellectual Property

If we are not able to obtain, maintain, and enforce patent protection for our product candidates, our Neoleukin platform technology, or other proprietary technologies we may develop, development and commercialization of our product candidates may be adversely affected.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Under our License Agreement with the University of Washington, dated July 8, 2019, we have an exclusive license to develop and commercialize products covered by patent applications with claims covering the composition of matter of key molecule families as well as methods of using the computational algorithms that form the basis of the Neoleukin platform. However, we may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce, and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing, and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our future issued or granted patents will not later be found to be invalid or unenforceable or that any future issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents, or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

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The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a large number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, for a given period after allowance or grant patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation action in court or before patent offices or similar proceedings, during which time third parties can raise objections against such initial grant. Such proceedings may continue for a protracted period of time and an adverse determination in any such proceedings could reduce the scope of the allowed or granted claims thus attacked, or could result in our patents being invalidated in whole or in part, or being held unenforceable, which could allow third parties to commercialize our product candidates and compete directly with us without payment to us. In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors, or our future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors, or our future collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed or that we may license in the future will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop additional proprietary technologies that are patentable;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors or collaborators fail to maintain patent applications and later-issued patents covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects. In addition, if the breadth or strength of protection provided by our patent applications and later-issued patents is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We could be required to incur significant expenses to strengthen our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position.

The patent prosecution process is expensive and time-consuming, and we or our future potential licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future potential licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our patent applications and the enforcement or defense of our issued patents may be impacted by the application of or changes in U.S. and foreign standards.

The standards that the USPTO and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product candidates. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validation enforceability, or term of our patent. For example, the U.S. Supreme Court has recently modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

While we cannot predict with certainty the impact the Leahy-Smith Act or any potential future changes to the U.S. or foreign patent systems will have on the operation of our business, the Leahy-Smith Act and such future changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

Obtaining and maintaining any patent protection we may receive will depend on compliance with various procedural, document submissions, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our future potential licensors fail to maintain the patents and patent applications covering our future product candidates, our competitive position would be adversely affected.

We may be subject to claims by third parties claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. In addition, third parties may from time to time make claims over what we regard as our intellectual property, or we may get into disputes with licensors or licensees of our intellectual property rights over the interpretation of the license terms. Our licensors may have the right to terminate their license agreements with us or pursue damages or other legal remedies. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturing organizations, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not currently clear how the FDA's disclosure policies may change in the future, if at all.

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

Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or future collaborators may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so 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 biopharmaceuticals, 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 cost and divert our efforts and attention from other aspects of our business. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Intellectual property rights do not necessarily address all potential threats to any competitive advantage we may have.

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

- Others may be able to make compounds that are the same as or similar to our future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Risks Related to Ownership of Our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance, resulting in substantial losses for investors.

The trading price of our common stock has been, and is likely to continue to be, volatile for the foreseeable future. The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials, including both safety and efficacy, of any of our future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our future product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in this “Risk Factors” section and elsewhere in this report, could have a dramatic and material adverse impact on the market price of our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The trading price of our common stock has been and will continue to be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our principal stockholders, directors and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together beneficially own a majority of our outstanding voting stock. These stockholders are able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders are able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We have ceased to be an "emerging growth company," which means we will no longer be able to take advantage of certain reduced disclosure requirements in our public filings. However, we are still a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

Although we ceased to be an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, on December 31, 2019, we are a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. As a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We cannot predict if investors will find our common stock less attractive because we may rely 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.

If we cease to be a "smaller reporting company" or a "non-accelerated filer" in the future, we may be subject to certain disclosure requirements that are applicable to other public companies that had not been applicable to us previously. These requirements include:

- compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting once we are an accelerated filer or large accelerated filer;
- compliance with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and
- full disclosure and analysis obligations regarding executive compensation.

There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our business, results of operations, financial condition and cash flows and future prospects, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we are not an accelerated filer or large accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

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Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we fail to identify and to remediate any significant deficiencies or material weaknesses that may be identified, or encounter problems or delays in the implementation of internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Stock Market, or NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We have incurred and will incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses will likely increase even more given we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and NASDAQ. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. The increased costs will increase our consolidated net loss. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

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

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

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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We have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of these stockholders and/or facilitate public offerings of our securities held by these stockholders, including in connection with potential future acquisition or capital-raising transactions. For example, in connection with our public offering of common stock on September 19, 2016, we entered into a registration rights agreement with the Baker Entities that together, based on information available to us, collectively beneficially owned approximately 45.1% of our common stock as of September 19, 2016. Under the registration rights agreement, we agree that, if at any time and from time to time after December 19, 2016, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act, we would be obligated to effect such registration. On January 6, 2017, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 10,536,092 shares of our common stock held by the Baker Entities. Our registration obligations under this registration rights agreement cover all shares now held or hereafter acquired by the Baker Entities, would be in effect for up to ten years, and would include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. If the Baker Entities or any other holders of registration rights with respect to our common stock, by exercising their registration and/or underwriting rights or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities or such holders intend to sell a large number of our shares, this could adversely affect the market price of our common stock. We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also filed registration statements covering the sale of up to \$250.0 million of any combination of our common stock, preferred stock, debt securities or warrants and may conduct one or more sales of securities pursuant to such registration statement, from time to time.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, including the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our stockholders. New investors could also gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our 2014 Equity Incentive Plan, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers, including officers, employees and service providers of our subsidiaries and affiliates. Future option grants and issuances of common stock under our 2014 Equity Incentive Plan may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, or our business. If one or more of the securities or industry analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are located at 360-1616 Eastlake Avenue East, Seattle, Washington 98102, where we lease approximately 6,272 square feet of office space pursuant to a lease agreement that expires on October 31, 2021.

We also lease approximately 10,946 square feet of office space in Vancouver, Canada pursuant to a lease agreement that expires on October 31, 2021, with the option to extend the lease to October 31, 2026. This facility houses some of our administration personnel.

On December 23, 2019, we entered into a lease in Seattle, Washington, where we will lease 33,300 square feet of office space pursuant to a lease agreement that expires on December 1, 2028. This space will be our future corporate headquarters which we expect to occupy in the fourth quarter of 2020.

We believe that our existing facility is adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Price Range of Our Common Stock

Our common stock is traded on The Nasdaq Global Market under the symbol “NLTX.”

Dividend Policy

We have not paid any cash dividends on our common stock since our inception. We do not intend to pay any cash dividends in the foreseeable future, but intend to retain all earnings, if any, for use in our business operations.

Stockholders

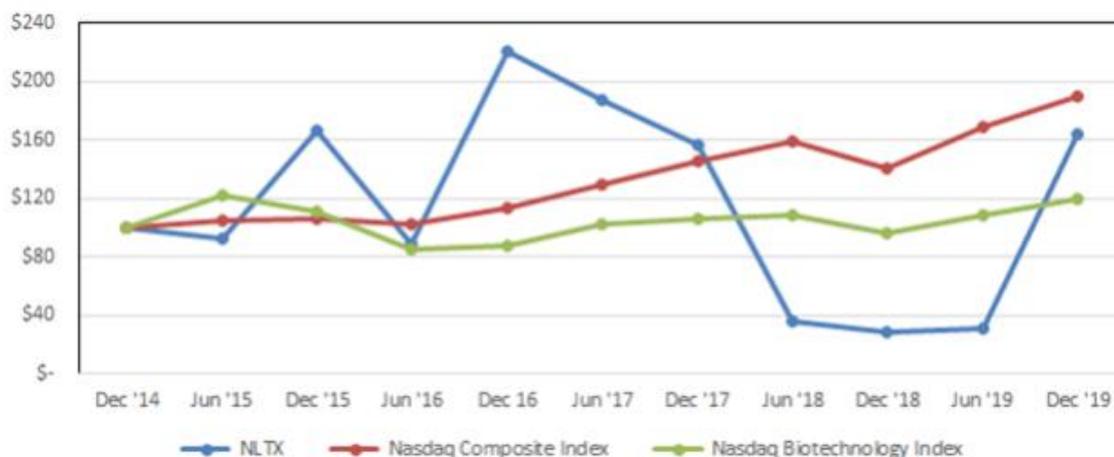
As of March 12, 2020, there were 38,373,160 shares of our common stock outstanding, which were held by 41 holders of record of our common stock, including The Depository Trust Company, which holds shares of our common stock on behalf of an indeterminate number of beneficial owners.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Stock Performance Graph

Our common stock trades on The Nasdaq Global Market. The graph and table below show the cumulative total return to our stockholders during the period from December 31, 2014 through December 31, 2019 in comparison to the cumulative return on the Nasdaq Composite Index and the Nasdaq Biotechnology Index during that same period. The results assume that \$100 was invested on December 31, 2014 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.



For the period December 31, 2014 to December 31, 2019

Neoleukin Therapeutics, Inc.	\$164.27
Nasdaq Composite Index	\$189.45
Nasdaq Biotechnology Index	\$119.17

This information under “Stock Performance Graph” is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any of our filings 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 this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

Recent Sales of Unregistered Equity Securities.

As additional consideration for the rights we license from UW under the Exclusive License Agreement, on December 20, 2019 we issued 12,647 shares of common stock to UW pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with our consolidated financial statements and notes to our consolidated financial statements and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2019, 2018 and 2017 and Consolidated Balance Sheet data as of December 31, 2019 and 2018 have been derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2016 and 2015 and Consolidated Balance Sheet data as of December 31, 2017, 2016 and 2015 have been derived from our audited consolidated financial statements prepared in accordance with U.S. GAAP which are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

Consolidated Statement of Operations Data

(In thousands of U.S. dollars, except per share and share amounts)

	Year Ended December 31, 2019	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2015
Revenue	\$ —	\$ 25,000	\$ —	\$ —	\$ —
Operating expenses:					
Research and development	4,417	41,789	36,267	28,382	15,799
Acquired in-process research & development	47,716	—	—	—	—
General and administrative	18,826	15,835	14,852	9,263	5,541
Total operating expenses	\$ 70,959	\$ 57,624	\$ 51,119	\$ 37,645	\$ 21,340
Loss from operations	\$ (70,959)	\$ (32,624)	\$ (51,119)	\$ (37,645)	\$ (21,340)
Net loss	\$ (69,442)	\$ (31,585)	\$ (50,183)	\$ (37,002)	\$ (21,860)
Total loss attributable to common stockholders	\$ (69,442)	\$ (31,585)	\$ (50,183)	\$ (37,002)	\$ (21,860)
Net loss per common stock—basic and diluted	\$ (2.57)	\$ (1.34)	\$ (2.14)	\$ (1.96)	\$ (1.73)
Basic and diluted weighted average common stock outstanding	27,030,355	23,519,508	23,450,315	18,893,515	12,637,839

Consolidated Balance Sheet Data⁽¹⁾

(In thousands of U.S. dollars)

	December 31, 2019	December 31, 2018	December 31, 2017	December 31, 2016	December 31, 2015
Cash, cash equivalents and short-term investments	\$ 143,093	\$ 76,928	\$ 108,085	\$ 103,059	\$ 74,482
Working capital	138,853	72,538	97,869	93,966	70,004
Total assets	147,023	77,618	110,329	154,380	113,343
Total liabilities	5,336	4,946	11,442	9,716	4,923
Total stockholders’ equity	141,687	72,672	98,887	144,664	108,420
Total liabilities and stockholders’ equity	147,023	77,618	110,329	154,380	113,343

(1) The 2019 Consolidated Balance Sheet Data reflect \$80.7 million in net proceeds received from an underwritten public offering of our common stock that was completed in December 2019. The 2016 Consolidated Balance Sheet Data reflect \$70.7 million in net proceeds received from an underwritten public offering of our common stock that was completed in September 2016. The 2015 Consolidated Balance Sheet Data reflect \$91.8 million in net proceeds received from an underwritten public offering of our common stock that was completed in September 2015.

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The following table contains selected financial data for each quarter of 2019 and 2018. The information should be read in conjunction with our consolidated financial statements and related notes included in the quarterly filings with the SEC in our Quarterly Reports on Form 10-Q. We believe that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

Quarterly Financial Data

(In thousands of U.S. dollars except per share information)

	THREE MONTHS ENDED			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
2019				
Total operating expenses	\$ 2,659	\$ 428	\$ 59,516	\$ 8,356
Net loss	\$ (2,208)	\$ (1)	\$ (59,132)	\$ (8,101)
Net loss attributable to common stockholders	\$ (2,208)	\$ (1)	\$ (59,132)	\$ (8,101)
Net loss per common stock—basic and diluted	\$ (0.09)	\$ —	\$ (2.26)	\$ (0.23)

	THREE MONTHS ENDED			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
2018				
Revenue	\$ —	\$25,000	\$ —	\$ —
Total operating expenses	\$ 14,817	\$22,310	\$ 15,197	\$ 5,300
Net loss	\$ (14,623)	\$ 2,918	\$ (14,993)	\$ (4,887)
Net loss attributable to common stockholders	\$ (14,623)	\$ 2,918	\$ (14,993)	\$ (4,887)
Net loss per common stock—basic and diluted	\$ (0.62)	\$ 0.12	\$ (0.64)	\$ (0.20)

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

Forward-Looking Statements

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs, and involve risks and uncertainties. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading “Item 1A—Risk Factors.” We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. We use sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Our lead product candidate, NL-201, is a combined IL-2 and IL-15 agonist designed to eliminate alpha receptor binding.

Neoleukin/Aquinox Merger

On August 8, 2019, Neoleukin Therapeutics, Inc., or Former Neoleukin, completed its merger with Aquinox Pharmaceuticals, Inc., or Aquinox, in accordance with the terms of the Agreement and Plan of Merger dated August 5, 2019, or the Merger Agreement, by and among Former Neoleukin, Aquinox and Apollo Sub, Inc., a wholly-owned subsidiary of Aquinox. Pursuant to the Merger Agreement, Apollo Sub, Inc. merged with and into Former Neoleukin, with Former Neoleukin surviving the Merger as a wholly-owned subsidiary of Aquinox, referred to herein as the Merger. Upon completion of the Merger, Aquinox was renamed Neoleukin Therapeutics, Inc. and our common stock trades under the ticker symbol “NLTX” on the Nasdaq Global Market.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2019 compared to the year ended December 31, 2018. For a discussion of the year ended December 31, 2018 compared to the year ended December 31, 2017, please refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2018.

Revenue

Prior to the Merger, we had entered into an exclusive license and collaboration agreement with Astellas US LLC, a subsidiary of Astellas Pharma Inc., or Astellas, in May 2018. As consideration for entering into this agreement, we received a non-refundable upfront payment of \$25.0 million and potential future royalties and milestone payments. On November 8, 2018, we entered into an Early Termination Agreement with Astellas to terminate the agreement. The upfront payment of \$25.0 million from Astellas was non-refundable and was recorded as revenue in 2018.

Operating Expenses

The following table summarizes our operating expenses for the years ended December 31, 2019, 2018 and 2017:

	YEAR ENDED DECEMBER 31, (in thousands of U.S. dollars)		
	2019	2018	2017
Research and development	\$ 4,417	\$41,789	\$36,267
Acquired in-process research and development	47,716	—	—
General and administrative	18,826	15,835	14,852
Total operating expenses	<u>\$70,959</u>	<u>\$57,624</u>	<u>\$51,119</u>

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Research and Development Expenses

Prior to the Merger, we had suspended all research and development activities. Since the completion of the Merger in August 2019, we have been actively engaged in research and development activities to advance our lead product candidate, NL-201 and other Neoleukin technologies.

Research and development expenses for the year ended December 31, 2019 were \$4.4 million compared to \$41.8 million for the year ended December 31, 2018. The lower research and development costs during the year ended December 31, 2019 was the result of the suspension of all research and development activities with rosiptor in June 2018 and a \$1.9 million credit arising from reductions to accrued research and development expenses following confirmation by vendors that final costs were less than contracted. This was partly offset by research and development expenses of NL-201 incurred following the completion of the Merger.

Acquired in-process Research and Development

The acquired in-process research and development that arose from the Merger was expensed immediately as management determined that the asset has no alternative future use in accordance with current accounting standards.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel related costs (including severance, stock-based compensation and travel expenses), facility-related costs, insurance, public company expenses, professional fees for consulting, legal and accounting services, and restructuring costs.

For the year ended December 31, 2019, general and administrative expenses were \$18.8 million compared to \$15.8 million for the year ended December 31, 2018. The increase in general and administrative expenses during the year ended December 31, 2019 as compared to the year ended December 31, 2018 was primarily due to Merger related severance costs and the recognition of stock based compensation expense for certain options that vested as a result of the Merger but partly offset by lower personnel and overhead costs as a result of the restructurings in the second half of 2018.

Other income, net

<i>(in thousands)</i>	DECEMBER 31, 2019	DECEMBER 31, 2018	DECEMBER 31, 2017
Interest income	\$ 1,542	\$ 1,563	\$ 998
Foreign exchange losses	(16)	(75)	(19)
Miscellaneous expenses	(8)	(445)	(39)
Total other income, net	<u>\$ 1,518</u>	<u>\$ 1,043</u>	<u>\$ 940</u>

Interest income during the year ended December 31, 2019 was consistent with 2018 as a result of an increase in interest rates offsetting a reduction in cash and investment balances for the year ended December 31, 2019. Interest income increased during the year ended December 31, 2018 compared to 2017 as a result of increase in interest rates, partly offset by a reduction in cash and investment balances during the year ended December 31, 2018.

Foreign exchange losses for the years ended December 31, 2019 and 2018 were insignificant as the net effect of change in foreign exchange rates on our foreign currency holdings was offset by the net effect on our foreign currency liabilities.

Miscellaneous expenses for the year ended December 31, 2019 were primarily normal recurring bank charges. Miscellaneous expenses during the year ended December 31, 2018 were higher in comparison to 2018 was the result of loss on disposal of property and equipment related to the closing of the San Bruno office.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations and relied upon sales of common and preferred stock to fund our operations. Our operating activities used \$15.4 million, \$31.6 million and \$44.7 million of cash flows during the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of \$299.5 million, working capital of \$138.9 million, and cash and cash equivalents of \$143.1 million. We believe that our existing capital resources will be sufficient to fund our operations for at least the next 12 months.

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Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2019, 2018 and 2017:

	YEAR ENDED DECEMBER 31, (in thousands of U.S. dollars)		
	2019	2018	2017
Net cash (used in) provided by:			
Operating activities	\$(15,394)	\$(31,577)	\$(44,718)
Investing activities	(688)	55,951	64,011
Financing activities	82,237	570	423
	66,155	24,944	19,716
Effect of exchange rate changes	10	(48)	15
Net change in cash and cash equivalents	\$ 66,165	\$ 24,896	\$ 19,731

Net cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2019 decreased significantly compared to the year ended December 31, 2018 primarily due to a reduction in operating expenses resulting from the restructuring in the second half of 2018 and the halt of all research and development activities relating to rosiptor in June 2018, partly offset by expenses incurred in connection with our research and development activities relating to NL-201 following the completion of the Merger. Net cash used in operating activities for the year ended December 31, 2018 decreased compared to the year ended December 31, 2017 due to the recognition of the non-refundable upfront payment received from Astellas in June 2018, partly offset by higher operating expenses.

Net cash (used in) provided by investing activities

Net cash used in investing activities for the year ended December 31, 2019 was primarily the result of the acquisition of laboratory and computer equipment, partly offset by net cash received on the completion of the Merger. Net cash provided by investing activities for the years ended December 31, 2018 and 2017 resulted from the maturity of short and long-term investments.

Net cash provided by financing activities

Net cash provided by financing activities for the year ended December 31, 2019 resulted from the public offering of shares of our common stock in December 2019 for gross proceeds of \$86.2 million, before underwriting discounts, commissions and offering expenses of \$5.5 million, and proceeds from the exercise of stock options of \$1.5 million. Net cash provided by financing activities for the years ended December 31, 2018 and 2017 resulted from the proceeds from the exercise of stock options.

Operating and Capital Expenditure Requirements

We have not generated product revenue or achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. As of December 31, 2019, we had approximately \$143.1 million in cash and cash equivalents. Based on our current operating plan, we believe that our available cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through 2022. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund expansion, develop new or enhanced products, or otherwise respond to competitive pressures, may vary significantly from our expectation and we may need to seek additional funds sooner than planned. Unless and until we generate sufficient revenue to be profitable, we will seek to fund our operations through public or private equity or debt financings or other sources. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a negative impact on our business, results of operations, financial condition, cash flows and future prospects. Our future capital requirements will depend on many factors, including:

- the number and characteristics of any future product candidates we develop or may acquire;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates;
- the cost of manufacturing our future product candidates and any products that may achieve regulatory approval;
- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs;

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- the timing, receipt and amount of sales of, or royalties on, future approved products, if any;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation.

Please see Item 1A of this Annual Report titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2019:

	<u>TOTAL</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>Thereafter</u>
Operating lease obligations ⁽¹⁾⁽²⁾	\$18,796	\$ 739	\$2,516	\$2,086	\$2,139	\$2,192	\$ 9,124
Finance lease obligations	245	66	60	60	59	—	—
Laboratory equipment	798	798	—	—	—	—	—
	<u>\$19,839</u>	<u>\$1,603</u>	<u>\$2,576</u>	<u>\$2,146</u>	<u>\$2,198</u>	<u>\$2,192</u>	<u>\$ 9,124</u>

1. We have a lease agreement for approximately 10,946 square feet of office space in Canada which was effective on November 1, 2016 and expires October 31, 2021, with the option to extend the lease to October 31, 2026. The dollar amounts shown in these columns reflect the U.S. dollar equivalent of the obligations. The amounts were converted to U.S. dollars from CAD dollars using the December 31, 2019 daily closing exchange rate of US\$0.76994.
We have a lease agreement for approximately 6,272 square feet of office space in Seattle, Washington which was commenced on October 1, 2019 and expires October 31, 2021. In addition to the basic rent, we are obligated to pay for taxes, operating costs, utilities, additional services and other amounts.
2. On December 23, 2019, we entered into a lease agreement for the lease of approximately 33,300 square feet of office space in Seattle, Washington, for our future principal executive offices, a laboratory for research and development and related uses. The lease was signed on December 23, 2019, rent commences on December 1, 2020 and expires on December 1, 2028, with the option to extend the lease for two five-year terms. We will be obligated to pay approximately \$2.0 million in annual basic rent for the first year of the lease, approximately \$2.1 million in the second year, approximately \$2.1 million in the third year, approximately \$2.2 million in the fourth year, approximately \$2.2 million in the fifth year and approximately \$9.1 million in the sixth, seventh and eighth years. We will also be responsible for the payment of additional rent to cover our share of the annual operating and tax expenses and utilities costs for the building. The operating lease obligation related to this office lease agreement is included in the table above as the lease was signed before December 31, 2019.

Purchase Commitments

We have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable purchase order basis.

Milestone, Royalty-Based and Other Commitments

We have an exclusive license agreement with the University of Washington, or UW, under which UW (on behalf of itself and Stanford University) granted us an exclusive worldwide license under certain patent rights, to make, have made, use, offer to sell, sell, offer to lease or lease, import, export or otherwise offer to dispose of licensed products in all fields of use, and a nonexclusive worldwide license to use certain know-how. The foregoing licenses are sublicensable without UW’s consent, subject to certain limited conditions.

As consideration for the licensed rights, Former Neoleukin issued shares of common stock to UW, which upon the Merger were exchanged for 188,974 shares of our common stock and 4,197 shares of our non-voting convertible preferred stock. Pursuant to the license agreement, we also granted to UW an assignable right to participate in any of our future sale of equity securities, subject to certain exclusions.

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Furthermore, we are required to pay; (i) an annual maintenance fee starting in January 2022 (but excluding any year in which minimum annual royalties are paid); (ii) up to \$0.9 million in combined development and regulatory milestone payments with respect to each distinct class of licensed product; (iii) up to \$10.0 million in combined commercial milestone payments based on cumulative net sales of licensed products within each distinct class of licensed products, beginning when cumulative net sales of the class of licensed products equals or exceeds \$100.0 million, with the majority payable when cumulative net sales of the class of licensed products equals or exceeds \$1.0 billion; (iv) a low single-digit royalty on net sales of licensed products sold by us and our sublicensees, which may be subject to reductions, and subject to minimum annual royalty payments following the first commercial sale of a licensed product; (v) a certain percentage of any sublicense consideration (other than royalties) we receive from sublicensees, based on the stage of development at the time the sublicense is executed; and (vi) a certain percentage of consideration we receive from an acquisition of us or our assets based on the stage of development at the relevant time. We are obligated to pay royalties on a country-by-country basis until the expiration of the last valid claim within the licensed patent rights in such country.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of these consolidated financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued liabilities, stock-based compensation and derivative liabilities. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our consolidated financial statements 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 consolidated financial statements.

Research and Development Expenses

Research and development costs are charged to expense as incurred and include, but are not limited to, employee-related expenses, including salaries, benefits and stock based compensation, expenses incurred under agreements with CROs and investigative sites that conduct clinical trials and preclinical studies, the cost of acquiring, developing and manufacturing clinical trial materials, costs incurred in relation to purchase of technology licenses and patent rights, facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, and other supplies and costs associated with clinical trials, preclinical activities, and regulatory operations. Restructuring costs associated with the termination of research and development programs and related employees are included in research and development costs.

Development costs are expensed in the period incurred unless we believe a development project meets generally accepted accounting criteria for deferral and amortization. No product development expenditures have been deferred to date. We record costs for certain development activities, such as clinical trials, based on our evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued liabilities, as the case may be.

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The cost of such award will be recognized over the period during which services are provided in exchange for the award, generally the vesting period. We account for forfeitures as they occur. All share-based payments to employees are recognized in the consolidated financial statements based upon their respective grant-date fair values.

We estimate the fair value of options granted using the Black-Scholes option pricing model. This approximation uses assumptions regarding a number of inputs that required us to make significant estimates and judgments, including the expected term of the options. We also make decisions regarding the method of calculating the expected stock price volatility and the risk-free interest rate used in the model. The expected volatility assumption is based on industry peer information and the Company expects to continue to do so until it has adequate and relevant historical volatility of its common stock. Additionally, because we have no significant history to calculate the expected term, the simplified method calculation is used.

There is inherent uncertainty in our forecasts and projections and, if we had made different assumptions and estimates than those described previously, the amount of our stock-based compensation expense, net loss and net loss per common stock amounts could have been materially different.

Asset Acquisition

We use assumptions and estimates in determining the fair value of assets acquired and liabilities assumed. We accounted for our transaction with Neoleukin as an asset acquisition as substantially all the value of the acquisition is concentrated in one identifiable intangible asset. The determination of the fair value of intangible assets, which represent a significant portion of the purchase price in our acquisition of Neoleukin, requires the use of significant judgment. We estimate the fair value of acquisition-related intangible assets principally based on projections of cash flows that will arise from the identifiable intangible assets acquired. The present value of the projected cash flow are used to estimate the fair value of the assets acquired at the date of acquisition. Actual cash flows arising from a particular intangible asset could vary from projected cash flows which could imply different carrying values from those established at the dates of acquisition. Other areas requiring significant judgement include (i) whether such intangibles have alternative future use; and (ii) whether such intangibles are amortizable or non-amortizable and, if the former, the period and the method by which the intangible asset will be amortized. In relation to the Merger, we determined that the asset related to acquired in-process research and development has no alternative future use and was expensed immediately upon the completion of the transaction.

Recent Accounting Pronouncements

See Note 2(s), *Recently issued and recently adopted accounting standards* in the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as of December 31, 2019.

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

We are exposed to market risks in the ordinary course of our business. The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates and foreign currency exchange rates.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. As of December 31, 2019, we had holdings in U.S. government securities of \$40.0 million. We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent (100 basis points) to have an immaterial impact in the fair value of our investment portfolio as of December 31, 2019.

Our exposure to foreign currency risk relates primarily to our Canadian operations, including payments we make to vendors and suppliers. We currently do not hedge against foreign currency risk. If the Canadian dollar strengthens against the U.S. dollar, it can result in higher expenditures and have a negative impact on our financial results. We also maintain bank balances in foreign currencies such as the Canadian dollar and the Euro. If these foreign currencies decline against the U.S. dollar, it can have a negative impact on our financial positions. Foreign exchange losses for the years ended December 31, 2019, 2018 and 2017 were insignificant as the impact of changes in foreign exchange rates on our foreign currency portfolio was offset by its impact on our foreign currency liabilities.

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

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Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Neoleukin Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Neoleukin Therapeutics, Inc. and subsidiaries (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, cash flows, and stockholders’ equity, for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Deloitte LLP

Chartered Professional Accountants

Vancouver, Canada

March 12, 2020

We have served as the Company’s auditor since 2007.

NEOLEUKIN THERAPEUTICS, INC.

Consolidated balance sheets

(In thousands of U.S. dollars, except share amounts)

	DECEMBER 31, 2019	DECEMBER 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 143,093	\$ 76,928
Receivables, prepayments and deposits	503	237
Total current assets	143,596	77,165
Property and equipment, net (Note 4)	2,060	400
Operating lease right-of-use asset (Note 7(a))	770	—
Intangible asset, net (Note 5)	567	—
Long-term prepayments and deposits	30	53
Total assets	<u>\$ 147,023</u>	<u>\$ 77,618</u>
Liabilities		
Current liabilities		
Accounts payable and other liabilities (Note 6)	\$ 4,125	\$ 4,618
Operating lease liability (Note 7)	556	—
Finance lease liability (Note 7)	62	9
Total current liabilities	4,743	4,627
Non-current operating lease liability (Note 7)	447	—
Non-current finance lease liability (Note 7)	146	6
Deferred rent	—	313
Total liabilities	<u>5,336</u>	<u>4,946</u>
Commitments and contingencies (Note 15)		
Stockholders' equity		
Share capital:		
Common stock—\$0.000001 par value—authorized, 100,000,000 as of December 31, 2019 (December 31, 2018—50,000,000); issued and outstanding, 37,996,849 as of December 31, 2019 (December 31, 2018—23,537,368) (Note 8(a))	—	—
Preferred stock—\$0.000001 par value—authorized, 5,000,000 as of December 31, 2019 and 2018; nil issued and outstanding as of December 31, 2019 and 2018 (Note 8(b))	—	—
Additional paid-in capital	441,216	302,759
Accumulated deficit	(299,529)	(230,087)
Total stockholders' equity	141,687	72,672
Total liabilities and stockholders' equity	<u>\$ 147,023</u>	<u>\$ 77,618</u>

The accompanying notes form an integral part of these consolidated financial statements

NEOLEUKIN THERAPEUTICS, INC.

Consolidated statements of operations and comprehensive loss

(In thousands of U.S. dollars, except per share and share amounts)

	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Revenue (Note 9)	\$ —	\$ 25,000	\$ —
Operating expenses			
Research and development (Note 10)	4,417	41,789	36,267
Acquired in-process research and development (Note 3)	47,716	—	—
General and administrative (Note 10)	18,826	15,835	14,852
Total operating expenses	70,959	57,624	51,119
Loss from operations	(70,959)	(32,624)	(51,119)
Other income, net			
Interest expense	(1)	(4)	(4)
Other income, net (Note 11)	1,518	1,043	940
	1,517	1,039	936
Net loss	\$ (69,442)	\$ (31,585)	\$ (50,183)
Net loss per common stock—basic and diluted (Note 12)	\$ (2.57)	\$ (1.34)	\$ (2.14)
Basic and diluted weighted average number of common stock outstanding (Note 12)	27,030,355	23,519,508	23,450,315
Comprehensive loss:			
Net loss	\$ (69,442)	\$ (31,585)	\$ (50,183)
Other comprehensive income—unrealized gain on available-for-sale securities	—	70	99
Comprehensive loss	\$ (69,442)	\$ (31,515)	\$ (50,084)

The accompanying notes form an integral part of these consolidated financial statements

NEOLEUKIN THERAPEUTICS, INC.
Consolidated statements of cash flows
(In thousands of U.S. dollars)

	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Operating activities			
Net loss	\$(69,442)	\$(31,585)	\$(50,183)
Non-cash items and reclassifications:			
Stock-based compensation (Note 8(g))	7,683	4,698	3,839
Acquired in-process research & development (Note 3)	47,716	—	—
Depreciation and amortization	340	289	360
Unrealized foreign exchange loss and others	263	452	349
Changes in operating assets and liabilities:			
Receivable, prepayments and deposits	290	1,041	(905)
Accounts payable and other liabilities	(2,244)	(6,472)	1,822
Cash used in operating activities	<u>(15,394)</u>	<u>(31,577)</u>	<u>(44,718)</u>
Investing activities			
Acquisition of Neoleukin Therapeutics, Inc., net of cash acquired (Note 3)	191	—	—
Purchase of investments	—	—	(5,995)
Proceeds from maturity of investments	—	56,000	70,500
Purchase of property and equipment	(879)	(49)	(494)
Cash (used in) provided by investing activities	<u>(688)</u>	<u>55,951</u>	<u>64,011</u>
Financing activities			
Public offering of common stock (Note 8(e))	86,216	—	—
Public offering costs (Note 8(e))	(5,525)	—	—
Proceeds from exercise of stock options	1,555	602	438
Payment on finance lease obligations	(9)	(32)	(15)
Cash provided by financing activities	<u>82,237</u>	<u>570</u>	<u>423</u>
Effect of exchange rate changes on cash and cash equivalents	10	(48)	15
Net change in cash and cash equivalents during the year	66,165	24,896	19,731
Cash and cash equivalents, beginning of year	76,928	52,032	32,301
Cash and cash equivalents, end of year	<u>\$ 143,093</u>	<u>\$ 76,928</u>	<u>\$ 52,032</u>
Supplemental disclosure of cash flow information:			
Interest paid	\$ 1	\$ 4	\$ 4
Interest received	1,544	1,684	1,342
Non-cash investing and financing activities:			
Receivables, prepayments and deposits acquired through the issuance of common stock	\$ 560	\$ —	\$ —
Property, equipment and intangibles acquired through the issuance of common stock	1,693	—	—
Accounts payable, finance lease and other liabilities assumed through the issuance of common stock	(1,673)	—	—
Accrued purchase of property & equipment	—	—	(77)
Accrued offering costs	—	—	(30)

The accompanying notes form an integral part of these consolidated financial statements

NEOLEUKIN THERAPEUTICS, INC.
Consolidated statements of stockholders' equity
(In thousands of U.S. dollars, except share amounts)

	COMMON STOCK		NON-VOTING CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE LOSS	TOTAL STOCKHOLDERS' EQUITY
	NUMBER	AMOUNT	NUMBER	AMOUNT				
Balances, December 31, 2016	23,423,150	\$ —	—	\$ —	\$ 293,111	\$ (148,278)	\$ (169)	\$ 144,664
Cumulative effect of adoption of new accounting standard	—	—	—	—	41	(41)	—	—
Balances January 1, 2017	23,423,150	—	—	—	293,152	(148,319)	(169)	144,664
Options exercised	49,280	—	—	—	468	—	—	468
Stock-based compensation	—	—	—	—	3,839	—	—	3,839
Other comprehensive income	—	—	—	—	—	—	99	99
Net loss	—	—	—	—	—	(50,183)	—	(50,183)
Balances, December 31, 2017	23,472,430	—	—	—	297,459	(198,502)	(70)	98,887
Options exercised	64,938	—	—	—	602	—	—	602
Stock-based compensation	—	—	—	—	4,698	—	—	4,698
Other comprehensive income	—	—	—	—	—	—	70	70
Net loss	—	—	—	—	—	(31,585)	—	(31,585)
Balances, December 31, 2018	23,537,368	—	—	—	302,759	(230,087)	—	72,672
Issuance of common stock for Former Neoleukin common stock (Note 3)	4,589,771	—	—	—	15,055	—	—	15,055
Issuance of convertible preferred stock for Former Neoleukin common stock (Note 3)	—	—	101,927	—	33,432	—	—	33,432
Conversion of convertible preferred stock into common shares	10,192,700	—	(101,927)	—	—	—	—	—
Issuance of common stock, net of share issuance costs of \$5,525 (Note 8(e))	10,263,750	—	—	—	80,691	—	—	80,691
Issuance of shares to University of Washington	12,647	—	—	—	41	—	—	41
Conversion of common stock to pre-funded warrants (Note 8 (d))	(10,925,481)	—	—	—	—	—	—	—
Options exercised	326,094	—	—	—	1,555	—	—	1,555
Stock-based compensation	—	—	—	—	7,683	—	—	7,683
Net loss	—	—	—	—	—	(69,442)	—	(69,442)
Balances, December 31, 2019	37,996,849	\$ —	—	\$ —	\$ 441,216	\$ (299,529)	\$ —	\$ 141,687

The accompanying notes form an integral part of these consolidated financial statements

NEOLEUKIN THERAPEUTICS, INC.

Notes to the consolidated financial statements

1. Nature of operations

Neoleukin Therapeutics, Inc. (“Neoleukin” or “the Company”) is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. The Company’s lead product candidate, NL-201, is a combined IL-2 and IL-15 agonist designed to eliminate alpha receptor binding.

The Company commenced operations in Canada in December 2003. Aquinox Pharmaceuticals (Canada) Inc., a corporation formed under the Canada Business Corporations Act, is a wholly owned subsidiary of Aquinox Pharmaceuticals, Inc., a Delaware corporation formed in May 2007 (“Aquinox”). On August 8, 2019, upon the merger of Aquinox with Neoleukin Therapeutics, Inc. (“Former Neoleukin”) pursuant to an Agreement and Plan of Merger dated August 5, 2019, Former Neoleukin merged with a wholly owned subsidiary of Aquinox. Upon completion of the transaction, Aquinox was renamed Neoleukin Therapeutics, Inc.

The Company’s head office is in Seattle, Washington.

2. Basis of presentation and summary of significant accounting policies

(a) Basis of presentation

The accompanying consolidated financial statements are presented in United States (“U.S.”) dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The financial results are presented on a consolidated basis. All intercompany transactions are eliminated on consolidation.

(b) Capital requirements

The Company operates in a capital intensive business. To finance its operations, the Company is likely to require additional capital. The Company may seek to raise funds through equity or debt financing. There is no assurance that financing will be available to the Company or at terms acceptable to the Company. Failure to obtain sufficient funds on acceptable terms can have a negative impact on the Company’s business, results of operations, financial condition, cash flows and future prospects.

(c) Foreign currency translation and transactions

The functional currency of the Company and its subsidiaries is the U.S. dollar. Monetary assets and liabilities of the Company’s operations denominated in a currency other than the U.S. dollar are re-measured into U.S. dollars at the exchange rate prevailing as at the balance sheet date. Non-monetary assets and liabilities acquired in a currency other than U.S. dollars are translated at historical exchange rates prevailing at each transaction date.

Income and expenses are translated at the exchange rates prevailing at each transaction date, with the exception of amortization which is translated at historical exchange rates. Exchange gains and losses on translation are included in the consolidated statements of operations and comprehensive loss.

(d) Use of estimates and assumptions

The preparation of consolidated 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 at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant areas requiring management estimates include valuation of stock options and restricted stock units, amortization and depreciation, determination of the fair values of assets and liabilities acquired in the acquisition of net assets of Former Neoleukin, accrual of expenses, determination of research and development costs, valuation allowance for deferred income taxes, and contingencies. Actual results could differ from those estimates.

(e) Cash and cash equivalents

All highly liquid investments with maturities of three months or less at the date of acquisition are considered to be cash equivalents.

(f) Property and equipment

Property and equipment are recorded at cost and are amortized using the straight-line basis over a range of three to seven years. Expenditures for improvements to the Company’s office spaces are capitalized and expenditures for maintenance and repairs are expensed as incurred. Leasehold improvements are amortized over the lesser of useful life and term of the lease.

The Company reviews the carrying value of property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. In cases where undiscounted expected future cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of assets. The factors considered by management in performing this assessment include current operating results, trends and prospects, the manner in which the property is used, and the effects of obsolescence, demand, competition, and other economic factors. Based on management’s assessment there were no indicators of impairment of property and equipment as at December 31, 2019 and 2018.

(g) Leases

At contract inception, the Company determines if the contract is a lease or contains a lease. Operating leases are recorded as operating lease right-of-use assets, operating lease liabilities and non-current operating lease liabilities. Finance leases are recorded as finance lease right-of-use assets, finance lease liabilities and non-current finance lease liabilities.

Right-of-use assets and lease liabilities are recognized on the lease commencement date based on the estimated present value of lease payments over the lease term. To determine the present value of the lease payments, the Company utilizes its estimated incremental borrowing rate based on information available at the lease commencement date as the rate implicit in the lease is not readily determinable. The right-of-use assets are recorded net of any lease incentives received. Variable lease cost primarily includes building operating expenses as charged to the Company by its landlords.

For leases of office space with a lease term of less than 12 months and which do not include an option to purchase the underlying asset, the Company has elected to recognize the lease payments in the statement of operations on a straight-line basis over the lease term.

For leases of office space, the Company has elected to not separate the lease components from the non-lease components.

(h) Asset acquisitions/Intangible assets

At the time of acquisition, the Company determines if a transaction should be accounted for as a business combination or acquisition of assets. The Company accounted for its transaction with Neoleukin as an asset acquisition as substantially all the value of the acquisition is concentrated in one identifiable intangible asset.

For an acquisition of assets, the cost of acquiring the asset group, including transaction costs, is allocated to the acquired assets and assumed liabilities based on their relative fair values without giving rise to goodwill. Acquired in-process research and development assets are expensed if management determines that the assets do not have an alternative future use. Other long-lived intangible assets are recorded at the acquired cost and amortized using the straight-line method over an estimated useful life of three years.

The intangible asset is tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. The Company recognizes an impairment loss when carrying amount is not recoverable and the estimated fair value of the intangible asset is less than its carrying value.

(i) Clinical trial accruals

As part of the process of preparing its consolidated financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors, consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company reflects the appropriate clinical trial expenses in the consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial.

During the course of a clinical trial, the Company adjusts the rate of clinical trial expense recognition if actual results differ from estimates. The Company prepares estimates of accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known at that time. Although the Company does not expect the estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

(j) Income taxes

The Company accounts for income taxes using ASC 740, Income Taxes which is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns. In estimating future tax consequences, ASC 740 generally considers all expected future events other than enactments of and changes in the tax law or rates. The measurement of deferred tax assets is reduced, if necessary, by the extent of the valuation allowance. ASC 740 clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. ASC 740 provides a benefit recognition model with a two-step approach consisting of a "more-likely-than-not" recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefits that are more than 50% likely of being realized upon ultimate settlement. ASC 740 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the consolidated financial statements.

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Investment tax credits relating to scientific research and experimental development are accounted for as a reduction in operating expenses. They are recorded in the period when there is reasonable assurance the credits will be realized. If investment tax credit amounts subsequently received are less or more than originally recorded, the difference is treated as a change in estimate.

(k) Revenue recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements subject to the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and identifies performance obligations that are distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when (or as) the performance obligation is satisfied.

The Company's only source of revenue was amounts earned under a license and collaboration agreement entered into and subsequently terminated in 2018.

(l) Research and development costs

Research and development costs are charged to expense as incurred and include items such as: employee related expenses, including salaries and benefits, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies, the cost of acquiring, developing and manufacturing clinical trial materials, facilities, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, and other supplies and costs associated with clinical trials, preclinical activities, and regulatory operations. Restructuring costs associated with the termination of research and development programs and related employees are included in research and development costs.

Development costs are expensed in the period incurred unless management believes a development project meets generally accepted accounting criteria for deferral and amortization. No product development expenditures have been deferred to date. The Company records costs for certain development activities, such as clinical trials, based on management's evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expense.

(m) Accounting for stock-based compensation

The Company has issued stock options and restricted stock units ("RSUs"). The Company measures the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The cost of such award will be recognized over the period during which services are provided in exchange for the award, generally the vesting period. The Company accounts for forfeitures as they occur. All share-based payments to employees are recognized in the consolidated financial statements based upon their respective grant date fair values.

The Company initially measures the compensation expense of stock-based awards granted to consultants using the grant date fair value of the award. Compensation expense is recognized over the period during which services are rendered by such consultants. At the end of each financial reporting period prior to completion of services being rendered, the compensation expense related to these awards is remeasured using the then current fair value of the Company's common stock for RSUs, or based upon updated assumptions in the Black-Scholes option pricing model for stock option awards.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model. This approximation uses assumptions regarding a number of inputs that requires management to make significant estimates and judgments. The expected volatility assumption is based on industry peer information and the Company expects to continue to do so until it has adequate historical volatility of its common stock. Additionally, because the Company has no significant history to calculate the expected term, the simplified method calculation is used.

The fair value of each RSU is measured using the closing price of the Company's common stock on the date of grant.

(n) Restructuring costs

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The Company accounts for restructuring costs in accordance with ASC 420, Exit or Disposal Cost Obligations. ASC 420 specifies that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, except for a liability where employees are required to render service until they are terminated in order to receive termination benefits and will be retained to render service beyond the minimum retention period. A liability for such one-time termination benefits shall be measured initially at the communication date based on the fair value of the liability as of the termination date and recognized ratably over the future service period.

The charges that the Company expects to incur in connection with the restructuring are subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the restructuring plan.

(o) Segment reporting

The Company operates in one segment, the research and development of de novo protein therapeutics using sophisticated computational algorithms and methods to address unmet medical needs in oncology, inflammation, and autoimmunity. The Company's operations and its assets are mostly held in the United States with an immaterial amount of long-lived assets in Canada.

(p) Net loss per common stock

Basic net loss per common stock is computed by dividing net loss by the weighted-average number of common stock and pre-funded warrants outstanding during the period. The pre-funded warrants are included in the computation of basic and diluted net loss per common stock as the warrants are fully vested and exercisable at any time and for a nominal cash consideration. Diluted net loss per common stock is determined using the weighted-average number of common stock outstanding during the period, adjusted for the dilutive effect of common stock equivalents, consisting of shares that might be issued upon exercise of common stock options and restricted stock units. In periods where losses are reported, the weighted-average number of common stock outstanding excludes common stock equivalents because their inclusion would be anti-dilutive.

(q) Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash, cash equivalents, receivables, accounts payable and other liabilities, approximate their fair values because of their nature and/or short maturities.

The Company has no financial instruments that are measured at fair value as of December 31, 2019 and December 31, 2018.

(r) Concentration of credit risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents. Cash and cash equivalents are invested in accordance with the Company's investment policy. The primary objective for the Company's investment portfolio is the preservation of capital and maintenance of liquidity and includes guidelines on the quality of financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

(s) Recently issued and recently adopted accounting standards

The Company adopted ASU 2016-02 "Leases (Topic 842)" effective January 1, 2019. ASU 2016-02 requires lessees to recognize right-of-use assets and lease liabilities for those leases with a lease term of greater than 12 months. The Company used a modified retrospective approach and elected to use the optional transition method to recognize a cumulative-effect adjustment to the opening balance of retained deficit on January 1, 2019. Consequently, comparative periods will continue to be accounted for in accordance with the current lease standard (Topic 840) and the disclosures will be in accordance with ASC 840. The Company elected to apply the "package of practical expedients", which permits it not to reassess under ASU 2016-02 its previous conclusions about lease identification, lease classification and initial direct costs and the practical expedient to not separate non-lease components from the associated lease component for the lease of office space. The adoption of ASU 2016-02 resulted in the recognition of right-of-use assets of \$0.2 million and lease liabilities of \$0.5 million and derecognition of the deferred rent liability of \$0.3 million for the Company's operating leases in the consolidated balance sheets and did not have a material impact to the Company's consolidated statements of operations or cash flows.

In December 2019, the FASB issued ASU 2019-12 "Simplifying the Accounting for Income Taxes." The objective of the standard is to improve areas of GAAP by removing certain exceptions permitted by ASC Topic 740-- Income Taxes and clarifying existing guidance to facilitate consistent application. ASU 2019-12 is effective for fiscal years and interim periods beginning after December 15, 2020. The Company is currently assessing the impact of ASU 2019-12 on its financial statements.

(t) Risks and uncertainties

The Company is subject to numerous risks and uncertainties. These risks, among others, included the following:

- the Company has no source of recurring revenue, has an accumulated deficit of \$299.5 million as of December 31, 2019, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as it continues its research and development programs;

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- the Company is likely to require additional capital to finance its operations which may not be available to it on acceptable terms, or at all;
- the Company's success is primarily dependent on the successful development, regulatory approval and commercialization of its drug product candidates;
- the Company is subject to regulatory approval processes that are lengthy, time consuming and inherently unpredictable; the Company may not be able to obtain approval for any drug product candidates from the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities;
- the Company's intellectual property rights may be subject to claims by third parties and can be difficult and costly to protect;
- the Company may not be able to recruit or retain key employees, including its senior management team;
- the Company depends on the performance of third parties, including contract research organizations and third-party manufacturers; and
- the Company faces competition from other pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others.

3. Merger of Neoleukin Therapeutics, Inc. and Aquinox Pharmaceuticals, Inc.

On August 8, 2019, Former Neoleukin and Aquinox completed a transaction pursuant to the Agreement and Plan of Merger dated August 5, 2019. Former Neoleukin became a wholly owned subsidiary of Aquinox and Aquinox subsequently changed its name to Neoleukin Therapeutics, Inc. All of the outstanding shares of common stock of the Former Neoleukin were exchanged for 4,589,771 shares of common stock of the Company and 101,927 shares of non-voting convertible preferred stock of the Company.

The total consideration paid was \$51.6 million and consisted of:

<i>(in thousands, except share data)</i>	
Fair value of 4,589,771 Aquinox common stock	\$ 15,055
Fair value of 101,927 Aquinox convertible preferred stock	33,432
Cash consideration for fractional shares	5
Transaction costs	3,086
Total consideration	<u>\$ 51,578</u>

The fair value of the Aquinox securities issued to stockholders of Former Neoleukin was based on the closing stock price on August 7, 2019, the last day of trading prior to the completion of the transaction.

The transaction was accounted for as an asset acquisition as Former Neoleukin did not meet the definition of a business as substantially all of the value was in the In-Process Research & Development ("IPR&D") asset. The estimated fair value of the IPR&D asset of \$47.7 million was expensed as the Company determined that the asset has no alternative future.

The following table summarizes the assets acquired and liabilities assumed:

<i>(in thousands)</i>	
Assets acquired:	
Cash and cash equivalents	\$ 3,282
Receivables, prepayments and deposits	560
Property and equipment	1,034
In-process research and development	47,716
Intangible asset	659
Total assets acquired	<u>53,251</u>
Liabilities assumed:	
Accounts payable and other liabilities	1,472
Financing lease liability	201
Total liabilities assumed	<u>1,673</u>
Total consideration	<u>\$ 51,578</u>

4. Property and equipment, net

<i>(in thousands)</i>	DECEMBER 31, 2019		
	COST	ACCUMULATED AMORTIZATION	NET BOOK VALUE
Leasehold improvements	\$ 490	\$ 333	\$ 157
Laboratory equipment	1,515	62	1,453
Office furniture, equipment and systems	743	293	450
	<u>\$ 2,748</u>	<u>\$ 688</u>	<u>\$ 2,060</u>

<i>(in thousands)</i>	DECEMBER 31, 2018		
	COST	ACCUMULATED AMORTIZATION	NET BOOK VALUE
Leasehold improvements	\$ 490	\$ 248	\$ 242
Office furniture, equipment and systems	353	195	158
	<u>\$ 843</u>	<u>\$ 443</u>	<u>\$ 400</u>

Depreciation expense on property and equipment totaled \$0.2 million, \$0.3 million and \$0.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

5. Intangible asset, net

<i>(in thousands)</i>	DECEMBER 31, 2019	DECEMBER 31, 2018
Cost	\$ 659	\$ —
Accumulated amortization	(92)	—
Net intangible asset	<u>\$ 567</u>	<u>\$ —</u>

6. Accounts payable and other liabilities

<i>(in thousands)</i>	DECEMBER 31, 2019	DECEMBER 31, 2018
Trade accounts payable	\$ 1,604	\$ 702
Accrued clinical/preclinical expenses	944	3,655
Accrued compensation and vacation	1,238	21
Other accrued liabilities	339	240
	<u>\$ 4,125</u>	<u>\$ 4,618</u>

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7. Lease liabilities

(a) ASU 2016-02 Leases disclosures

The Company has a lease agreement for approximately 6,272 square feet of office space in Seattle, Washington, for the Company's principal executive offices, a laboratory for research and development and related uses. The lease was effective on September 23, 2019, commenced on October 1, 2019 and expires on October 31, 2021, unless terminated earlier. The Company is also responsible for the payment of additional rent to cover the Company's share of the annual operating and tax expenses and utilities costs for the building.

The Company has a lease agreement for approximately 10,946 square feet of office space in Canada, which commenced on November 1, 2016 and expires October 31, 2021, with the option to extend the lease to October 31, 2026. On December 22, 2016, the Company signed a lease agreement for an additional 2,500 square feet of office space in Canada. The lease for the additional 2,500 square feet expired on June 30, 2019. In addition to the basic rent, the Company is obligated to pay for taxes, operating costs, utilities, additional services and other amounts.

As part of the transaction with Former Neoleukin, the Company assumed a finance lease liability for laboratory equipment. The Company is obligated to make five annual payments for an aggregate purchase price of \$0.3 million. All rights and title will transfer to the Company upon receipt of the final payment.

As of December 31, 2019, the Company's operating lease right of use asset was \$0.8 million and its finance lease right of use asset was \$0.3 million.

The components of the lease expense were as follows:

<i>(in thousands)</i>	YEAR ENDED DECEMBER 31, 2019
Finance lease cost	
Amortization of right-of-use asset	\$ 19
Interest on lease liabilities	—
Operating lease cost	197
Short term lease cost	105
Variable lease cost	181
Total net lease cost	<u>\$ 502</u>

Supplemental balance sheet information related to leases is as follows:

	YEAR ENDED DECEMBER 31, 2019
Weighted average remaining lease term—finance leases	3.33 years
Weighted average remaining lease term—operating leases	1.83 years
Weighted average discount rate—finance leases	7.11%
Weighted average discount rate—operating leases	5.37%

Supplemental cash flow information related to leases was as follows:

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<i>(in thousands)</i>	YEAR ENDED DECEMBER 31, 2019
Cash paid for amounts included in the measurement of operating lease liabilities	\$ 236
Cash paid for amounts included in the measurement of finance lease liabilities	9
Operating lease liabilities arising from obtaining right-of-use assets	1,182

The calculation of the present value of the operating lease payments for the Vancouver lease did not include the option to extend the lease to October 31, 2026.

At December 31, 2019, the future payments under the Company's operating and finance lease liabilities were as follows:

<i>(in thousands)</i>	FINANCE LEASE	OPERATING LEASE
December 31, 2020	\$ 66	\$ 570
December 31, 2021	60	481
December 31, 2022	60	—
December 31, 2023	59	—
Total undiscounted lease payments	245	1,051
Less: imputed interest	(37)	(48)
Total lease liabilities	208	1,003
Less: current portion	(62)	(556)
Non-current lease liabilities—December 31, 2019	<u>\$ 146</u>	<u>\$ 447</u>

On December 23, 2019, the Company entered into a lease agreement for the lease of approximately 33,300 square feet of office space in Seattle, Washington, for the Company's future principal executive offices, a laboratory for research and development and related uses. The lease was effective on December 23, 2019, rent obligations commence on December 1, 2020 and the lease expires on December 1, 2028, unless terminated earlier. The Company will be obligated to pay approximately \$2.0 million per annum in annual basic rent for the first year of the lease and will increase by 2.5% per annum over the term of the lease. The Company will also be responsible for the payment of additional rent to cover the Company's share of the annual operating and tax expenses and utilities costs for the building.

(b) Disclosures related to periods prior to adoption of ASC 842 Leases

Prior to the adoption of ASC 842, and pursuant to the legacy guidance within ASC 840, the Company recorded rent expense on a straight-line basis through the end of the lease term. Scheduled rent increases, rent holidays and tenant improvement allowance were included in deferred rent and recognized as a reduction in deferred rent over the term of the lease. As at December 31, 2018, the Company recorded a deferred rent liability of \$0.3 million.

The minimum lease payments under the non-cancelable operating leases as at December 31, 2018 are payable in the following amounts over the following years.

	2019	2020	2021	Total
Operating lease obligations	\$ 362	\$ 336	\$ 280	\$ 978
	<u>\$ 362</u>	<u>\$ 336</u>	<u>\$ 280</u>	<u>\$ 978</u>

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During the years ended December 31, 2018 and 2017, the Company incurred operating lease costs of \$0.7 million and \$0.7 million, respectively.

8. Stockholders' equity

(a) Common stock

The Company is authorized to issue 100,000,000 shares of common stock with a par value of \$0.000001 per share (December 31, 2018—50,000,000). On November 12, 2019, the Company's stockholders approved the increase in the number of authorized shares of common stock from 50,000,000 to 100,000,000. As of December 31, 2019, total number of shares of common stock issued and outstanding was 37,996,849 (December 31, 2018—23,537,368).

(b) Preferred stock

The Company is authorized to issue 5,000,000 shares of preferred stock with a par value of \$0.000001 per share (December 31, 2018—5,000,000). As of December 31, 2019 and December 31, 2018, no shares of preferred stock were issued or outstanding.

(c) Merger with Former Neoleukin

On August 8, 2019, the Company issued 4,589,771 shares of common stock and 101,927 shares of non-voting convertible preferred stock as consideration in the Merger among Aquinox, Former Neoleukin and Apollo Merger Inc. (see Note 3). Each share of non-voting convertible preferred stock was convertible into 100 shares of common stock and was entitled to receive dividends, on an as-is converted to common stock basis, when dividends are paid to common stockholders. The holders of preferred stock were only entitled to vote when it impacts the rights of the preferred stockholder.

On November 12, 2019, the Company's stockholders approved the conversion of 101,927 shares of non-voting convertible preferred stock into 10,192,700 shares of the Company's common stock. As of December 31, 2019, the Company did not have any outstanding non-voting convertible preferred stock.

(d) Pre-funded common stock warrants

On December 17, 2019, Neoleukin entered into an exchange agreement (the "Exchange Agreement") with certain stockholders, pursuant to which the Company exchanged an aggregate of 10,925,481 shares of common stock held by the stockholders for pre-funded warrants (the "Exchange Warrants") to purchase an aggregate of 10,925,481 shares of common stock (subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting common stock), with an exercise price of \$0.000001 per share. The Exchange Warrants may be exercised at any time after the date of issuance, except that the Exchange Warrants cannot be exercised by the stockholders if, after giving effect thereto, the stockholders would beneficially own more than 9.99% of the outstanding common stock, subject to certain exceptions. The holders of the Exchange Warrants will not have the right to vote on any matter except to the extent required by Delaware law.

As the Exchange Warrants meet the conditions for equity classification, the proceeds previously received for the shares of common stock will remain in additional paid-in capital. Upon the exercise of the warrants the proceeds received along with the exercise price will be recorded in common stock.

(e) Public offerings

On December 20, 2019, the Company completed an underwritten public offering of 10,263,750 shares of its common stock at a price to the public of \$8.40 per share. The aggregate net proceeds received by the Company from the offering, net of underwriting discounts and commissions and offering costs of approximately \$5.5 million, were \$80.7 million.

(f) Stock option plan

In January 2014, the Company's stockholders approved the 2014 Equity Incentive Plan ("2014 Plan") which became effective in March 2014. The 2014 Plan is the successor to and continuation of the Joint Canadian Stock Option Plan (the "2006 Plan"). No further grants will be made under the 2006 Plan. The 2014 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards, and other forms of equity awards to employees, directors, and consultants.

As of December 31, 2019, the maximum number of shares of common stock that may be issued under the 2014 Plan was 9,080,445. The number of shares of common stock reserved for issuance under the 2014 Plan will be increased by the number of shares subject to stock options granted under the 2006 Plan that would have otherwise returned to the 2006 Plan, such as upon the expiration or termination of a stock award prior to vesting. As of December 31, 2019, there were 88,627 shares subject to stock options granted under the 2006 Plan. Additionally, the number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year for a period of up to 10 years, beginning on January 1, 2015 and ending on and including January 1, 2024, by 4% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the board of directors. On November 12, 2019, the Company's stockholders approved the increase in the number of shares reserved from issuance under the 2014 Plan by 4,500,000 shares.

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At December 31, 2019, the number of shares available to be granted under the 2014 Plan was 6,556,534 (December 31, 2018—1,156,378).

Stock option transactions and the number of stock options outstanding are summarized below:

	<u>NUMBER OF SHARES</u>	<u>WEIGHTED AVERAGE EXERCISE PRICE</u>	<u>WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)</u>	<u>AGGREGATE INTRINSIC VALUE (IN THOUSANDS)</u>
Outstanding at December 31, 2018	2,897,294	\$ 9.04	7.96	\$ —
Options granted	4,016,500	2.91		
Options exercised	(326,094)	4.77		
Options forfeited	(747,162)	8.71		
Outstanding at December 31, 2019	<u>5,840,538</u>	<u>\$ 5.11</u>	<u>7.72</u>	<u>\$ 45,037</u>
Exercisable as of December 31, 2019	1,805,043	\$ 9.85	3.36	\$ 7,264

During the year ended December 31, 2019, the Company granted 3,830,000 stock options to employees, 76,500 stock options to consultants and 110,000 stock options to non-employee directors. The stock options granted to employees during the year ended December 31, 2019 have exercise prices per share ranging from \$2.71 to \$5.30 and vest 25% one year after the beginning of the vesting period and thereafter ratably each month over the following thirty-six months. The stock options granted to consultants during the year ended December 31, 2019 have exercise prices per share ranging from \$2.82 to \$3.76 and have a vesting period of one year in equal monthly installments from the beginning of the vesting period for certain grants and a vesting period of 25% one year after the beginning of the vesting period and thereafter ratably each month over the following thirty-six months for other grants. In the event of a change in control, the unvested options of the August and November 2018 grants will vest immediately if the employee has been terminated without cause within twelve months prior to the change in control or if within twelve months of the change in control the employee is terminated without cause. If a change in control does not occur within the twelve months prior to an employee being terminated without cause, the options will continue to vest until the earlier of the change in control or one year from the date of being terminated without cause. The stock options granted to non-employee directors during the year ended December 31, 2019 have an exercise price per share of \$2.82 and have a vesting period of three years in equal annual installments from the beginning of the vesting period. All stock options under the 2014 Plan are subject to a 10-year expiration period.

During the year ended December 31, 2019, 326,094 shares of common stock were issued upon exercise of options with an aggregate intrinsic value of \$1.3 million. During the year ended December 31, 2018, 64,938 shares of common stock were issued upon exercise of options with an aggregate intrinsic value of \$0.3 million.

Restricted stock units

During the year ended December 31, 2019, the Company granted 72,000 restricted stock units to employees and consultants with a weighted average grant date fair value per share of \$3.47. The restricted stock units vest 50% on the first anniversary of the grant and 50% on the second anniversary of the grant. All restricted stock units under the 2014 Plan are subject to a 10-year expiration period.

(g) Stock-based compensation

The fair value of stock options granted is estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Expected volatility	90%	80%	84%
Expected dividends	0%	0%	0%
Expected terms (years)	6.07	6.00	6.00
Risk free rate	1.43%	2.80%	1.90%
Weighted average grant-date fair value of stock options	\$ 2.17	\$ 6.24	\$ 11.85

Stock options are granted with exercise prices as determined by the Board of Directors at the date of grant. The expected term represents the period that the Company's stock-based awards are expected to be outstanding. As the Company does not have sufficient historical experience for determining the expected term of the stock option awards granted the Company has based its expected term for awards issued to employees on the simplified method, which represents the average period from vesting to the expiration of the stock option. In addition, the Company does not have sufficient trading history for the Company's common stock, and therefore, the expected stock price volatility for the Company's common stock was estimated by taking the average historical price volatility for industry peers. The Company has never declared or paid any cash dividends to common stockholders and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero. The risk-free interest rate was based on the yields of treasury securities with maturities similar to the expected term of the options for each option group.

The Company recognizes as an expense the fair value of the stock options on a straight-line basis over the applicable requisite service periods of the awards, which is generally the vesting period. Stock-based compensation expense charged to research and development expenses was \$0.5 million, \$0.8 million and \$1.1 million for the years ended December 31, 2019, 2018 and 2017, respectively. Stock-based compensation expense charged to general and administration expenses was \$7.2 million, \$3.9 million and \$2.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. Total unrecognized compensation cost for all stock-based compensation plans was \$8.4 million and \$7.8 million as of December 31, 2019 and December 31, 2018, respectively, which is expected to be recognized over a weighted-average period of 3.53 years (December 31, 2018—2.79 years).

9. Previous license and collaboration agreement

The Company had previously entered into an exclusive license and collaboration agreement with Astellas US LLC, a subsidiary of Astellas Pharma Inc. ("Astellas") in May 2018. The Company granted Astellas an exclusive, royalty-bearing license to use, research, develop, manufacture and commercialize the Company's drug candidate, rosiptor, and related compounds for all human diseases and conditions in Japan and certain other countries in the Asia-Pacific region. The license and collaboration agreement also included an upfront payment of \$25.0 million and contractual milestones.

The Company determined that its performance obligations under the agreement are the license and transfer of data, ongoing information sharing with Astellas and the material right granted to Astellas to acquire rosiptor at the Company's cost. The upfront payment of \$25.0 million was allocated between each of the performance obligations.

On November 8, 2018, the Company entered into an Early Termination Agreement with Astellas to terminate the exclusive license and collaboration agreement between the Company and Astellas effective immediately. The \$25.0 million upfront payment from Astellas is non-refundable and the full amount was recorded as revenue.

10. Restructuring

In July 2018, the Company's Board of Directors approved a restructuring plan to reduce operating costs and better align the Company's workforce with the needs of its business following the June 27, 2018 announcement that its Phase 3 Leadership 301 clinical trial evaluating once-daily, oral rosiptor for the treatment of IC/BPS failed to meet its primary endpoint. The Company has halted all further development activities with rosiptor.

Under the restructuring plan, the Company reduced its workforce by 30 employees (approximately 53% of total employees) and closed its office in San Bruno, California. Affected employees were eligible to receive severance payments and outplacement services. The Company incurred aggregate restructuring charges of \$7.4 million related to clinical trial closing costs, contract cancellations, closing of its office in San Bruno, severance payments and other employee-related costs. Substantially all of these charges were paid as at June 30, 2019.

During the second quarter of 2019, the Company revised its original estimate of aggregate restructuring charges lower by \$2.0 million based upon updated information from its vendors related to a completed project.

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The following table shows the total amount expected to be incurred and the liability related to the July 2018 restructuring as at December 31, 2019:

<i>(in thousands)</i>	CLINICAL TRIAL CLOSING COSTS	ONE-TIME EMPLOYEE TERMINATION BENEFITS	CONTRACT TERMINATION COSTS	SAN BRUNO OFFICE CLOSING COSTS	TOTAL EXPENSES
Amounts accrued as at January 1, 2018	\$ —	\$ —	\$ —	\$ —	\$ —
Charges—July 2018	5,703	1,879	1,108	465	9,155
Revised estimates during 2018	41	2	187	5	235
Total restructuring costs expected to be incurred	5,744	1,881	1,295	470	9,390
Amounts paid during 2018	(2,204)	(1,881)	(1,201)	(470)	(5,756)
Amounts accrued at December 31, 2018	3,540	—	94	—	3,634
Revised estimates during 2019	(1,957)	—	12	—	(1,945)
Amounts paid during 2019	(1,583)	—	(106)	—	(1,689)
Amounts accrued at December 31, 2019	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

On November 6, 2018, the Company's Board of Directors approved an additional restructuring plan to further reduce operating costs. Under the restructuring plan, the Company reduced its workforce by 16 employees effective December 31, 2018. Further reduction of staff occurred in 2019. Affected employees were eligible to receive severance payments and outplacement services. The Company incurred restructuring charges of \$1.0 million in 2018 related to one-time termination severance payments and other employee-related costs. Substantially all of these charges were paid as at December 31, 2018. Additional restructuring charges of \$0.7 million were incurred in 2019.

The following table shows the total amount expected to be incurred and the liability related to the November 2018 restructuring as at December 31, 2019:

<i>(in thousands)</i>	ONE-TIME EMPLOYEE TERMINATION BENEFITS
Total restructuring costs expected to be incurred	\$ 984
Amount paid in 2018	(922)
Amount accrued at December 31, 2018	62
Restructuring costs incurred during 2019	655
Amount paid during the period ended December 31, 2019	(702)
Amount accrued at December 31, 2019	<u>\$ 15</u>
Restructuring charges expected to be incurred	1,645
Cumulative restructuring costs incurred as at December 31, 2019	(1,639)
Restructuring charges expected to be incurred in future periods	<u>\$ 6</u>

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For the year ended December 31, 2019, restructuring recoveries of \$1.9 million were recorded in research and development expenses and restructuring costs of \$0.7 million in general and administrative expenses. For the year ended December 31, 2018, restructuring costs of \$9.0 million were recorded in research and development expenses, \$1.1 million in general and administrative expenses and \$0.3 million in miscellaneous expenses (Note 11). Substantially all restructuring costs were paid by September 30, 2019.

11. Other income, net

<i>(in thousands)</i>	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Interest income	\$ 1,542	\$ 1,563	\$ 998
Foreign exchange losses	(16)	(75)	(19)
Miscellaneous expenses (Note 10)	(8)	(445)	(39)
	<u>\$ 1,518</u>	<u>\$ 1,043</u>	<u>\$ 940</u>

12. Net loss per common stock

Basic and diluted net loss per common stock is computed by dividing net loss by the weighted average number of common stock outstanding. The Company excluded the following outstanding stock options and restricted stock units from the computation of basic and diluted net loss per common stock as the effect would have been antidilutive for all periods presented.

	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Outstanding stock options	5,840,538	2,897,294	2,069,167
Restricted stock units	72,000	—	—
	<u>5,912,538</u>	<u>2,897,294</u>	<u>2,069,167</u>

13. Income taxes

Income tax recovery varies from the amounts that would be computed by applying the expected U.S. federal income tax rate (21%) as shown in the following table:

	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Statutory federal income tax rate	(21.0)%	(21.0)%	(35.0)%
Change in tax rate	0.0	(0.1)	(3.6)
State income taxes	0.0	(1.4)	(0.6)
Foreign rate differential	(0.2)	(4.3)	7.9
Acquired in-process research and development	14.4	0.0	0.0
Stock compensation	2.6	2.8	2.0
Change in valuation allowance	(0.6)	24.8	25.4
Expiration of NOLs (section 382)	5.4	—	—
Effect of the U.S. Tax Cuts and Jobs Act	—	—	4.6
Other	(0.6)	(0.8)	(0.7)
Income tax recovery	<u>—</u>	<u>—</u>	<u>—</u>

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On December 22, 2017, the U.S. passed into law the “Tax Cuts and Jobs Act”, or the Act, which significantly overhaul the U.S. tax system. Significant changes to the Internal Revenue Code included a reduction in the U.S. federal corporate tax rate from 35% to 21%. The Company’s accounting for the provisions of the Act, based on the Company’s understanding of the Act and the latest guidance available, resulted in a \$2.3 million reduction in its net deferred income tax assets as of December 31, 2017 to reflect the new statutory tax rate. This reduction to the net deferred income tax assets was fully offset by a corresponding reduction in the valuation allowance.

<i>(in thousands)</i> Net loss before taxes:	YEARS ENDED DECEMBER 31,		
	2019	2018	2017
Canada	\$ (2,129)	\$ (22,477)	\$ (43,758)
U.S.	(67,313)	(9,108)	(6,425)
Total	<u>\$ (69,442)</u>	<u>\$ (31,585)</u>	<u>\$ (50,183)</u>

Deferred income tax assets and liabilities result from the temporary differences between the amount of assets and liabilities recognized for financial statement and income tax purposes. The significant components of the deferred income tax assets are as follows:

<i>(in thousands)</i>	DECEMBER 31, 2019	DECEMBER 31, 2018
Canadian net operating losses	\$ 39,574	\$ 40,252
U.S. net operating losses	5,347	5,588
Research and development deductions and credits	11,062	9,588
Other	1,831	1,797
Less: valuation allowance	(57,814)	(57,225)
Net deferred income tax assets	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2019, the Company had Canadian net operating losses carried forward for tax purposes which were available to reduce taxable income of future years of approximately \$146.6 million (December 31, 2018—approximately \$149.1 million) expiring commencing in 2025 through 2039.

At December 31, 2019, the Company had U.S. net operating losses carried forward for tax purposes which were available to reduce taxable income of future years of approximately \$25.5 million (December 31, 2018—approximately \$21.8 million), of which approximately \$nil million (December 31, 2018—approximately \$14.6 million) arose in California. Of the \$25.5 million of U.S. net operating loss carryforwards, \$2.3 million will expire between the years 2028 and 2037 and the remaining \$23.2 million are indefinite. The Company completed a formal study under IRC Section 382 to determine the U.S. tax attributes available for use. The results of the study indicated significant restriction on the Company’s ability to utilize the U.S. net operating losses carried forward. The U.S. tax attributes disclosed reflected the conclusion of that study. However, future ownership changes may further affect the limitation in future years.

The Company also had unclaimed Canadian tax deductions with no expiry for scientific research and experimental development expenditures of approximately \$22.5 million at December 31, 2019 (December 31, 2018—approximately \$19.7 million). In addition, at December 31, 2019, the Company had approximately \$5.8 million (December 31, 2018—approximately \$5.2 million) of investment tax credits available to offset Canadian federal and provincial taxes payable expiring commencing in 2020 through 2038.

Under ASC 740, the benefit of an uncertain tax position that is more likely than not of being sustained upon audit by the relevant taxing authority must be recognized at the largest amount that is more likely than not to be sustained. No portion of the benefit of an uncertain tax position may be recognized if the position has less than a 50% likelihood of being sustained. The Company currently does not have any unrecognized tax benefits of uncertain tax positions. The Company does not expect any significant increases to its unrecognized tax benefits within twelve months of the reporting date.

The Company currently files income tax returns in the United States and Canada, the jurisdictions in which the Company believes that it is subject to tax. Further, while the statute of limitations in each jurisdiction where an income tax return has been filed generally limits the examination period, as a result of loss carry-forwards, the limitation period for examination generally does not expire until several years after the loss carry-forwards are utilized. Other than routine audits by tax authorities for tax credits and tax refunds that the Company has claimed, the Company is not aware of any other material income tax examination currently in progress by any taxing jurisdiction.

14. License and patent agreements

The Company has an exclusive license agreement with the University of Washington, or UW, under which UW (on behalf of itself and Stanford University) granted the Company an exclusive worldwide license under certain patent rights, to make, have made, use, offer to sell, sell, offer to lease or lease, import, export or otherwise offer to dispose of licensed products in all fields of use, and a nonexclusive worldwide license to use certain know-how. The foregoing licenses are sublicensable by the Company without UW's consent, subject to certain limited conditions.

As consideration for the licensed rights, the Former Neoleukin issued 536,813 shares of common stock to UW. These shares were exchanged for 188,974 shares of common stock of the Company and 4,197 shares of non-voting convertible preferred stock on the completion of the Merger. Pursuant to the agreement, the Company also granted to UW an assignable right to participate in any future sale of equity securities by the Company, subject to certain exclusions.

Furthermore, the Company is required to pay; (i) an annual maintenance fee starting in January 2022 (but excluding any year in which minimum annual royalties are paid); (ii) up to \$0.9 million in combined development and regulatory milestone payments with respect to each distinct class of licensed product; (iii) up to \$10.0 million in combined commercial milestone payments based on cumulative net sales of licensed products within each distinct class of licensed products, beginning when cumulative net sales of the class of licensed products equals or exceeds \$100.0 million, with the majority payable when cumulative net sales of the class of licensed products equals or exceeds \$1.0 billion; (iv) a low single-digit royalty on net sales of licensed products sold by the Company and its sublicensees, which may be subject to reductions, and subject to minimum annual royalty payments following the first commercial sale of a licensed product; (v) a certain percentage of any sublicense consideration (other than royalties) the Company receives from sublicensees, based on the stage of development at the time the sublicense is executed; and (vi) a certain percentage of consideration the Company receives from an acquisition of the Company or its assets based on the stage of development at the relevant time. The Company is obligated to pay royalties on a country-by-country basis until the expiration of the last valid claim within the licensed patent rights in such country.

The agreement will expire upon the expiration of the last valid claim within the licensed patent rights. The Company may terminate the agreement upon prior written notice to UW. UW may terminate the agreement by a specified number of days' notice if the Company permanently ceases operations, becomes insolvent or similar, or if the Company challenges the validity of the licensed patent rights. In addition, UW may terminate the agreement for material breach that is not cured within a specified number of days, which cure period is to be at least doubled if the Company is proceeding diligently to cure the default.

The Company has an agreement with Biolipox AB of Sweden for patent rights relating exclusively or principally to a specific class of compounds, which include rosiptor. The terms of the agreement required the Company to pay CAD \$50,000 immediately, CAD \$250,000 in shares of common stock upon the first submission to the FDA of an Investigational New Drug (IND) for a compound from the acquired class of compounds, and CAD \$3.0 million upon the advancement of one of the compounds from the acquired class of compounds into a Phase 3 clinical trial. Certain other milestone payments, totaling CAD \$1.5 million are payable upon the first commercial sale following regulatory approval of the first compound in each of the United States, Europe and Japan. There are no royalty payments due under this agreement. In June 2014, the Company issued 19,762 shares of common stock to Biolipox AB as payment for achievement of the milestone related to the first submission to the FDA of an IND for rosiptor. A CAD \$3.0 million milestone payment was paid in November 2016 as a result of the advancement of rosiptor into a Phase 3 clinical trial. As all research and development activities related to rosiptor have been suspended, the Company does not currently have any product candidates under development that are covered by this agreement.

The Company has an exclusive license agreement with the University of British Columbia ("UBC") for a worldwide license to certain small molecule compounds and pharmaceutical compositions that are modulators of SHIP1 activity. The agreement expires at the earlier of the last expiry of any patent obtained related to the technology or through enactment of one of the termination clauses stipulated in the agreement. The Company paid annual maintenance fees of CAD \$1,000 related to this agreement for the year ended December 31, 2019 (December 31, 2018—CAD \$1,000) and have contingent payments totaling up to CAD \$2.2 million for the first drug product and CAD \$1.5 million for each subsequent drug product plus low single-digit royalties. The Company does not currently have any product candidates under development that are covered by the UBC license agreement. On February 14, 2020, the Company and UBC entered into an agreement to terminate this license agreement. Upon the termination of this license agreement, the Company has no further obligations under this license agreement.

The Company has an agreement with the British Columbia Cancer Agency and StemCell Technologies, Inc. for the assignment to the Company of certain patents to technology relating to SHIP1 in return for low single-digit royalty payment on product sales or low double-digit percentage of sublicense revenue. The agreement is to expire at the later of 20 years from the effective date of the agreement or upon the expiration of the last patent covered by the license. The Company incurred maintenance fees of CAD \$5,000 related to this agreement during the years ended December 31, 2019, 2018 and 2017. The Company does not currently have any product candidates under development that are covered by this agreement.

15. Commitments and Contingencies

In 2019, the Company entered into a non-cancelable contract to purchase laboratory equipment for \$0.8 million. The equipment is expected to be delivered in the first half of 2020.

In the ordinary course of business, the Company may be subject from time to time to various proceedings, lawsuits, disputes, or claims. Although the Company cannot predict with assurance the outcome of any litigation, it does not believe there are currently any such actions that, if resolved unfavorable, would have a material impact on the Company's financial condition, results of operations or cash flows.

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

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures. Our Chief Executive Officer (our principal executive officer) and our Interim Chief Financial Officer (our principal accounting officer) have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this annual report. Based on that evaluation, they have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were, in design and operation, effective at a reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in internal control over financial reporting. There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control. The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report.

Item 9B. Other Information.

None

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2019 fiscal year pursuant to Regulation 14A for our 2020 Annual Meeting of Stockholders, or the 2020 Proxy Statement, and the information to be included in the 2020 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

(1) The information required by this Item concerning our executive officers and our directors and nominees for director, including information with respect to our audit committee and audit committee financial expert, may be found under the section entitled “Proposal No. 1 Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “Information About Our Executive Officers” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning our code of ethics may be found under the section entitled “Information Regarding the Board of Directors and Corporate Governance” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

(3) The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled “Delinquent Section 16(a) Reports” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item may be found under the sections entitled “Director Compensation,” “Executive Compensation” and “Equity Compensation Plan Information” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

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

(1) The information required by this Item with respect to security ownership of certain beneficial owners and management may be found under the section entitled “Security Ownership of Certain Beneficial Owners and Management” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item with respect to securities authorized for issuance under our equity compensation plans may be found under the sections entitled “Equity Compensation Plan Information” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

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

(1) The information required by this Item concerning related party transactions may be found under the section entitled “Transactions with Related Persons” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning director independence may be found under the sections entitled “Information Regarding the Board of Directors and Corporate Governance—Independence of the Board of Directors” and “Information Regarding the Board of Directors and Corporate Governance—Information Regarding Committees of the Board of Directors” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item may be found under the section entitled “Proposal No. 2 Ratification of Appointment of Independent Registered Public Accounting Firm” appearing in the 2020 Proxy Statement. Such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

- (1) Financial Statements and Report of Independent Registered Public Accounting Firm
- (2) Financial Statement Schedules

Financial Statement Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

- (3) Exhibits are incorporated herein by reference or are filed with this report as indicated below (numbered in accordance with Item 601 of Regulation S-K).

(b) Exhibits

The exhibits listed below on the Exhibit Index are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
2.1*	Agreement and Plan of Merger by and between Aquinox Pharmaceuticals, Inc., Apollo Sub, Inc., and Neoleukin Therapeutics, Inc., dated August 5, 2019—Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2019
2.2	Form of Support Agreement, by and among Aquinox Pharmaceuticals, Inc., Neoleukin Therapeutics, Inc. and each of the parties named in each agreement therein—Incorporated by reference to Exhibit 2.2 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2019
2.3	Form of Lock-Up Agreement, by each of the parties named in each agreement therein—Incorporated by reference to Exhibit 2.3 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2019
3.1	Amended and Restated Certificate of Incorporation of Neoleukin Therapeutics, Inc.—Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2014
3.2	Amended and Restated Bylaws of Neoleukin Therapeutics, Inc.—Incorporated by reference to Exhibit 3.6 to our Registration Statement on Form S-1, as amended (File No. 333-193615), filed with the Securities and Exchange Commission on February 28, 2014
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Stock, filed August 8, 2019—Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission August 12, 2019
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Neoleukin Therapeutics, Inc., filed August 9, 2019—Incorporated by reference to Exhibit 3.4 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 filed with the Securities and Exchange Commission on November 13, 2019.
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Neoleukin Therapeutics, Inc., filed November 13, 2019—Incorporated by reference to Exhibit 3.5 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 filed with the Securities and Exchange Commission on November 13, 2019.
4.1	Specimen Common Stock Certificate of the Registrant—Incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 filed with the Securities and Exchange Commission on May 13, 2014

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Number	Description
4.2	<u>Registration Rights Agreement, dated September 19, 2016, by and between Aquinox Pharmaceuticals, Inc. and the persons listed on Schedule A attached thereto—Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 20, 2016</u>
4.3	<u>Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934, as amended</u>
4.4	<u>Form of Pre-Funded Warrant—Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on December 19, 2019</u>
10.1	<u>Exclusive Start-Up License Agreement, dated July 8, 2019, by and between the University of Washington and Neoleukin Therapeutics, Inc.—Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission August 12, 2019</u>
10.2	<u>Facility Use Agreement, dated December 4, 2018, by and between Institute for Systems Biology and Neoleukin Therapeutics, Inc.—Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the Securities and Exchange Commission August 12, 2019</u>
10.3	<u>Amendment No. 1 to the Facility Use Agreement, dated April 17, 2019, by and between Institute for Systems Biology and Neoleukin Therapeutics, Inc.—Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed with the Securities and Exchange Commission August 12, 2019</u>
10.4+	<u>Separation Agreement and Release, dated August 5, 2019, by and between Aquinox Pharmaceuticals, Inc., and David J. Main—Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2019</u>
10.5+	<u>Employment Agreement, dated August 5, 2019, by and between Aquinox Pharmaceuticals, Inc., and Jonathan G. Drachman—Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2019</u>
10.6+	<u>Transition Retention Agreement, dated August 5, 2019, by and between Aquinox Pharmaceuticals, Inc., and Kamran Alam—Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 6, 2019</u>
10.7	<u>Lease Agreement, dated September 23, 2019, by and between Neoleukin Therapeutics, Inc. and ARE-Eastlake Avenue No. 3, LLC. Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 filed with the Securities and Exchange Commission on November 13, 2019</u>
10.8	<u>Lease Agreement, dated December 23, 2019, by and between Neoleukin Therapeutics, Inc. and ARE-Eastlake Avenue No. 3, LLC</u>
10.9+	<u>Joint Canadian Stock Option Plan—Incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-193615) filed with the Securities and Exchange Commission on January 28, 2014</u>
10.10+	<u>Forms of Option Agreement for Registrant’s Joint Canadian Stock Option Plan—Incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-193615) filed with the Securities and Exchange Commission on January 28, 2014</u>
10.11+	<u>Neoleukin Therapeutics, Inc. 2014 Equity Incentive Plan, as amended November 12, 2019—Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on November 14, 2019</u>
10.12+	<u>Forms of Option Agreement and Option Grant Notice for Registrant’s 2014 Equity Incentive Plan—Incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-193615) filed with the Securities and Exchange Commission on January 28, 2014</u>
10.13	<u>Form of Indemnity Agreement entered into between the Registrant and each of its directors and its executive officers—Incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1 (File No. 333-193615) filed with the Securities and Exchange Commission on January 28, 2014</u>
10.14*	<u>Exchange Agreement, dated December 17, 2019, by and among Neoleukin Therapeutics, Inc., 667, L.P. and Baker Brothers Life Sciences, L.P.—Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on December 19, 2019</u>

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Number	Description
10.15	<u>Lease Agreement, dated February 5, 2016, by and between Aquinox Pharmaceuticals (Canada) Inc. and 560677 B.C. Ltd. Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2016</u>
21.1	<u>List of subsidiaries of the Registrant</u>
23.1	<u>Consent of Deloitte LLP, Independent Registered Public Accounting Firm.</u>
31.1	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a).</u>
31.2	<u>Certification of Interim Chief Financial Officer pursuant to Rule 13a-14(a).</u>
32.1#	<u>Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.</u>
32.2#	<u>Certification of Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350.</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

+ Indicates a management contract or compensatory plan.

This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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

Item 16. Form 10-K Summary.

N/A

SIGNATURES

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

Neoleukin Therapeutics, Inc.

Date: March 12, 2020

By: /s/ Jonathan G. Drachman
Jonathan G. Drachman
President & Chief Executive Officer
(Principal Executive Officer)

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u> /s/ Jonathan G. Drachman </u> Jonathan G. Drachman	Director, President & Chief Executive Officer (Principal Executive Officer)	March 12, 2020
<u> /s/ Kamran Alam </u> Kamran Alam	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2020
<u> /s/ M. Cantey Boyd </u> M. Cantey Boyd	Director	March 12, 2020
<u> /s/ Sean Nolan </u> Sean Nolan	Director	March 12, 2020
<u> /s/ Todd Simpson </u> Todd Simpson	Director	March 12, 2020
<u> /s/ Lewis T. Williams </u> Lewis T. Williams	Director	March 12, 2020

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

As of December 31, 2019, Neoleukin Therapeutics, Inc. (the "*Company*," "*we*" or "*our*") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934: our common stock, \$0.000001 par value per share. The following summary describes the material terms of our common stock. The description of common stock is qualified by reference to our certificate of incorporation and our bylaws, which are included as exhibits to our most recent Annual Report on Form 10-K and to the applicable provisions of the Delaware General Corporation Law.

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. Under our certificate of incorporation and bylaws, our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

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

Liquidation

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

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.

Preferred Stock

Under our certificate of incorporation, our board of directors is authorized by resolution to divide the authorized preferred stock into series and, with respect to each series, to determine the designations and the powers, preferences and rights, and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights, redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. Our board of directors can, without stockholder approval but subject to the terms of the certificate of incorporation, issue preferred stock with voting and other rights that could adversely affect the voting power of the holders of our common stock and which could have certain anti-takeover effects. Before we may issue any series of preferred stock, our board of directors will be required to adopt resolutions creating and designating such series of preferred stock.

Anti-Takeover Effects of Our Charter Documents and Some Provisions of Delaware Law

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) 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

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws

Our certificate of incorporation provides for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding are able to elect all of our directors. Our certificate of incorporation and our bylaws also provide that directors may be removed by the stockholders only for cause upon the vote of at least 66 2/3% of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Our certificate of incorporation and bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminates the right of stockholders to act by written consent without a meeting. Our bylaws also provide that only our chairman of the board, chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder’s notice.

Our certificate of incorporation and bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2/3% or more of our outstanding common stock. *Choice of Forum*

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

However, several lawsuits involving other companies have been brought challenging the validity of choice of forum provisions in certificates of incorporation, and it is possible that a court could note such provision is inapplicable or unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing on The Nasdaq Global Market

Our common stock is listed on The Nasdaq Global Market under the symbol "NLTX."

LEASE AGREEMENT

THIS LEASE AGREEMENT (this “**Lease**”) is made this _____ day of December, 2019, between **ARE-EASTLAKE AVENUE NO. 3, LLC**, a Delaware limited liability company (“**Landlord**”), and **NEOLEUKIN THERAPEUTICS, INC.**, a Delaware corporation (“**Tenant**”).

Building: 188 East Blaine Street, Seattle, Washington 98102

Premises: That portion of the east side of the 4th floor of the Building, containing approximately 33,300 rentable square feet, as determined by Landlord, as shown on **Exhibit A**.

Project: The real property on which the Building in which the Premises are located, together with all improvements thereon and appurtenances thereto as described on **Exhibit B**.

Base Rent: \$61.00 per rentable square foot of the Premises per year, subject to adjustment pursuant to Section 4 hereof.

Rentable Area of Premises: 33,300 sq. ft.

Rentable Area of Project: 211,917 sq. ft.

Tenant’s Share of Operating Expenses: 15.71%

Security Deposit: \$507,825.00, subject to reduction pursuant to the terms of Section 6.

Target Commencement Date: December 15, 2019

Rent Adjustment Percentage: 2.5%

Base Term: Beginning on the Commencement Date and ending 96 months from the first day of the first full month following the Rent Commencement Date. For clarity, if the Rent Commencement Date occurs on the first day of a month, the expiration of the Base Term shall be measured from that date. If the Rent Commencement Date occurs on a day other than the first day of a month, the expiration of the Base Term shall be measured from the first day of the following month.

Permitted Use: Research and development laboratory, related office and other related uses consistent with the character of the Project and otherwise in compliance with the provisions of Section 7 hereof.

Address for Rent Payment:
Fifth Third Wholesale Lockbox
Lockbox 234078
4900 West 95th Street
Oak Lawn, IL 60453

Landlord’s Notice Address:
26 North Euclid Avenue
Pasadena, CA 91101
Attention: Corporate Secretary

Tenant’s Notice Address:
188 E. Blaine Street, Suite 450
Seattle, Washington 98102
Attention: Lease Administrator

The following Exhibits and Addenda are attached hereto and incorporated herein by this reference:

[X] **EXHIBIT A**—PREMISES DESCRIPTION
[X] **EXHIBIT C**—WORK LETTER
[X] **EXHIBIT E**—RULES AND REGULATIONS
[X] **EXHIBIT G**—SHARED LAB AREA

[X] **EXHIBIT B**—DESCRIPTION OF PROJECT
[X] **EXHIBIT D**—COMMENCEMENT DATE
[X] **EXHIBIT F**—TENANT'S PERSONAL PROPERTY

1. Lease of Premises. Upon and subject to all of the terms and conditions hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The portions of the Project which are for the non-exclusive use of tenants of the Project, are collectively referred to herein as the "Common Areas." Landlord reserves the right to modify Common Areas, provided that such modifications do not materially adversely affect Tenant's use of the Premises for the Permitted Use. From and after the Rent Commencement Date through the expiration of the Term, Tenant shall have access to the Building and the Premises 24 hours a day, 7 days a week, except (i) in the case of emergencies, (ii) as the result of Legal Requirements, (iii) as reasonably necessary for the performance by Landlord of any installation, maintenance or repairs provided for under this Lease, or (iv) any other temporary interruptions, and otherwise subject to the terms of this Lease.

2. Delivery; Acceptance of Premises; Commencement Date. Landlord shall use reasonable efforts to deliver the Premises to Tenant ("Delivery" or "Deliver") for Tenant's construction of the Tenant Improvements pursuant to the Work Letter on or before the Target Commencement Date. If Landlord fails to Deliver the Premises to Tenant on or before the Target Commencement Date, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as provided herein. If Landlord does not Deliver the Premises to Tenant within 90 days of the Target Commencement Date for any reason other than Force Majeure delays, this Lease may be terminated by Tenant by written notice to Landlord, and if so terminated by Tenant: (a) the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant, and (b) neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions which expressly survive termination of this Lease. As used herein, the term "Tenant Improvements" shall have the meaning set forth for such term in the Work Letter. If Tenant does not elect to terminate this Lease within 5 business days of the lapse of such 90 day period, such right to void this Lease shall be waived and this Lease shall remain in full force and effect.

The "Commencement Date" shall be the date that Landlord Delivers the Premises to Tenant. The "Rent Commencement Date" shall be December 1, 2020. The period commencing on the Commencement Date and expiring on the day immediately preceding the Rent Commencement Date may be referred to herein as the "Abatement Period." Upon request of Landlord, Tenant shall execute and deliver a written acknowledgment of the Commencement Date, the Rent Commencement Date and the expiration date of the Term when such are established in the form of the "Acknowledgement of Commencement Date" attached to this Lease as Exhibit D; provided, however, Tenant's failure to execute and deliver such acknowledgment shall not affect Landlord's rights hereunder. The "Term" of this Lease shall be the Base Term, as defined above on the first page of this Lease and the Extension Terms which Tenant may elect pursuant to Section 40 hereof.

Except as set forth in the Work Letter: (i) Tenant shall accept the Premises in their condition as of the Commencement Date; (ii) Landlord shall have no obligation for any defects in the Premises; and (iii) Tenant's taking possession of the Premises shall be conclusive evidence that Tenant accepts the Premises and that the Premises were in good condition at the time possession was taken. Any occupancy of the Premises by Tenant before the Commencement Date shall be subject to all of the terms and conditions of this Lease, excluding the obligation to pay Base Rent and Operating Expenses.

Tenant agrees and acknowledges that, except as otherwise expressly set forth in this Lease, neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of all or any portion of the Premises or the Project, and/or the suitability of the Premises or the Project for the conduct of Tenant's business, and Tenant waives any implied warranty that the Premises or the Project are suitable for the Permitted Use. This Lease constitutes the complete agreement of Landlord and Tenant with respect to the subject matter hereof and supersedes any and all prior representations, inducements, promises, agreements, understandings and negotiations which are not contained herein. Landlord in executing this Lease does so in reliance upon Tenant's representations, warranties, acknowledgments and agreements contained herein.

3. Rent.

(a) **Base Rent.** Base Rent for the first full month after the Rent Commencement Date occurs and the Security Deposit shall be due and payable on delivery of an executed copy of this Lease to Landlord. Tenant shall pay to Landlord in advance, without demand, abatement, deduction or set-off, equal monthly installments of Base Rent on or before the first day of each calendar month during the Term hereof, after the Rent Commencement Date, in lawful money of the United States of America, at the office of Landlord for payment of Rent set forth above, or to such other person or at such other place as Landlord may from time to time designate in writing. Payments of Base Rent for any fractional calendar month shall be prorated. The obligation of Tenant to pay Base Rent and other sums to Landlord and the obligations of Landlord under this Lease are independent obligations. Tenant shall have no right at any time to abate, reduce, or set-off any Rent (as defined in Section 5) due hereunder except for any abatement as may be expressly provided in this Lease.

(b) **Additional Rent.** In addition to Base Rent, Tenant agrees to pay to Landlord as additional rent ("Additional Rent"): (i) commencing on the "OPEX Commencement Date," which shall be the earlier to occur of (i) the Rent Commencement Date, or (ii) the date that Tenant Substantially Completes (as defined in the Work Letter) the Tenant Improvements, Tenant's Share of "Operating Expenses" (as defined in Section 5), and (ii) any and all other amounts Tenant assumes or agrees to pay under the provisions of this Lease, including, without limitation, any and all other sums that may become due by reason of any default of Tenant or failure to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after any applicable notice and cure period.

4. Base Rent Adjustments.

(a) **Annual Adjustments.** Base Rent shall be increased on each annual anniversary of the Rent Commencement Date (or if the Rent Commencement Date occurs on a date other than the first day of a calendar month, then on each annual anniversary of the first full calendar month immediately following the Rent Commencement Date) (each an "Adjustment Date") by multiplying the Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage and adding the resulting amount to the Base Rent payable immediately before such Adjustment Date. Base Rent, as so adjusted, shall thereafter be due as provided herein. Base Rent adjustments for any fractional calendar month shall be prorated.

(b) **Additional TI Allowance.** In addition to the Tenant Improvement Allowance (as defined in the Work Letter), Landlord shall, subject to the terms of the Work Letter, provide to Tenant the Additional Tenant Improvement Allowance (as defined in the Work Letter). Commencing on the Rent Commencement Date and continuing thereafter on the first day of each month during the Base Term, Tenant shall pay the amount necessary to fully amortize the full amount of the Additional Tenant Improvement Allowance in equal monthly payments with interest at a rate of 2.5% per annum over the Base Term, which interest shall begin to accrue on the date that Landlord first disburses such Additional Tenant Improvement Allowance or any portion(s) thereof ("TI Rent"). Any TI Rent remaining unpaid as of the expiration or earlier termination of the Lease shall be paid to Landlord in a lump sum at the expiration or earlier termination of this Lease.

5. **Operating Expense Payments.** Landlord shall deliver to Tenant a written estimate of Operating Expenses for each calendar year during the Term (the "Annual Estimate"), which may be revised by Landlord from time to time during such calendar year upon not less than 30 days' written notice to Tenant; provided, however, that Landlord shall not revise the Annual Estimate more than twice in any calendar year. Commencing on the OPEX Commencement Date and continuing thereafter on the first day of each month during the Term, Tenant shall pay Landlord an amount equal to 1/12th of Tenant's Share of the Annual Estimate. Payments for any fractional calendar month shall be prorated.

The term "Operating Expenses" means all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year by Landlord with respect to the Project (including, without duplication or limitation, Taxes (as defined in Section 9), transportation services (including the Shuttle Service Costs (as defined in Section 40(p)), capital repairs, improvements and replacements amortized over the lesser of 10 years or the useful life of such capital items (except for capital repairs, replacements and improvements to the roof, which shall be amortized over 15 years), adjusted to reflect Building operations 24 hours per day, 7 days per week and 365 days per year (provided that those Operating Expenses incurred or accrued by Landlord with respect to any capital repairs, replacements or improvements which are for the intended purpose of promoting sustainability (for example, without limitation, by reducing energy usage at the Project) (a "Capital Sustainability Expenditure") may be amortized over a shorter period, at Landlord's discretion, to the extent the cost of a Capital Sustainability Expenditure is offset by a reduction in Operating Expenses), and (z) and the costs of Landlord's third party property manager or, if there is no third party property manager (not to exceed 3% of Base Rent), administration rent in the amount of 3% of Base Rent (provided that Tenant shall not be required to pay administration rent during the Abatement Period)), excluding only:

- (a) the original construction costs of the Project and renovation prior to the date of the Lease and costs of correcting defects in such original construction or renovation;
- (b) capital expenditures for expansion of the Project;
- (c) interest, principal payments of Mortgage (as defined in Section 27) debts of Landlord, financing costs and amortization of funds borrowed by Landlord, whether secured or unsecured;
- (d) depreciation of the Project (except for capital improvements, the cost of which are includable in Operating Expenses);
- (e) advertising, legal and space planning expenses and leasing commissions and other costs and expenses incurred in procuring and leasing space to tenants for the Project, including any leasing office maintained in the Project, free rent and construction allowances for tenants;
- (f) legal and other expenses incurred in the negotiation or enforcement of leases;
- (g) completing, fixturing, improving, renovating, painting, redecorating or other work, which Landlord pays for or performs for other tenants within their premises, and costs of correcting defects in such work;
- (h) costs to be reimbursed by other tenants of the Project or Taxes to be paid directly by Tenant or other tenants of the Project, whether or not actually paid;
- (i) salaries, wages, benefits and other compensation paid to officers and employees of Landlord who are not assigned in whole or in part to the operation, management, maintenance or repair of the Project;
- (j) general organizational, administrative and overhead costs relating to maintaining Landlord's existence, either as a corporation, partnership, or other entity, including general corporate, legal and accounting expenses;
- (k) costs (including attorneys' fees and costs of settlement, judgments and payments in lieu thereof) incurred in connection with disputes with tenants, other occupants, or prospective tenants, and costs and expenses, including legal fees, incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;
- (l) costs incurred by Landlord due to the violation by Landlord, its employees, agents or contractors or any tenant of the terms and conditions of any lease of space in the Project or any Legal Requirement (as defined in Section 7);
- (m) penalties, fines or interest incurred as a result of Landlord's inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord's failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency;

(n) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;

(o) costs of Landlord's charitable or political contributions, or of fine art maintained at the Project;

(p) costs in connection with services (including electricity), items or other benefits of a type which are not standard for the Project and which are not available to Tenant without specific charges therefor, but which are provided to another tenant or occupant of the Project, whether or not such other tenant or occupant is specifically charged therefor by Landlord;

(q) costs incurred in the sale or refinancing of the Project;

(r) net income taxes of Landlord or the owner of any interest in the Project, franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein; and

(s) any expenses otherwise includable within Operating Expenses to the extent actually reimbursed by persons other than tenants of the Project under leases for space in the Project.

Within 90 days after the end of each calendar year (or such longer period as may be reasonably required but in no event more than 120 days), Landlord shall furnish to Tenant a statement (an "Annual Statement") showing in reasonable detail (along with, upon written request from Tenant, reasonable supporting documents): (a) the total and Tenant's Share of actual Operating Expenses for the previous calendar year, and (b) the total of Tenant's payments in respect of Operating Expenses for such year. If Tenant's Share of actual Operating Expenses for such year exceeds Tenant's payments of Operating Expenses for such year, the excess shall be due and payable by Tenant as Rent within 30 days after delivery of such Annual Statement to Tenant. If Tenant's payments of Operating Expenses for such year exceed Tenant's Share of actual Operating Expenses for such year Landlord shall pay the excess to Tenant within 30 days after delivery of such Annual Statement, except that after the expiration, or earlier termination of the Term or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord. Landlord's and Tenant's obligations to pay any overpayments or deficiencies due pursuant to this paragraph shall survive the expiration or earlier termination of this Lease.

The Annual Statement shall be final and binding upon Tenant unless Tenant, within 60 days after Tenant's receipt thereof, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reason therefor. If, during such 60 day period, Tenant reasonably and in good faith questions or contests the accuracy of Landlord's statement of Tenant's Share of Operating Expenses, Landlord will provide Tenant with access to Landlord's books and records relating to the operation of the Project and such information as Landlord reasonably determines to be responsive to Tenant's questions (the "Expense Information"). If after Tenant's review of such Expense Information, Landlord and Tenant cannot agree upon the amount of Tenant's Share of Operating Expenses, then Tenant shall have the right to have a regionally or nationally recognized independent public accounting firm selected by Tenant and approved by Landlord (which approval shall not be unreasonably withheld or delayed), working pursuant to a fee arrangement other than a contingent fee (at Tenant's sole cost and expense), audit and/or review the Expense Information for the year in question (the "Independent Review"). The results of any such Independent Review shall be binding on Landlord and Tenant. If the Independent Review shows that the payments actually made by Tenant with respect to Operating Expenses for the calendar year in question exceeded Tenant's Share of Operating Expenses for such calendar year, Landlord shall at Landlord's option either (i) credit the excess amount to the next succeeding installments of estimated Operating Expenses or (ii) pay the excess to Tenant within 30 days after delivery of such statement, except that after the expiration or earlier termination of this Lease or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord. If the Independent Review shows that Tenant's payments with respect to Operating Expenses for such calendar year were less than Tenant's Share of Operating Expenses for the calendar year, Tenant shall pay the deficiency to Landlord within 30 days after delivery of such statement. If the Independent Review shows that Tenant has overpaid with respect to Operating Expenses by more than 5% then Landlord shall reimburse Tenant for all costs incurred by Tenant for the Independent Review. Operating Expenses for the calendar years in which Tenant's obligation to share therein begins and ends shall be prorated. Notwithstanding anything set forth herein to the contrary, if the Building is not at least 95% occupied on average during any year of the Term, Tenant's Share of Operating Expenses for such year shall be computed as though the Building had been 95% occupied on average during such year.

“Tenant’s Share” shall be the percentage set forth on the first page of this Lease as Tenant’s Share as reasonably adjusted by Landlord for changes in the physical size of the Premises or the Project occurring thereafter. Landlord may equitably increase Tenant’s Share for any item of expense or cost reimbursable by Tenant that relates to a repair, replacement, or service that benefits only the Premises or only a portion of the Project that includes the Premises or that varies with occupancy or use. Base Rent, Tenant’s Share of Operating Expenses and all other amounts payable by Tenant to Landlord hereunder are collectively referred to herein as “Rent.”

6. Security Deposit. Tenant shall deposit with Landlord, upon delivery of an executed copy of this Lease to Landlord, a security deposit (the “Security Deposit”) for the performance of all of Tenant’s obligations hereunder in the amount set forth on page 1 of this Lease, which Security Deposit shall be in the form of an unconditional and irrevocable letter of credit (the “Letter of Credit”): (i) in form and substance satisfactory to Landlord, (ii) naming Landlord as beneficiary, (iii) expressly allowing Landlord to draw upon it at any time from time to time by delivering to the issuer notice that Landlord is entitled to draw thereunder, (iv) issued by an FDIC-insured financial institution satisfactory to Landlord, and (v) redeemable by presentation of a sight draft in the state of Landlord’s choice. If Tenant does not provide Landlord with a substitute Letter of Credit complying with all of the requirements hereof at least 10 days before the stated expiration date of any then current Letter of Credit, Landlord shall have the right to draw the full amount of the current Letter of Credit and hold the funds drawn in cash without obligation for interest thereon as the Security Deposit. The Security Deposit shall be held by Landlord as security for the performance of Tenant’s obligations under this Lease. The Security Deposit is not an advance rental deposit or a measure of Landlord’s damages in case of Tenant’s default. Upon each occurrence of a Default (as defined in Section 20), Landlord may use all or any part of the Security Deposit to pay delinquent payments due under this Lease, future rent damages, and the cost of any damage, injury, expense or liability caused by such Default, without prejudice to any other remedy provided herein or provided by law. Landlord’s right to use the Security Deposit under this Section 6 includes the right to use the Security Deposit to pay future rent damages following the termination of this Lease pursuant to Section 21(c) below. Upon any use of all or any portion of the Security Deposit, Tenant shall pay Landlord on demand the amount that will restore the Security Deposit to the amount set forth on Page 1 of this Lease. Tenant hereby waives the provisions of any law, now or hereafter in force which provide that Landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of Rent, to repair damage caused by Tenant or to clean the Premises, it being agreed that Landlord may, in addition, claim those sums reasonably necessary to compensate Landlord for any other loss or damage, foreseeable or unforeseeable, caused by the act or omission of Tenant or any officer, employee, agent or invitee of Tenant. Upon bankruptcy or other debtor-creditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for periods prior to the filing of such proceedings. If Tenant shall fully perform every provision of this Lease to be performed by Tenant, the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant (or, at Landlord’s option, to the last assignee of Tenant’s interest hereunder) within 90 days after the expiration or earlier termination of this Lease.

If Landlord transfers its interest in the Project or this Lease, Landlord shall either (a) transfer any Security Deposit then held by Landlord to a person or entity assuming Landlord’s obligations under this Section 6, or (b) return to Tenant any Security Deposit then held by Landlord and remaining after the deductions permitted herein. Upon such transfer to such transferee or the return of the Security Deposit to Tenant, Landlord shall have no further obligation with respect to the Security Deposit, and Tenant’s right to the return of the Security Deposit shall apply solely against Landlord’s transferee. The Security Deposit is not an advance rental deposit or a measure of Landlord’s damages in case of Tenant’s default. Landlord’s obligation respecting the Security Deposit is that of a debtor, not a trustee, and no interest shall accrue thereon.

If, as of the expiration of the 36th month after the Rent Commencement Date, (i) Tenant is not then in Default under this Lease, and (ii) Tenant has not been in Default under this Lease at any time during the Term (collectively, the “Reduction Requirements” and each a “Reduction Requirement”), then the Security Deposit shall be reduced to an amount equal to \$338,550.00 (the “Reduced Security Deposit”). If Tenant delivers a written request to Landlord for such reduction of the Security Deposit then, so long as the Reduction Requirements have been satisfied, Landlord shall cooperate with Tenant, at no cost, expense or liability to Landlord, to reduce the Letter of Credit then held by Landlord to the amount of the Reduced Security Deposit. If the Security Deposit is reduced as provided in this paragraph, then from and after the date of such reduction, the “Security Deposit” shall be deemed to be the Reduced Security Deposit, for all purposes of this Lease.

If, as of the expiration of the 72th month after the Rent Commencement Date, the reduction Requirements have been satisfied, then the Security Deposit shall be reduced to an amount equal to \$169,275.00 (the "Further Reduced Security Deposit"). If Tenant delivers a written request to Landlord for such further reduction of the Security Deposit then, so long as the Reduction Requirements have been satisfied, Landlord shall cooperate with Tenant, at no cost, expense or liability to Landlord, to reduce the Letter of Credit then held by Landlord to the amount of the Further Reduced Security Deposit. If the Security Deposit is reduced as provided in this paragraph, then from and after the date of such reduction, the "Security Deposit" shall be deemed to be the Further Reduced Security Deposit, for all purposes of this Lease.

7. Use. The Premises shall be used solely for the Permitted Use set forth in the basic lease provisions on page 1 of this Lease, and in compliance with all laws, orders, judgments, ordinances, regulations, codes, directives, permits, licenses, covenants and restrictions now or hereafter applicable to the Premises, and to the use and occupancy thereof, including, without limitation, the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with the regulations promulgated pursuant thereto, "ADA") (collectively, "Legal Requirements" and each, a "Legal Requirement"). Tenant shall, upon 5 days' written notice from Landlord, discontinue any use of the Premises which is declared by any Governmental Authority (as defined in Section 9) having jurisdiction to be a violation of a Legal Requirement. Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant's or Landlord's insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits. Tenant shall not permit any part of the Premises to be used as a "place of public accommodation", as defined in the ADA or any similar legal requirement. Tenant shall reimburse Landlord promptly upon demand for any additional premium charged for any such insurance policy by reason of Tenant's failure to comply with the provisions of this Section or otherwise caused by Tenant's use and/or occupancy of the Premises. Tenant will use the Premises in a careful, safe and proper manner and will not commit or permit waste, overload the floor or structure of the Premises, subject the Premises to use that would damage the Premises or obstruct or interfere with the rights of Landlord or other tenants or occupants of the Project, including conducting or giving notice of any auction, liquidation, or going out of business sale on the Premises, or using or allowing the Premises to be used for any unlawful purpose. Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending outside the Premises into the Common Areas, or other space in the Project. Tenant shall not place any machinery or equipment which would overload the floor in or upon the Premises or transport or move such items through the Common Areas of the Project or in the Project elevators without the prior written consent of Landlord. Except as may be provided under the Work Letter, Tenant shall not, without the prior written consent of Landlord, use the Premises in any manner which will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Project as proportionately allocated to the Premises based upon Tenant's Share as usually furnished for the Permitted Use.

Landlord shall, at Landlord's sole cost and expense, be responsible for the compliance of the Premises and Common Areas of the Project with Legal Requirements as of the Commencement Date. Landlord shall, as an Operating Expense (to the extent such Legal Requirement is generally applicable to similar buildings in the area in which the Project is located) and at Tenant's expense (to the extent such Legal Requirement is triggered by reason of Tenant's, as compared to other tenants of the Project, specific use of the Premises or Tenant's Alterations) make any alterations or modifications to the Common Areas or the exterior of the Building that are required by Legal Requirements. Except as provided in the 2 immediately preceding sentences, Tenant, at its sole expense, shall make any alterations or modifications to the interior of the Premises that are required by Legal Requirements (including, without limitation, compliance of the Premises with the ADA) related to Tenant's use or occupancy of the Premises. Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys' fees, charges and disbursements and costs of suit) (collectively, "Claims") arising out of or in connection with Legal Requirements related to Tenant's use or occupancy of the Premises or Tenant's Alterations, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any failure of the Premises to comply with any Legal Requirement related to Tenant's use or occupancy of the Premises or Tenant's Alterations.

Tenant acknowledges that Landlord may, but shall not be obligated to, seek to obtain Leadership in Energy and Environmental Design (LEED), WELL Building Standard, or other similar “green” certification with respect to the Project and/or the Premises, and Tenant agrees to reasonably cooperate with Landlord, and to provide such information and/or documentation as Landlord may reasonably request, in connection therewith.

8. Holding Over. If, with Landlord’s express written consent, Tenant retains possession of the Premises after the termination of the Term, (i) unless otherwise agreed in such written consent, such possession shall be subject to termination by Landlord at any time upon 30 days’ notice to Tenant, (ii) all of the other terms and provisions of this Lease (including, without limitation, the adjustment of Base Rent pursuant to Section 4 hereof) shall remain in full force and effect (excluding any expansion or renewal option or other similar right or option) during such holdover period, (iii) Tenant shall continue to pay Base Rent in the amount payable upon the date of the expiration or earlier termination of this Lease or such other amount as Landlord may indicate, in Landlord’s sole and absolute discretion, in such written consent, and (iv) all other payments shall continue under the terms of this Lease. If Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without the express written consent of Landlord, (A) Tenant shall become a tenant at sufferance upon the terms of this Lease except that the monthly rental shall be equal to 150% of Rent in effect during the last 30 days of the Term, and (B) Tenant shall be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant’s holding over, including consequential damages. Lease except as otherwise expressly provided, and this Section 8 shall not be construed as consent for Tenant to retain possession of the Premises. Acceptance by Landlord of Rent after the expiration of the Term or earlier termination of this Lease shall not result in a renewal or reinstatement of this Lease.

9. Taxes. Landlord shall pay, as part of Operating Expenses, all taxes, levies, fees, assessments and governmental charges of any kind, existing as of the Commencement Date or thereafter enacted (collectively referred to as “Taxes”), imposed by any federal, state, regional, municipal, local or other governmental authority or agency, including, without limitation, quasi-public agencies (collectively, “Governmental Authority”) during the Term, including, without limitation, all Taxes: (i) imposed on or measured by or based, in whole or in part, on rent payable to (or gross receipts received by) Landlord under this Lease and/or from the rental by Landlord of the Project or any portion thereof, or (ii) based on the square footage, assessed value or other measure or evaluation of any kind of the Premises or the Project, or (iii) assessed or imposed by or on the operation or maintenance of any portion of the Premises or the Project, including parking, or (iv) assessed or imposed by, or at the direction of, or resulting from Legal Requirements, or interpretations thereof, promulgated by any Governmental Authority, or (v) imposed as a license or other fee, charge, tax, or assessment on Landlord’s business or occupation of leasing space in the Project. Landlord may contest by appropriate legal proceedings the amount, validity, or application of any Taxes or liens securing Taxes. Taxes shall not include any net income taxes imposed on Landlord except to the extent such net income taxes are in substitution for any Taxes payable hereunder. If any such Tax is levied or assessed directly against Tenant, then Tenant shall be responsible for and shall pay the same at such times and in such manner as the taxing authority shall require. Tenant shall pay, prior to delinquency, any and all Taxes levied or assessed against any personal property or trade fixtures placed by Tenant in the Premises, whether levied or assessed against Landlord or Tenant. If any Taxes on Tenant’s personal property or trade fixtures are levied against Landlord or Landlord’s property, or if the assessed valuation of the Project is increased by a value attributable to improvements in or alterations to the Premises, whether owned by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, higher than the base valuation on which Landlord from time-to-time allocates Taxes to all tenants in the Project, Landlord shall have the right, but not the obligation, to pay such Taxes. Landlord’s determination of any excess assessed valuation shall be binding and conclusive, absent manifest error. The amount of any such payment by Landlord shall constitute Additional Rent due from Tenant to Landlord immediately upon demand.

10. Parking. Subject to all applicable Legal Requirements, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Landlord shall allocate to Tenant, Tenant’s pro rata share of parking spaces (which, as of the Rent Commencement Date, is equal to 1.6 parking spaces per 1,000 rentable square feet of the Premises) in accordance with the rentable area of the Premises and the rentable areas of the Project occupied by other tenants, which shall be located in areas of the subterranean parking garage serving the Project designated for non-reserved parking, subject in each case to Landlord’s rules and regulations and the payment, commencing on the Commencement Date, of \$250.00 per month for each parking space allocated to Tenant plus applicable taxes (“Parking Charges”). On each annual anniversary of the Rent Commencement Date, the per parking space Parking Charges payable by Tenant shall be increased annually by Landlord to the then-current market rate for parking spaces in similar parking garages serving Class A laboratory/office buildings in the South Lake Union area of Seattle, as reasonably determined by Landlord, not to exceed 3% per year. Landlord shall not be responsible for enforcing Tenant’s parking rights against any third parties, including other tenants of the Project.

11. Utilities, Services. Landlord shall provide, subject to the terms of this Section 11, water, electricity, heat, light, power, sewer, and other utilities (including gas and fire sprinklers to the extent the Project is plumbed for such services), and, with respect to the Common Areas, refuse and trash collection and janitorial services (collectively, "Utilities"). Landlord shall pay, as Operating Expenses or subject to Tenant's reimbursement obligation, for all Utilities used on the Premises, all maintenance charges for Utilities, and any storm sewer charges or other similar charges for Utilities imposed by any Governmental Authority or Utility provider, and any taxes, penalties, surcharges or similar charges thereon. Landlord may cause, at Tenant's expense, any Utilities to be separately metered or charged directly to Tenant by the provider. Tenant shall pay directly to the Utility provider, prior to delinquency, any separately metered Utilities and services which may be furnished to Tenant or the Premises during the Term. Tenant shall pay, as part of Operating Expenses, its share of all charges for jointly metered Utilities based upon consumption, as reasonably determined by Landlord. No interruption or failure of Utilities, from any cause whatsoever other than Landlord's willful misconduct, shall result in eviction or constructive eviction of Tenant, termination of this Lease or the abatement of Rent. Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use. Tenant shall retain third parties reasonably acceptable to Landlord to provide janitorial services and trash collection services to the Premises and Tenant shall pay such third parties directly for such janitorial and trash collection services.

Landlord's sole obligation for either providing emergency generators or providing emergency back-up power to Tenant shall be: (i) to provide emergency generators with not less than the capacity of the emergency generators located in the Building as of the Commencement Date, and (ii) to contract with a third party to maintain the emergency generators as per the manufacturer's standard maintenance guidelines. Except as otherwise provided in the immediately preceding sentence, Landlord shall have no obligation to provide Tenant with operational emergency generators or back-up power or to supervise, oversee or confirm that the third party maintaining the emergency generators is maintaining the generators as per the manufacturer's standard guidelines or otherwise. Landlord shall, upon written request from Tenant (not more frequently than once per calendar year), make available for Tenant's inspection the maintenance contract and maintenance records for the emergency generators for the 12 month period immediately preceding Landlord's receipt of Tenant's written request. During any period of replacement, repair or maintenance of the emergency generators when the emergency generators are not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up generator or generators or alternative sources of back-up power. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such emergency generators will be operational at all times or that emergency power will be available to the Premises when needed.

Tenant agrees, to the extent required by Legal Requirements, to provide Landlord with access to Tenant's water and/or energy usage data on a monthly basis, either by providing Tenant's applicable utility login credentials to Landlord's Measurabl online portal, or by another delivery method reasonably agreed to by Landlord and Tenant. The costs and expenses incurred by Landlord in connection with receiving and analyzing such water and/or energy usage data (including, without limitation, as may be required pursuant to applicable Legal Requirements) shall be included as part of Operating Expenses.

12. Alterations and Tenant's Property. Any alterations, additions, or improvements made to the Premises by or on behalf of Tenant, including additional locks or bolts of any kind or nature upon any doors or windows in the Premises, but excluding installation, removal or realignment of furniture systems (other than removal of furniture systems owned or paid for by Landlord) not involving any modifications to the structure or connections (other than by ordinary plugs or jacks) to Building Systems (as defined in Section 13) ("Alterations") shall be subject to Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion if any such Alteration affects the structure or Building Systems and shall not be otherwise unreasonably withheld, conditioned or delayed. Tenant may construct nonstructural Alterations in the Premises without Landlord's prior approval if the aggregate cost of all such work in any 12 month period does not exceed \$60,000 (a "Notice-Only Alteration"), provided Tenant notifies Landlord in writing of such intended Notice-Only Alteration, and such notice shall be accompanied by plans, specifications, work contracts and such other information concerning the nature and cost of the Notice-Only Alteration as may be reasonably requested by Landlord, which notice and accompanying materials shall be delivered to Landlord not less than 15 business days in advance of any proposed construction. If Landlord approves any Alterations, Landlord may impose such conditions on Tenant in connection with the commencement, performance and completion of such Alterations as Landlord may deem appropriate in Landlord's sole and absolute discretion. Any request for approval shall be in writing, delivered not less than 15 business days in advance of any proposed construction, and accompanied by plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord, including the identities and mailing addresses of all persons performing work or supplying materials. Landlord's right to review plans and specifications and to monitor construction shall be solely for its own benefit, and Landlord shall have no duty to ensure that such plans and specifications or construction comply with applicable Legal Requirements. Tenant shall cause, at its sole cost and expense, all Alterations to comply with insurance requirements and with Legal Requirements and shall implement at its sole cost and expense any alteration or modification required by Legal Requirements as a result of any Alterations. Tenant shall pay to Landlord, as Additional Rent, on demand an amount equal to 2% of all hard costs incurred by Tenant or its contractors or agents in connection with any Alteration to cover Landlord's overhead and expenses for plan review, coordination, scheduling and supervision. Before Tenant begins any Alteration, Landlord may post on and about the Premises notices of non-responsibility pursuant to applicable law. Tenant shall reimburse Landlord for, and indemnify and hold Landlord harmless from, any expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, delays caused by such work, or inadequate cleanup.

Tenant shall furnish security or make other arrangements satisfactory to Landlord to assure payment for the completion of all Alterations work free and clear of liens, and shall provide (and cause each contractor or subcontractor to provide) certificates of insurance for workers' compensation and other coverage in amounts and from an insurance company satisfactory to Landlord protecting Landlord against liability for personal injury or property damage during construction. Upon completion of any Alterations, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and subcontractors who did the work and final lien waivers from all such contractors and subcontractors; and (ii) "as built" plans for any such Alteration.

Except for Removable Installations (as hereinafter defined), all Installations (as hereinafter defined) shall be and shall remain the property of Landlord during the Term and following the expiration or earlier termination of the Term, shall not be removed by Tenant at any time during the Term, and shall remain upon and be surrendered with the Premises as a part thereof. Notwithstanding the foregoing, Landlord may, at the time its approval of any such Installation is requested, or at the time it received notice of a Notice-Only Alteration, notify Tenant that Landlord requires that Tenant remove such Installation upon the expiration or earlier termination of the Term, in which event Tenant shall remove such Installation in accordance with the immediately succeeding sentence. Upon the expiration or earlier termination of the Term, Tenant shall remove (i) all wires, cables or similar equipment which Tenant has installed in the Premises or in the risers or plenums of the Building, (ii) any Installations for which Landlord has given Tenant notice of removal in accordance with the immediately preceding sentence, and (iii) all of Tenant's Property (as hereinafter defined), and Tenant shall restore and repair any damage caused by or occasioned as a result of such removal, including, without limitation, capping off all such connections behind the walls of the Premises and repairing any holes. During any restoration period beyond the expiration or earlier termination of the Term, Tenant shall pay Rent to Landlord as provided herein as if said space were otherwise occupied by Tenant. If Landlord is requested by Tenant or any lender, lessor or other person or entity claiming an interest in any of Tenant's Property to waive any lien Landlord may have against any of Tenant's Property, and Landlord consents to such waiver, then Landlord shall be entitled to be paid as administrative rent a fee of \$1,000 per occurrence for its time and effort in preparing and negotiating such a waiver of lien.

For purposes of this Lease, (x) "Removable Installations" means any items listed on Exhibit F attached hereto and any items agreed by Landlord in writing to be included on Exhibit F in the future, (y) "Tenant's Property" means Removable Installations and, other than Installations, any personal property or equipment of Tenant that may be removed without material damage to the Premises, and (z) "Installations" means all property of any kind paid for with the TI Fund, all Alterations, all fixtures, and all partitions, hardware, built-in machinery, built-in casework and cabinets and other similar additions, equipment, property and improvements built into the Premises so as to become an integral part of the Premises, including, without limitation, fume hoods which penetrate the roof or plenum area, built-in cold rooms, built-in warm rooms, walk-in cold rooms, walk-in warm rooms, deionized water systems, glass washing equipment, autoclaves, chillers, built-in plumbing, electrical and mechanical equipment and systems, and any power generator and transfer switch.

13. Landlord's Repairs. Landlord, as an Operating Expense, shall maintain all of the structural, exterior, parking and other Common Areas of the Project, including HVAC, plumbing, fire sprinklers, elevators and all other building systems serving the Premises and other portions of the Project ("Building Systems"), in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of Tenant, or by any of Tenant's assignees, sublessees, licensees, agents, servants, employees, invitees and contractors (or any of Tenant's assignees, sublessees and/or licensees respective agents, servants, employees, invitees and contractors) (collectively, "Tenant Parties") excluded. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant's sole cost and expense. Landlord reserves the right to stop Building Systems services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 72 hours advance notice of any planned stoppage of Building Systems services for routine maintenance, repairs, alterations or improvements. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section, after which Landlord shall make a commercially reasonable effort to effect such repair. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant's written notice of the need for such repairs or maintenance. Tenant waives its rights under any state or local law to terminate this Lease or to make such repairs at Landlord's expense and agrees that the parties' respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by Section 18.

14. Tenant's Repairs. Subject to Section 13 hereof, Tenant, at its expense, shall repair, replace and maintain in good condition all portions of the Premises, including, without limitation, entries, doors, ceilings, interior windows, interior walls, and the interior side of demising walls. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 10 days of Landlord's notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed by Tenant for the reasonable costs incurred by Landlord in connection with such work within 10 days after demand therefor along with Landlord's delivery of an invoice and reasonable supporting documents reflecting the costs incurred; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the costs of such cure from Tenant. Subject to Sections 17 and 18, Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.

15. Mechanic's Liens. Tenant shall discharge, by bond or otherwise, any mechanic's lien filed against the Premises or against the Project for work claimed to have been done for, or materials claimed to have been furnished to, Tenant within 10 days after the filing thereof, at Tenant's sole cost and shall otherwise keep the Premises and the Project free from any liens arising out of work performed, materials furnished or obligations incurred by Tenant. Should Tenant fail to discharge any lien described herein, Landlord shall have the right, but not the obligation, to pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title to the Project and the cost thereof shall be immediately due from Tenant as Additional Rent. If Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code Financing Statement filed as a matter of public record by any lessor or creditor of Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Project be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in an identified suite held by Tenant.

16. Indemnification. Tenant hereby indemnifies and agrees to defend, save and hold Landlord, its officers, directors, employees, managers, agents, sub-agents, constituent entities and lease signators (collectively, "Landlord Indemnified Parties") harmless from and against any and all Claims for injury or death to persons or damage to property occurring within or about the Premises or the Project arising directly or indirectly out of use or occupancy of the Premises or the Project by Tenant or any Tenant Parties (including, without limitation, any act, omission or neglect by Tenant or any Tenant's Parties in or about the Premises or at the Project) or the a breach or default by Tenant in the performance of any of its obligations hereunder, except to the extent caused by the willful misconduct or negligence of Landlord Indemnified Parties. Landlord shall not be liable to Tenant for, and Tenant assumes all risk of damage to, personal property (including, without limitation, loss of records kept within the Premises). Tenant further waives any and all Claims for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property (including, without limitation, any loss of records). Landlord Indemnified Parties shall not be liable for any damages arising from any act, omission or neglect of any tenant in the Project or of any other third party or Tenant Parties.

17. Insurance. Landlord shall maintain all risk property and, if applicable, sprinkler damage insurance covering the full replacement cost of the Project. Landlord shall further procure and maintain commercial general liability insurance with a single loss limit of not less than \$2,000,000 for bodily injury and property damage with respect to the Project. Landlord may, but is not obligated to, maintain such other insurance and additional coverages as it may deem necessary, including, but not limited to, flood, environmental hazard and earthquake, loss or failure of building equipment, errors and omissions, rental loss during the period of repair or rebuilding, workers' compensation insurance and fidelity bonds for employees employed to perform services and insurance for any improvements installed by Tenant or which are in addition to the standard improvements customarily furnished by Landlord without regard to whether or not such are made a part of the Project. All such insurance shall be included as part of the Operating Expenses. The Project may be included in a blanket policy (in which case the cost of such insurance allocable to the Project will be determined by Landlord based upon the insurer's cost calculations). Tenant shall also reimburse Landlord for any increased premiums or additional insurance which Landlord reasonably deems necessary as a result of Tenant's use of the Premises.

Tenant, at its sole cost and expense, shall maintain during the Term: all risk property insurance with business interruption and extra expense coverage, covering the full replacement cost of all property and improvements installed or placed in the Premises by Tenant at Tenant's expense; workers' compensation insurance with no less than the minimum limits required by law; employer's liability insurance with employers liability limits of \$1,000,000 bodily injury by accident – each accident, \$1,000,000 bodily injury by disease – policy limit, and \$1,000,000 bodily injury by disease – each employee; and commercial general liability insurance, with a minimum limit of not less than \$2,000,000 per occurrence for bodily injury and property damage with respect to the Premises. The commercial general liability insurance maintained by Tenant shall name Alexandria Real Estate Equities, Inc., and Landlord, its officers, directors, employees, managers, agents, sub-agents, constituent entities and lease signators (collectively, "Landlord Insured Parties"), as additional insureds; insure on an occurrence and not a claims-made basis; be issued by insurance companies which have a rating of not less than policyholder rating of A and financial category rating of at least Class X in "Best's Insurance Guide"; shall not be cancelable for nonpayment of premium unless 30 days prior written notice shall have been given to Landlord from the insurer; not contain a hostile fire exclusion; contain a contractual liability endorsement; and provide primary coverage to Landlord Insured Parties (any policy issued to Landlord Insured Parties providing duplicate or similar coverage shall be deemed excess over Tenant's policies, regardless of limits). Copies of such policies (if requested by Landlord), or certificates of insurance showing the limits of coverage required hereunder and showing Landlord as an additional insured, along with reasonable evidence of the payment of premiums for the applicable period, shall be delivered to Landlord by Tenant prior to (i) the earlier to occur of (x) the Commencement Date, or (y) the date that Tenant accesses the Premises under this Lease, and (ii) each renewal of said insurance. Tenant's policy may be a "blanket policy" with an aggregate per location endorsement which specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, at least 5 days prior to the expiration of such policies, furnish Landlord with renewal certificates. Notwithstanding anything to the contrary contained herein, the minimum coverage limits set forth herein may be satisfied by Tenant using a combination of commercial general liability and umbrella policies.

In each instance where insurance is to name Landlord as an additional insured, Tenant shall upon written request of Landlord also designate and furnish certificates so evidencing Landlord as additional insured to: (i) any lender of Landlord holding a security interest in the Project or any portion thereof, (ii) the landlord under any lease wherein Landlord is tenant of the real property on which the Project is located, if the interest of Landlord is or shall become that of a tenant under a ground or other underlying lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Project.

The property insurance obtained by Landlord and Tenant shall include a waiver of subrogation by the insurers and all rights based upon an assignment from its insured, against Landlord or Tenant, and their respective officers, directors, employees, managers, agents, invitees and contractors (“Related Parties”), in connection with any loss or damage thereby insured against. Neither party nor its respective Related Parties shall be liable to the other for loss or damage caused by any risk insured against under property insurance required to be maintained hereunder, and each party waives any claims against the other party, and its respective Related Parties, for such loss or damage. The failure of a party to insure its property shall not void this waiver. Landlord and its respective Related Parties shall not be liable for, and Tenant hereby waives all claims against such parties for, business interruption and losses occasioned thereby sustained by Tenant or any person claiming through Tenant resulting from any accident or occurrence in or upon the Premises or the Project from any cause whatsoever. If the foregoing waivers shall contravene any law with respect to exculpatory agreements, the liability of Landlord or Tenant shall be deemed not released but shall be secondary to the other’s insurer.

Landlord may require insurance policy limits to be raised to conform with requirements of Landlord’s lender and/or to bring coverage limits to levels then being generally required of new tenants within the Project; provided, however, that the increased amount of coverage is consistent with coverage amounts then being required by institutional owners of similar projects with tenants occupying similar size premises in the geographical area in which the Project is located.

18. Restoration. If, at any time during the Term, the Project or the Premises are damaged or destroyed by a fire or other insured casualty, Landlord shall notify Tenant within 45 days after discovery of such damage as to the amount of time Landlord reasonably estimates it will take to restore the Project or the Premises, as applicable (the “Restoration Period”). If the Restoration Period is estimated to exceed 12 months (the “Maximum Restoration Period”), Landlord may, in such notice, elect to terminate this Lease as of the date that is 75 days after the date of discovery of such damage or destruction; provided, however, that notwithstanding Landlord’s election to restore, Tenant may elect to terminate this Lease by written notice to Landlord delivered within 5 business days of receipt of a notice from Landlord estimating a Restoration Period for the Premises longer than the Maximum Restoration Period. Unless either Landlord or Tenant so elects to terminate this Lease, Landlord shall, subject to receipt of sufficient insurance proceeds (with any deductible to be treated as a current Operating Expense), promptly restore the Premises (excluding the improvements installed by Tenant or by Landlord and paid for by Tenant), subject to delays arising from the collection of insurance proceeds, from Force Majeure events or as needed to obtain any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials (as defined in Section 30) in, on or about the Premises (collectively referred to herein as “Hazardous Materials Clearances”); provided, however, that if repair or restoration of the Premises is not substantially complete as of the end of the Maximum Restoration Period or, if longer, the Restoration Period, Landlord may, in its sole and absolute discretion, elect not to proceed with such repair and restoration, or Tenant may by written notice to Landlord delivered within 5 business days of the expiration of the Maximum Restoration Period or, if longer, the Restoration Period, elect to terminate this Lease, in which event Landlord shall be relieved of its obligation to make such repairs or restoration and this Lease shall terminate as of the date that is 75 days after the later of: (i) discovery of such damage or destruction, or (ii) the date all required Hazardous Materials Clearances are obtained, but Landlord shall retain any Rent paid and the right to any Rent payable by Tenant prior to such election by Landlord or Tenant.

Tenant, at its expense, shall promptly perform, subject to delays arising from the collection of insurance proceeds, from Force Majeure (as defined in Section 34) events or to obtain Hazardous Material Clearances, all repairs or restoration not required to be done by Landlord and shall promptly re-enter the Premises and commence doing business in accordance with this Lease. Notwithstanding the foregoing, either Landlord or Tenant may terminate this Lease upon written notice to the other if the Premises are damaged during the last year of the Term and Landlord reasonably estimates that it will take more than 2 months to repair such damage; provided, however, that such notice is delivered within 10 business days after the date that Landlord provides Tenant with written notice of the estimated Restoration Period. Notwithstanding anything to the contrary contained herein, Landlord shall also have the right to terminate this Lease if insurance proceeds are not available for such restoration. Rent shall be abated from the date all required Hazardous Material Clearances are obtained until the Premises are repaired and restored, in the proportion which the area of the Premises, if any, which is not usable by Tenant bears to the total area of the Premises, unless Landlord provides Tenant with other space during the period of repair that is suitable for the temporary conduct of Tenant’s business. In the event that no Hazardous Material Clearances are required to be obtained by Tenant with respect to the Premises, rent abatement shall commence on the date of discovery of the damage or destruction. Such abatement shall be the sole remedy of Tenant, and except as provided in this Section 18, Tenant waives any right to terminate the Lease by reason of damage or casualty loss.

The provisions of this Lease, including this Section 18, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, or any other portion of the Project, and any statute or regulation which is now or may hereafter be in effect shall have no application to this Lease or any damage or destruction to all or any part of the Premises or any other portion of the Project, the parties hereto expressly agreeing that this Section 18 sets forth their entire understanding and agreement with respect to such matters.

19. Condemnation. If the whole or any material part of the Premises or the Project is taken for any public or quasi-public use under governmental law, ordinance, or regulation, or by right of eminent domain, or by private purchase in lieu thereof (a "Taking" or "Taken"), and the Taking would in Landlord's reasonable judgment, either prevent or materially interfere with Tenant's use of the Premises or materially interfere with or impair Landlord's ownership or operation of the Project, then upon written notice by Landlord this Lease shall terminate and Rent shall be apportioned as of said date. If part of the Premises shall be Taken, and this Lease is not terminated as provided above, Landlord shall promptly restore the Premises and the Project as nearly as is commercially reasonable under the circumstances to their condition prior to such partial Taking and the rentable square footage of the Building, the rentable square footage of the Premises, Tenant's Share of Operating Expenses and the Rent payable hereunder during the unexpired Term shall be reduced to such extent as may be fair and reasonable under the circumstances. Upon any such Taking, Landlord shall be entitled to receive the entire price or award from any such Taking without any payment to Tenant, and Tenant hereby assigns to Landlord Tenant's interest, if any, in such award. Tenant shall have the right, to the extent that same shall not diminish Landlord's award, to make a separate claim against the condemning authority (but not Landlord) for such compensation as may be separately awarded or recoverable by Tenant for moving expenses and damage to Tenant's trade fixtures, if a separate award for such items is made to Tenant. Tenant hereby waives any and all rights it might otherwise have pursuant to any provision of state law to terminate this Lease upon a partial Taking of the Premises or the Project.

20. Events of Default. Each of the following events shall be a default ("Default") by Tenant under this Lease:

(a) Payment Defaults. Tenant shall fail to pay any installment of Rent or any other payment hereunder when due; provided, however, that Landlord will give Tenant notice and an opportunity to cure any failure to pay Rent within 3 days of any such notice not more than once in any 12 month period.

(b) Insurance. Any insurance required to be maintained by Tenant pursuant to this Lease shall be canceled or terminated or shall expire or shall be reduced or materially changed, or Landlord shall receive a notice of nonrenewal of any such insurance and Tenant shall fail to obtain replacement insurance before the expiration of the current coverage.

(c) Abandonment. Tenant shall abandon the Premises.

(d) Improper Transfer. Tenant shall assign, sublease or otherwise transfer or attempt to transfer all or any portion of Tenant's interest in this Lease or the Premises except as expressly permitted herein, or Tenant's interest in this Lease shall be attached, executed upon, or otherwise judicially seized and such action is not released within 90 days of the action.

(e) Liens. Tenant shall fail to discharge or otherwise obtain the release of any lien placed upon the Premises in violation of this Lease within 10 days after any such lien is filed against the Premises.

(f) Insolvency Events. Tenant or any guarantor or surety of Tenant's obligations hereunder shall: (A) make a general assignment for the benefit of creditors; (B) commence any case, proceeding or other action seeking to have an order for relief entered on its behalf as a debtor or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, liquidation, dissolution or composition of it or its debts or seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or of any substantial part of its property (collectively a "Proceeding for Relief"); (C) become the subject of any Proceeding for Relief which is not dismissed within 90 days of its filing or entry; or (D) die or suffer a legal disability (if Tenant, guarantor, or surety is an individual) or be dissolved or otherwise fail to maintain its legal existence (if Tenant, guarantor or surety is a corporation, partnership or other entity).

(g) Estoppel Certificate or Subordination Agreement. Tenant fails to execute any document required from Tenant under Sections 23 or 27 within 5 days after a second notice requesting such document.

(h) Other Defaults. Tenant shall fail to comply with any provision of this Lease other than those specifically referred to in this Section 20, and, except as otherwise expressly provided herein, such failure shall continue for a period of 30 days after written notice thereof from Landlord to Tenant.

Any notice given under Section 20(h) hereof shall: (i) specify the alleged default, (ii) demand that Tenant cure such default, (iii) be in lieu of, and not in addition to, or shall be deemed to be, any notice required under any provision of applicable law, and (iv) not be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice; provided that if the nature of Tenant's default pursuant to Section 20(h) is such that it cannot be cured by the payment of money and reasonably requires more than 30 days to cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said 30 day period and thereafter diligently prosecutes the same to completion; provided, however, that such cure shall be completed no later than 45 days from the date of Landlord's notice.

21. Landlord's Remedies.

(a) Payment By Landlord; Interest. Upon a Default by Tenant hereunder, Landlord may, without waiving or releasing any obligation of Tenant hereunder, make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to 12% per annum or the highest rate permitted by law (the "Default Rate"), whichever is less, shall be payable to Landlord on demand as Additional Rent. Nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant's Default hereunder.

(b) Late Payment Rent. Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges which may be imposed on Landlord under any Mortgage covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within 5 days after the date such payment is due, Tenant shall pay to Landlord an additional sum equal to 6% of the overdue Rent as a late charge. Notwithstanding the foregoing, before assessing a late charge the first time in any calendar year, Landlord shall provide Tenant written notice of the delinquency and will waive the right if Tenant pays such delinquency within 5 days thereafter. The parties agree that this late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest at the Default Rate from the 5th day after the date due until paid.

(c) Remedies. Upon the occurrence of a Default, Landlord, at its option, without further notice or demand to Tenant, shall have in addition to all other rights and remedies provided in this Lease, at law or in equity, the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

(i) Terminate this Lease, or at Landlord's option, Tenant's right to possession only, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim or damages therefor;

(ii) Upon any termination of this Lease, whether pursuant to the foregoing Section 21(c)(i) or otherwise, Landlord may recover from Tenant the following:

- (A) *The worth at the time of award of any unpaid rent which has been earned at the time of such termination; plus*
- (B) *The worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus*
- (C) *The worth at the time of award of the amount by which the unpaid rent for the balance of the Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus*
- (D) *Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, specifically including, but not limited to, brokerage commissions and advertising expenses incurred, expenses of remodeling the Premises or any portion thereof for a new tenant, whether for the same or a different use, and any special concessions made to obtain a new tenant; and*
- (E) *At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.*

The term "rent" as used in this Section 21 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used in Sections 21(c)(i)(A) and (B), above, the "worth at the time of award" shall be computed by allowing interest at the Default Rate. As used in Section 21(c)(i)(C) above, the "worth at the time of award" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus 1%.

(iii) Landlord may continue this Lease in effect after Tenant's Default and recover rent as it becomes due (Landlord and Tenant hereby agreeing that Tenant has the right to sublet or assign hereunder, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease following a Default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies hereunder, including the right to recover all Rent as it becomes due.

(iv) Whether or not Landlord elects to terminate this Lease following a Default by Tenant, Landlord shall have the right to terminate any and all subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant and affecting the Premises or may, in Landlord's sole discretion, succeed to Tenant's interest in such subleases, licenses, concessions or arrangements. Upon Landlord's election to succeed to Tenant's interest in any such subleases, licenses, concessions or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

(v) Independent of the exercise of any other remedy of Landlord hereunder or under applicable law, Landlord may conduct an environmental test of the Premises as generally described in Section 30(d) hereof, at Tenant's expense.

(d) Effect of Exercise. Exercise by Landlord of any remedies hereunder or otherwise available shall not be deemed to be an acceptance of surrender of the Premises and/or a termination of this Lease by Landlord, it being understood that such surrender and/or termination can be effected only by the express written agreement of Landlord and Tenant. Any law, usage, or custom to the contrary notwithstanding, Landlord shall have the right at all times to enforce the provisions of this Lease in strict accordance with the terms hereof; and the failure of Landlord at any time to enforce its rights under this Lease strictly in accordance with same shall not be construed as having created a custom in any way or manner contrary to the specific terms, provisions, and covenants of this Lease or as having modified the same and shall not be deemed a waiver of Landlord's right to enforce one or more of its rights in connection with any subsequent default. A receipt by Landlord of Rent or other payment with knowledge of the breach of any covenant hereof shall not be deemed a waiver of such breach, and no waiver by Landlord of any provision of this Lease shall be deemed to have been made unless expressed in writing and signed by Landlord. To the greatest extent permitted by law, Tenant waives the service of notice of Landlord's intention to re-enter, re-take or otherwise obtain possession of the Premises as provided in any statute, or to institute legal proceedings to that end, and also waives all right of redemption in case Tenant shall be dispossessed by a judgment or by warrant of any court or judge. Any reletting of the Premises or any portion thereof shall be on such terms and conditions as Landlord in its sole discretion may determine. Landlord shall not be liable for, nor shall Tenant's obligations hereunder be diminished because of, Landlord's failure to relet the Premises or collect rent due in respect of such reletting or otherwise to mitigate any damages arising by reason of Tenant's Default.

22. Assignment and Subletting.

(a) General Prohibition. Without Landlord's prior written consent subject to and on the conditions described in this Section 22, Tenant shall not, directly or indirectly, voluntarily or by operation of law, assign this Lease or sublease the Premises or any part thereof or mortgage, pledge, or hypothecate its leasehold interest or grant any concession or license within the Premises, and any attempt to do any of the foregoing shall be void and of no effect. If Tenant is a corporation, partnership or limited liability company, the shares or other ownership interests thereof which are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby 25% or more of the issued and outstanding shares or other ownership interests of such corporation are, or voting control is, transferred (but excepting transfers upon deaths of individual owners) from a person or persons or entity or entities which were owners thereof at time of execution of this Lease to persons or entities who were not owners of shares or other ownership interests of the corporation, partnership or limited liability company at time of execution of this Lease, shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in this Section 22.

(b) Permitted Transfers. If Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Premises other than pursuant to a Permitted Assignment (as defined below), then at least 15 business days, but not more than 45 business days, before the date Tenant desires the assignment or sublease to be effective (the "Assignment Date"), Tenant shall give Landlord a notice (the "Assignment Notice") containing such information about the proposed assignee or sublessee, including the proposed use of the Premises and any Hazardous Materials proposed to be used, stored handled, treated, generated in or released or disposed of from the Premises, the Assignment Date, any relationship between Tenant and the proposed assignee or sublessee, and all material terms and conditions of the proposed assignment or sublease, including a copy of any proposed assignment or sublease in its final form, and such other information as Landlord may deem reasonably necessary or appropriate to its consideration whether to grant its consent. Landlord may, by giving written notice to Tenant within 15 business days after receipt of the Assignment Notice: (i) grant such consent (provided that Landlord shall further have the right to review and approve or disapprove the proposed form of sublease prior to the effective date of any such subletting), (ii) refuse such consent, in its reasonable discretion; or (iii) terminate this Lease with respect to the space described in the Assignment Notice as of the Assignment Date (an "Assignment Termination"). Among other reasons, it shall be reasonable for Landlord to withhold its consent in any of these instances: (1) the proposed assignee or subtenant is a governmental agency; (2) in Landlord's reasonable judgment, the use of the Premises by the proposed assignee or subtenant would entail any alterations that would lessen the value of the leasehold improvements in the Premises, or would require increased services by Landlord; (3) in Landlord's reasonable judgment, the proposed assignee or subtenant is engaged in areas of scientific research or other business concerns that are controversial; (4) in Landlord's reasonable judgment, the proposed assignee or subtenant lacks the creditworthiness to support the financial obligations it will incur under the proposed assignment or sublease; (5) in Landlord's reasonable judgment, the character, reputation, or business of the proposed assignee or subtenant is inconsistent with the desired tenant-mix or the quality of other tenancies in the Project or is inconsistent with the type and quality of the nature of the Building; (6) Landlord has received from any prior landlord to the proposed assignee or subtenant a negative report concerning such prior landlord's experience with the proposed assignee or subtenant; (7) Landlord has experienced previous defaults by or is in litigation with the proposed assignee or subtenant; (8) the use of the Premises by the proposed assignee or subtenant will violate any applicable Legal Requirement; (9) the proposed assignee or subtenant, or any entity that, directly or indirectly, controls, is controlled by, or is under common control with the proposed assignee or subtenant, is then an occupant of the Project; (10) the proposed assignee or subtenant is an entity with whom Landlord is negotiating to lease space in the Project; or (11) the assignment or sublease is prohibited by Landlord's lender. If Landlord delivers notice of its election to exercise an Assignment Termination, Tenant shall have the right to withdraw such Assignment Notice by written notice to Landlord of such election within 5 business days after Landlord's notice electing to exercise the Assignment Termination. If Tenant withdraws such Assignment Notice, this Lease shall continue in full force and effect. If Tenant does not withdraw such Assignment Notice, this Lease, and the term and estate herein granted, shall terminate as of the Assignment Date with respect to the space described in such Assignment Notice. No failure of Landlord to exercise any such option to terminate this Lease, or to deliver a timely notice in response to the Assignment Notice, shall be deemed to be Landlord's consent to the proposed assignment, sublease or other transfer. Tenant shall pay to Landlord a fee equal to Two Thousand Five Hundred Dollars (\$2,500) in connection with its consideration of any Assignment Notice and/or its preparation or review of any consent documents. Notwithstanding the foregoing, Landlord's consent to an assignment of this Lease or a subletting of any portion of the Premises to any entity controlling, controlled by or under common control with Tenant (a "Control Permitted Assignment") shall not be required, provided that Landlord shall have the right to approve the form of any such sublease or assignment. In addition, Tenant shall have the right to assign this Lease, upon 30 days prior written notice to Landlord but without obtaining Landlord's prior written consent, to a corporation or other entity which is a successor-in-interest to Tenant, by way of merger, consolidation or corporate reorganization, or by the purchase of all or substantially all of the assets or the ownership interests of Tenant provided that (i) such merger or consolidation, or such acquisition or assumption, as the case may be, is for a good business purpose and not principally for the purpose of transferring the Lease, and (ii) the net worth (as determined in accordance with GAAP) of Tenant as of (A) the Commencement Date, or (B) as of the date of Tenant's most current quarterly or annual financial statements, and (iii) such assignee shall agree in writing to assume all of the terms, covenants and conditions of this Lease (a "Corporate Permitted Assignment"). Control Permitted Assignments and Corporate Permitted Assignments are hereinafter referred to as "Permitted Assignments."

(c) Additional Conditions. As a condition to any such assignment or subletting, whether or not Landlord's consent is required, Landlord may require:

(i) that any assignee or subtenant agree, in writing at the time of such assignment or subletting, that if Landlord gives such party notice that Tenant is in default under this Lease, such party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability except to credit such payment against those due under the Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, in no event shall Landlord or its successors or assigns be obligated to accept such attornment; and

(ii) A list of Hazardous Materials, certified by the proposed assignee or sublessee to be true and correct, which the proposed assignee or sublessee intends to use, store, handle, treat, generate in or release or dispose of from the Premises, together with copies of all documents relating to such use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by the proposed assignee or subtenant in the Premises or on the Project, prior to the proposed assignment or subletting, including, without limitation: permits; approvals; reports and correspondence; storage and management plans; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); and all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks. Neither Tenant nor any such proposed assignee or subtenant is required, however, to provide Landlord with any portion(s) of the such documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities.

(d) No Release of Tenant, Sharing of Excess Rents. Notwithstanding any assignment or subletting, Tenant and any guarantor or surety of Tenant's obligations under this Lease shall at all times remain fully and primarily responsible and liable for the payment of Rent and for compliance with all of Tenant's other obligations under this Lease. If the Rent due and payable by a sublessee or assignee (or a combination of the rental payable under such sublease or assignment plus any bonus or other consideration therefor or incident thereto in any form) exceeds the sum of the rental payable under this Lease, (excluding however, any Rent payable under this Section) and actual and reasonable brokerage fees, legal costs and any design or construction fees directly related to and required pursuant to the terms of any such sublease) ("Excess Rent"), then Tenant shall be bound and obligated to pay Landlord as Additional Rent hereunder 50% of such Excess Rent within 10 days following receipt thereof by Tenant. If Tenant shall sublet the Premises or any part thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and Landlord as assignee and as attorney-in-fact for Tenant, or a receiver for Tenant appointed on Landlord's application, may collect such rent and apply it toward Tenant's obligations under this Lease; except that, until the occurrence of a Default, Tenant shall have the right to collect such rent.

(e) No Waiver. The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or any sublessees of the Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of Tenant from full and primary liability under the Lease. The acceptance of Rent hereunder, or the acceptance of performance of any other term, covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to any subletting, assignment or other transfer of the Premises.

(f) Prior Conduct of Proposed Transferee. Notwithstanding any other provision of this Section 22, if (i) the proposed assignee or sublessee of Tenant has been required by any prior landlord, lender or Governmental Authority to take remedial action in connection with Hazardous Materials contaminating a property, where the contamination resulted from such party's action or use of the property in question, (ii) the proposed assignee or sublessee is subject to an enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority), or (iii) because of the existence of a pre-existing environmental condition in the vicinity of or underlying the Project, the risk that Landlord would be targeted as a responsible party in connection with the remediation of such pre-existing environmental condition would be materially increased or exacerbated by the proposed use of Hazardous Materials by such proposed assignee or sublessee, Landlord shall have the absolute right to refuse to consent to any assignment or subletting to any such party.

23. Estoppel Certificate. Tenant shall, within 10 business days of written notice from Landlord, execute, acknowledge and deliver a statement in writing in any form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advance, if any, (ii) acknowledging that there are not any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (iii) setting forth such further information with respect to the status of this Lease or the Premises as may be requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. Tenant's failure to deliver such statement within such time shall be conclusive upon Tenant that the Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

24. Quiet Enjoyment. So long as Tenant is not in Default under this Lease, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet enjoyment of the Premises against any person claiming by, through or under Landlord.

25. Prorations. All prorations required or permitted to be made hereunder shall be made on the basis of a 360 day year and 30 day months.

26. Rules and Regulations. Tenant shall, at all times during the Term and any extension thereof, comply with all reasonable rules and regulations at any time or from time to time established by Landlord covering use of the Premises and the Project. The current rules and regulations are attached hereto as Exhibit E. If there is any conflict between said rules and regulations and other provisions of this Lease, the terms and provisions of this Lease shall control. Landlord shall not have any liability or obligation for the breach of any rules or regulations by other tenants in the Project and shall not enforce such rules and regulations in a discriminatory manner.

27. Subordination. This Lease and Tenant's interest and rights hereunder are hereby made and shall be subject and subordinate at all times to the lien of any Mortgage now existing or hereafter created on or against the Project or the Premises, and all amendments, restatements, renewals, modifications, consolidations, refinancing, assignments and extensions thereof, without the necessity of any further instrument or act on the part of Tenant; provided, however that so long as there is no Default hereunder, Tenant's right to possession of the Premises shall not be disturbed by the Holder of any such Mortgage. Tenant agrees, at the election of the Holder of any such Mortgage, to attorn to any such Holder. Tenant agrees upon demand to execute, acknowledge and deliver such instruments, confirming such subordination, and such instruments of attornment as shall be requested by any such Holder, provided any such instruments contain appropriate non-disturbance provisions assuring Tenant's quiet enjoyment of the Premises as set forth in Section 24 hereof. Notwithstanding the foregoing, any such Holder may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such Mortgage without regard to their respective dates of execution, delivery or recording and in that event such Holder shall have the same rights with respect to this Lease as though this Lease had been executed prior to the execution, delivery and recording of such Mortgage and had been assigned to such Holder. The term "Mortgage" whenever used in this Lease shall be deemed to include deeds of trust, security assignments and any other encumbrances, and any reference to the "Holder" of a Mortgage shall be deemed to include the beneficiary under a deed of trust. As of the date of this Lease, there is no existing Mortgage encumbering the Project.

28. Surrender. Upon the expiration of the Term or earlier termination of Tenant's right of possession, Tenant shall surrender the Premises to Landlord in the same condition as received, subject to any Alterations or Installations permitted by Landlord to remain in the Premises, free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than a Landlord Party (collectively, "Tenant HazMat Operations") and released of all Hazardous Materials Clearances, broom clean, ordinary wear and tear and casualty loss and condemnation covered by Sections 18 and 19 excepted. At least 3 months prior to the surrender of the Premises or such earlier date as Tenant may elect to cease operations at the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Installations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, free from any residual impact from the Tenant HazMat Operations and otherwise released for unrestricted use and occupancy (the "Decommissioning and HazMat Closure Plan"). Such Decommissioning and HazMat Closure Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord's environmental consultant. In connection with the review and approval of the Decommissioning and HazMat Closure Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the approved Decommissioning and HazMat Closure Plan shall have been satisfactorily completed and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of the Lease, free from any residual impact from Tenant HazMat Operations. Tenant shall reimburse Landlord, as Additional Rent, for the actual out-of-pocket expense incurred by Landlord for Landlord's environmental consultant to review and approve the Decommissioning and HazMat Closure Plan and to visit the Premises and verify satisfactory completion of the same, which cost shall not exceed \$5,000. Landlord shall have the unrestricted right to deliver such Decommissioning and HazMat Closure Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties.

If Tenant shall fail to prepare or submit a Decommissioning and HazMat Closure Plan approved by Landlord, or if Tenant shall fail to complete the approved Decommissioning and HazMat Closure Plan, or if such Decommissioning and HazMat Closure Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of Tenant HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Project are surrendered free from any residual impact from Tenant HazMat Operations, the cost of which actions shall be reimbursed by Tenant as Additional Rent, without regard to the limitation set forth in the first paragraph of this Section 28.

Tenant shall immediately return to Landlord all keys and/or access cards to parking, the Project, restrooms or all or any portion of the Premises furnished to or otherwise procured by Tenant. If any such access card or key is lost, Tenant shall pay to Landlord, at Landlord's election, either the cost of replacing such lost access card or key or the cost of reprogramming the access security system in which such access card was used or changing the lock or locks opened by such lost key. Any Tenant's Property, Alterations and property not so removed by Tenant as permitted or required herein shall be deemed abandoned and may be stored, removed, and disposed of by Landlord at Tenant's expense, and Tenant waives all claims against Landlord for any damages resulting from Landlord's retention and/or disposition of such property. All obligations of Tenant hereunder not fully performed as of the termination of the Term, including the obligations of Tenant under Section 30 hereof, shall survive the expiration or earlier termination of the Term, including, without limitation, indemnity obligations, payment obligations with respect to Rent and obligations concerning the condition and repair of the Premises.

29. Waiver of Jury Trial. TO THE EXTENT PERMITTED BY LAW, TENANT AND LANDLORD WAIVE ANY RIGHT TO TRIAL BY JURY OR TO HAVE A JURY PARTICIPATE IN RESOLVING ANY DISPUTE, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE, BETWEEN LANDLORD AND TENANT ARISING OUT OF THIS LEASE OR ANY OTHER INSTRUMENT, DOCUMENT, OR AGREEMENT EXECUTED OR DELIVERED IN CONNECTION HERewith OR THE TRANSACTIONS RELATED HERETO.

30. Environmental Requirements.

(a) Prohibition/Compliance/Indemnity. Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises or the Project in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Party. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises during the Term or any holding over results in contamination of the Premises, the Project or any adjacent property or if contamination of the Premises, the Project or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord's employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims, damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises or the Project, or the loss of, or restriction on, use of the Premises or any portion of the Project), expenses (including, without limitation, attorneys', consultants' and experts' fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse effects upon, the environment, water tables or natural resources), liabilities or losses (collectively, "Environmental Claims") which arise during or after the Term as a result of such contamination. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Premises, the Building, the Project or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination of the Premises, the Building, the Project or any adjacent property, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, the Building, the Project or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained, which approval shall not unreasonably be withheld so long as such actions would not potentially have any material adverse long-term or short-term effect on the Premises, the Building or the Project. Notwithstanding anything to the contrary contained in this Section 30, Tenant shall not be responsible for, and the indemnification and hold harmless obligation set forth in this paragraph shall not apply to (i) contamination in the Premises which Tenant can prove to Landlord's reasonable satisfaction existed in the Premises immediately prior to the Commencement Date, or (ii) the presence of any Hazardous Materials in the Premises which Tenant can prove to Landlord's reasonable satisfaction migrated from outside of the Premises into the Premises, unless in either case, the presence of such Hazardous Materials (x) is the result of a breach by Tenant of any of its obligations under this Lease, or (y) was caused, contributed to or exacerbated by Tenant or any Tenant Party.

(b) Business. Landlord acknowledges that it is not the intent of this Section 30 to prohibit Tenant from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Commencement Date a list identifying each type of Hazardous Materials to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises (“Hazardous Materials List”). Upon Landlord’s request, or any time that Tenant is required to deliver a Hazardous Materials List to any Governmental Authority (e.g., the fire department) in connection with Tenant’s use or occupancy of the Premises, Tenant shall deliver to Landlord a copy of such Hazardous Materials List. Tenant shall deliver to Landlord true and correct copies of the following documents (the “Haz Mat Documents”) relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials prior to the Commencement Date, or if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits; approvals; reports and correspondence; storage and management plans, notice of violations of any Legal Requirements; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord’s sole and absolute discretion); all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks; and a Decommissioning and HazMat Closure Plan (to the extent surrender in accordance with Section 28 cannot be accomplished in 3 months). Tenant is not required, however, to provide Landlord with any portion(s) of the Haz Mat Documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information which could be detrimental to Tenant’s business should such information become possessed by Tenant’s competitors.

(c) Tenant Representation and Warranty. Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord, lender or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property which contamination was permitted by Tenant of such predecessor or resulted from Tenant’s or such predecessor’s action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority). If Landlord determines that this representation and warranty was not true as of the date of this lease, Landlord shall have the right to terminate this Lease in Landlord’s sole and absolute discretion.

(d) Testing. Landlord shall have the right to conduct annual tests of the Premises to determine whether any contamination of the Premises or the Project has occurred as a result of Tenant’s use. Tenant shall be required to pay the cost of such annual test of the Premises; provided, however, that if Tenant conducts its own tests of the Premises using third party contractors and test procedures acceptable to Landlord which tests are certified to Landlord, Landlord shall accept such tests in lieu of the annual tests to be paid for by Tenant. In addition, at any time, and from time to time, prior to the expiration or earlier termination of the Term, Landlord shall have the right to conduct appropriate tests of the Premises and the Project to determine if contamination has occurred as a result of Tenant’s use of the Premises. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. If contamination has occurred for which Tenant is liable under this Section 30, Tenant shall pay all costs to conduct such tests. If no such contamination is found, Landlord shall pay the costs of such tests (which shall not constitute an Operating Expense). Landlord shall provide Tenant with a copy of all third party, non-confidential reports and tests of the Premises made by or on behalf of Landlord during the Term without representation or warranty and subject to a confidentiality agreement. Tenant shall, at its sole cost and expense, promptly and satisfactorily remediate any environmental conditions identified by such testing in accordance with all Environmental Requirements. Landlord’s receipt of or satisfaction with any environmental assessment in no way waives any rights which Landlord may have against Tenant.

(e) Control Areas. Tenant shall be allowed to utilize up to its pro rata share of the Hazardous Materials inventory within any control area or zone (located within the Premises), as designated by the applicable building code, for chemical use or storage. As used in the preceding sentence, Tenant's pro rata share of any control areas or zones located within the Premises shall be determined based on the rentable square footage that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant's premises are located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant's pro rata share of such control area would be 20%.

(f) Underground Tanks. Tenant shall have no right to use or install any underground or other storage tanks at the Project.

(g) Tenant's Obligations. Tenant's obligations under this Section 30 shall survive the expiration or earlier termination of the Lease. During any period of time after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Decommissioning and HazMat Closure Plan), Tenant shall continue to pay the full Rent in accordance with this Lease for any portion of the Premises not relet by Landlord in Landlord's sole discretion, which Rent shall be prorated daily.

(h) Definitions. As used herein, the term "Environmental Requirements" means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Premises or the Project, or the environment, including without limitation, the following: the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; and all state and local counterparts thereto, and any regulations or policies promulgated or issued thereunder. As used herein, the term "Hazardous Materials" means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). As defined in Environmental Requirements, Tenant is and shall be deemed to be the "operator" of Tenant's "facility" and the "owner" of all Hazardous Materials brought on the Premises by Tenant or any Tenant Party, and the wastes, by-products, or residues generated, resulting, or produced therefrom.

31. Tenant's Remedies/Limitation of Liability. Landlord shall not be in default hereunder unless Landlord fails to perform any of its obligations hereunder within 30 days after written notice from Tenant specifying such failure (unless such performance will, due to the nature of the obligation, require a period of time in excess of 30 days, then after such period of time as is reasonably necessary). Upon any default by Landlord, Tenant shall give notice by registered or certified mail to any Holder of a Mortgage covering the Premises and to any landlord of any lease of property in or on which the Premises are located and Tenant shall offer such Holder and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Project by power of sale or a judicial action if such should prove necessary to effect a cure; provided Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices. All obligations of Landlord hereunder shall be construed as covenants, not conditions; and, except as may be otherwise expressly provided in this Lease, Tenant may not terminate this Lease for breach of Landlord's obligations hereunder.

All obligations of Landlord under this Lease will be binding upon Landlord only during the period of its ownership of the Premises and not thereafter. The term "Landlord" in this Lease shall mean only the owner for the time being of the Premises. Upon the transfer by such owner of its interest in the Premises, such owner shall thereupon be released and discharged from all obligations of Landlord thereafter accruing, but such obligations shall be binding during the Term upon each new owner for the duration of such owner's ownership.

32. Inspection and Access. Landlord and its agents, representatives, and contractors may enter the Premises at any reasonable time to inspect the Premises and to make such repairs as may be required or permitted pursuant to this Lease and for any other business purpose. Landlord and Landlord's representatives may enter the Premises during business hours on not less than 48 hours advance written notice (except in the case of emergencies in which case no such notice shall be required and such entry may be at any time) for the purpose of effecting any such repairs, inspecting the Premises, showing the Premises to prospective purchasers and, during the last 18 months of the Term, to prospective tenants or for any other business purpose. Landlord may erect a suitable sign on the Premises stating the Premises are available to let or that the Project is available for sale. Landlord may grant easements, make public dedications, designate Common Areas and create restrictions on or about the Premises, provided that no such easement, dedication, designation or restriction materially, adversely affects Tenant's use or occupancy of the Premises for the Permitted Use. At Landlord's request, Tenant shall execute such instruments as may be necessary for such easements, dedications or restrictions. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord's access rights hereunder.

33. Security. Tenant acknowledges and agrees that security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts and that Landlord is not providing any security services with respect to the Premises. Tenant agrees that Landlord shall not be liable to Tenant for, and Tenant waives any claim against Landlord with respect to, any loss by theft or any other damage suffered or incurred by Tenant in connection with any unauthorized entry into the Premises or any other breach of security with respect to the Premises. Tenant shall be solely responsible for the personal safety of Tenant's officers, employees, agents, contractors, guests and invitees while any such person is in, on or about the Premises and/or the Project. Tenant shall at Tenant's cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.

34. Force Majeure. Landlord shall not be responsible or liable for delays in the performance of its obligations hereunder when caused by, related to, or arising out of acts of God, sinkholes or subsidence, strikes, lockouts, or other labor disputes, embargoes, quarantines, weather, national, regional, or local disasters, calamities, or catastrophes, inability to obtain labor or materials (or reasonable substitutes therefor) at reasonable costs or failure of, or inability to obtain, utilities necessary for performance, governmental restrictions, orders, limitations, regulations, or controls, national emergencies, delay in issuance or revocation of permits, enemy or hostile governmental action, terrorism, insurrection, riots, civil disturbance or commotion, fire or other casualty, and other causes or events beyond the reasonable control of Landlord ("Force Majeure").

35. Brokers. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "Broker") in connection with this transaction and that no Broker brought about this transaction, other than Newmark Knight Frank and Kidder Matthews. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than the broker, other than Newmark Knight Frank and Kidder Matthews, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

36. Limitation on Landlord's Liability. NOTWITHSTANDING ANYTHING SET FORTH HEREIN OR IN ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT TO THE CONTRARY: (A) LANDLORD SHALL NOT BE LIABLE TO TENANT OR ANY OTHER PERSON FOR (AND TENANT AND EACH SUCH OTHER PERSON ASSUME ALL RISK OF) LOSS, DAMAGE OR INJURY, WHETHER ACTUAL OR CONSEQUENTIAL TO: TENANT'S PERSONAL PROPERTY OF EVERY KIND AND DESCRIPTION, INCLUDING, WITHOUT LIMITATION TRADE FIXTURES, EQUIPMENT, INVENTORY, SCIENTIFIC RESEARCH, SCIENTIFIC EXPERIMENTS, LABORATORY ANIMALS, PRODUCT, SPECIMENS, SAMPLES, AND/OR SCIENTIFIC, BUSINESS, ACCOUNTING AND OTHER RECORDS OF EVERY KIND AND DESCRIPTION KEPT AT THE PREMISES AND ANY AND ALL INCOME DERIVED OR DERIVABLE THEREFROM; (B) THERE SHALL BE NO PERSONAL RECOURSE TO LANDLORD FOR ANY ACT OR OCCURRENCE IN, ON OR ABOUT THE PREMISES OR ARISING IN ANY WAY UNDER THIS LEASE OR ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT WITH RESPECT TO THE SUBJECT MATTER HEREOF AND ANY LIABILITY OF LANDLORD HEREUNDER SHALL BE STRICTLY LIMITED SOLELY TO LANDLORD'S INTEREST IN THE PROJECT OR ANY PROCEEDS FROM SALE OR CONDEMNATION THEREOF AND ANY INSURANCE PROCEEDS PAYABLE IN RESPECT OF LANDLORD'S INTEREST IN THE PROJECT OR IN CONNECTION WITH ANY SUCH LOSS; AND (C) IN NO EVENT SHALL ANY PERSONAL LIABILITY BE ASSERTED AGAINST LANDLORD IN CONNECTION WITH THIS LEASE NOR SHALL ANY RECOURSE BE HAD TO ANY OTHER PROPERTY OR ASSETS OF LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS. UNDER NO CIRCUMSTANCES SHALL LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS BE LIABLE FOR INJURY TO TENANT'S BUSINESS OR FOR ANY LOSS OF INCOME OR PROFIT THEREFROM.

37. Severability. If any clause or provision of this Lease is illegal, invalid or unenforceable under present or future laws, then and in that event, it is the intention of the parties hereto that the remainder of this Lease shall not be affected thereby. It is also the intention of the parties to this Lease that in lieu of each clause or provision of this Lease that is illegal, invalid or unenforceable, there be added, as a part of this Lease, a clause or provision as similar in effect to such illegal, invalid or unenforceable clause or provision as shall be legal, valid and enforceable.

38. Signs; Exterior Appearance. Tenant shall not, without the prior written consent of Landlord, which may be granted or withheld in Landlord's sole discretion: (i) attach any awnings, exterior lights, decorations, balloons, flags, pennants, banners, painting or other projection to any outside wall of the Project, (ii) use any curtains, blinds, shades or screens other than Landlord's standard window coverings, (iii) coat or otherwise sunscreen the interior or exterior of any windows, (iv) place any bottles, parcels, or other articles on the window sills, (v) place any equipment, furniture or other items of personal property on any exterior balcony, or (vi) paint, affix or exhibit on any part of the Premises or the Project any signs, notices, window or door lettering, placards, decorations, or advertising media of any type which can be viewed from the exterior of the Premises. Suite entry signage and Tenant's name on the directory tablet shall be inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord. Nothing may be placed on the exterior of corridor walls or corridor doors other than Landlord's standard lettering. The directory tablet shall be provided exclusively for the display of the name and location of tenants.

39. Right to Extend Term. Tenant shall have the right to extend the Term of the Lease upon the following terms and conditions:

(a) Extension Rights. Tenant shall have 2 consecutive rights (each, an "Extension Right") to extend the term of this Lease for 5 years each (each, an "Extension Term") on the same terms and conditions as this Lease (other than with respect to Base Rent and the TI Allowance) by giving Landlord written notice of its election to exercise each Extension Right at least 9 months prior, and no earlier than 12 months prior, to the expiration of the Base Term of the Lease or the expiration of the prior Extension Term.

Base Rent for the first year of the first Extension Term shall be 102.5% of the Base Rent for the final year of the Base Term, and Base Rent shall increase on each annual anniversary of the commencement date of such first Extension Term by the Rent Adjustment Percentage. In addition, Landlord may impose a market rent for the parking rights provided hereunder.

Upon the commencement of second Extension Term, Base Rent shall be payable at the Market Rate (as defined below). Base Rent shall thereafter be adjusted on each annual anniversary of the commencement of such Extension Term by a percentage as determined by Landlord and agreed to by Tenant at the time the Market Rate is determined. As used herein, "Market Rate" shall mean the rate that comparable landlords of comparable buildings have accepted in current transactions from non-equity (i.e., not being offered equity in the buildings) and nonaffiliated tenants of similar financial strength for space of comparable size, quality (including all Tenant Improvements, Alterations and other improvements) and floor height in Class A laboratory/office buildings in the Seattle area for a comparable term, with the determination of the Market Rate to take into account all relevant factors, including tenant inducements, views, parking costs, leasing commissions, allowances or concessions, if any. In addition, Landlord may impose a market rent for the parking rights provided hereunder.

If, on or before the date which is 240 days prior to the expiration of the first Extension Term, Tenant has not agreed with Landlord's determination of the Market Rate and the rent escalations during the second Extension Term after negotiating in good faith, Tenant shall be deemed to have elected arbitration as described in Section 39(b). Tenant acknowledges and agrees that, if Tenant has elected to exercise an Extension Right by delivering notice to Landlord as required in this Section 39(a), Tenant shall have no right thereafter to rescind or elect not to extend the term of the Lease for such Extension Term.

(b) Arbitration.

(i) Within 10 days of Tenant's notice to Landlord of its election (or deemed election) to arbitrate Market Rate and escalations, each party shall deliver to the other a proposal containing the Market Rate and escalations that the submitting party believes to be correct ("Extension Proposal"). If either party fails to timely submit an Extension Proposal, the other party's submitted proposal shall determine the Base Rent and escalations for the Second Extension Term. If both parties submit Extension Proposals, then Landlord and Tenant shall meet within 7 days after delivery of the last Extension Proposal and make a good faith attempt to mutually appoint a single Arbitrator (and defined below) to determine the Market Rate and escalations. If Landlord and Tenant are unable to agree upon a single Arbitrator, then each shall, by written notice delivered to the other within 10 days after the meeting, select an Arbitrator. If either party fails to timely give notice of its selection for an Arbitrator, the other party's submitted proposal shall determine the Base Rent for the Second Extension Term. The 2 Arbitrators so appointed shall, within 5 business days after their appointment, appoint a third Arbitrator. If the 2 Arbitrators so selected cannot agree on the selection of the third Arbitrator within the time above specified, then either party, on behalf of both parties, may request such appointment of such third Arbitrator by application to any state court of general jurisdiction in the jurisdiction in which the Premises are located, upon 10 days prior written notice to the other party of such intent.

(ii) The decision of the Arbitrator(s) shall be made within 30 days after the appointment of a single Arbitrator or the third Arbitrator, as applicable. The decision of the single Arbitrator shall be final and binding upon the parties. The average of the two closest Arbitrators in a three Arbitrator panel shall be final and binding upon the parties. Each party shall pay the fees and expenses of the Arbitrator appointed by or on behalf of such party and the fees and expenses of the third Arbitrator shall be borne equally by both parties. If the Market Rate and escalations are not determined by the first day of the Second Extension Term, then Tenant shall pay Landlord Base Rent in an amount equal to the Base Rent in effect immediately prior to the Second Extension Term and increased by the Rent Adjustment Percentage until such determination is made. After the determination of the Market Rate and escalations, the parties shall make any necessary adjustments to such payments made by Tenant. Landlord and Tenant shall then execute an amendment recognizing the Market Rate and escalations for the Second Extension Term.

(iii) An "Arbitrator" shall be any person appointed by or on behalf of either party or appointed pursuant to the provisions hereof and: (i) shall be (A) a member of the American Institute of Real Estate Appraisers with not less than 10 years of experience in the appraisal of improved office and high tech industrial real estate in the greater Seattle metropolitan area, or (B) a licensed commercial real estate broker with not less than 15 years' experience representing landlords and/or tenants in the leasing of high tech or life sciences space in the greater Seattle metropolitan area, (ii) devoting substantially all of their time to professional appraisal or brokerage work, as applicable, at the time of appointment and (iii) be in all respects impartial and disinterested.

(c) Rights Personal. Extension Rights are personal to Tenant and are not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease, except that they may be assigned in connection with any Permitted Assignment of this Lease.

(d) Exceptions. Notwithstanding anything set forth above to the contrary, Extension Rights shall, at Landlord's option, not be in effect and Tenant may not exercise any of the Extension Rights:

(i) during any period of time that Tenant is in Default under any provision of this Lease; or

(ii) if Tenant has been in Default under any provision of this Lease 3 or more times, whether or not the Defaults are cured, during the 12 month period immediately prior to the date that Tenant intends to exercise an Extension Right, whether or not the Defaults are cured.

(e) No Extensions. The period of time within which any Extension Rights may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Extension Rights.

(f) Termination. The Extension Rights shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of an Extension Right, if, after such exercise, but prior to the commencement date of an Extension Term, (i) Tenant fails to timely cure any default by Tenant under this Lease; or (ii) Tenant has Defaulted 3 or more times during the period from the date of the exercise of an Extension Right to the date of the commencement of the Extension Term, whether or not such Defaults are cured.

40. Shared Lab Area.

(a) License. During the Term, Landlord hereby grants to Tenant, and Tenant hereby accepts, a non-exclusive license ("License") to use that certain area of the Project described as the "Shared Lab Area" on Exhibit G attached hereto, subject to the terms and provisions of this Section 40.

(b) Use. Tenant shall exercise its rights under this Section 40 and use the Shared Lab Area in a manner that complies with all applicable Legal Requirements and any and all rules and regulations which may be adopted by Landlord from time to time and provided to Tenant in writing including, without limitation, any schedule(s) which may be implemented by Landlord for the use of the Shared Lab Area by all parties entitled to use the same. Tenant agrees to cause its employees who will be using the Shared Lab Area to complete all training programs, if any, mandated by Landlord relating to the use of the Shared Lab Area.

Tenant shall use the Shared Lab Area in a manner that will not interfere with the rights of any other tenants, other licensees or Landlord's service providers. Landlord assumes no responsibility for enforcing Tenant's rights or for protecting the Shared Lab Area from interference or use from any person including, without limitation, other tenants or licensees of the Project. Landlord may terminate the License granted to Tenant hereunder at any time during the Term, upon 10 days' notice to Tenant, for Tenant's failure to comply with the terms of this Section 40 or any rules and regulations adopted by Landlord with respect to the Shared Lab Area. The expiration or earlier termination of this Lease shall automatically terminate the license hereby granted to Tenant to so use the Shared Lab Area.

Use by Tenant of the Shared Lab Area shall be in common with others entitled to use the Shared Lab Area in accordance with scheduling procedures reasonably determined by Landlord. Landlord shall use commercially reasonable efforts to schedule users of the Shared Lab Area on a first-come, first-served basis, but Landlord reserves the right to exercise its discretion in the event of conflicting scheduling requests among users.

(c) Relocation and Modification of Shared Lab Area. Tenant acknowledges and agrees that Landlord shall have the right at any time and from time to time, upon no less than 30 days' notice to Tenant, to reconfigure, relocate, modify or remove the Shared Lab Area and/or to revise, expand or discontinue any of the services (if any) provided therein, and to add, change, reconfigure, remove or relocate any of the Equipment (as hereinafter defined) located therein, provided that Landlord shall not permanently remove from the Shared Lab Area the shared glass wash.

(d) Waiver.

(i) Landlord's sole obligation for providing any equipment, systems, furnishings or personal property to the Shared Lab Area whether or not affixed to the Building (collectively, "Equipment") shall be (i) to provide such Equipment as is determined by Landlord in its sole and absolute discretion, and (ii) to contract with a third party to maintain the Equipment that is deemed by Landlord (in its sole and absolute discretion) to need periodic maintenance per the manufacturer's standard maintenance guidelines. Landlord shall, upon written request from Tenant (not more frequently than once per calendar year), make available for Tenant's inspection the maintenance records for the Equipment for the 12-month period immediately preceding Landlord's receipt of Tenant's written request. Landlord shall have no obligation to provide Tenant with operational Equipment, back-up Equipment or back-up utilities or to supervise, oversee or confirm that the third party maintaining the Equipment is maintaining the Equipment as per the manufacturer's standard guidelines or otherwise. During any period of replacement, repair or maintenance of the Equipment when such Equipment is not operational, including any delays thereto due to the inability to obtain parts or replacements, Landlord shall have no obligation to provide Tenant with alternative or back-up Equipment. Tenant expressly acknowledges and agrees that Landlord does not guaranty that the Equipment will be operational at all times, will function or perform adequately and Landlord shall not be liable for any damages resulting from the failure of such Equipment.

(ii) Landlord makes no warranties of any kind, express or implied, with respect to the Shared Lab Area or the Equipment, and Landlord disclaims any such warranties. Without limiting the foregoing, Tenant expressly acknowledges and agrees that Landlord does not guaranty or warrant that that the Shared Lab Area of any Equipment will be operational at all times, will be of sufficient capacity to accommodate Tenant's use thereof, will be free of Hazardous Materials, or will function or perform adequately, and Landlord shall not be liable for any damages resulting from the failure of the Shared Lab Area and/or any Equipment.

(e) Tenant acknowledges and agrees that Landlord is under no obligation to provide any type of instruction or implement any training programs relating to the use of the Shared Lab Area for Tenant or any other parties entitled to use the Shared Lab Area.

41. Right to Expand.

(a) Subject to rights granted to tenants of the Project prior to the date of this Lease, Tenant shall have the right during the Base Term, but not the obligation, to expand the Premises (the "Expansion Right") to include any Available Space upon the terms and conditions in this Section. For purposes of this Section 41(a), "Available Space" shall mean any space on the 4th floor which is not occupied by a tenant or which is occupied by an existing tenant whose lease is expiring within 9 months or less and such tenant does not wish to renew (whether or not such tenant has a right to renew) its occupancy of such space. If there is any Available Space in the Building, Landlord shall, at such time as Landlord shall elect so long as Tenant's rights hereunder are preserved, deliver to Tenant written notice (the "Expansion Notice") of such Available Space, together with the terms and conditions on which Landlord is prepared to lease Tenant such Available Space. Tenant shall be entitled to exercise its right under this Section 41(a) only with respect to the entire Available Space described in the Expansion Notice. Tenant shall have 10 days following delivery of the Expansion Notice to deliver to Landlord written notification of Tenant's exercise of the Expansion Right. Tenant shall be entitled to lease such Available Space upon the terms and conditions set forth in the Expansion Notice.

(b) Amended Lease. If: (i) Tenant fails to timely deliver notice accepting the terms of an Expansion Notice, or (ii) Landlord tenders to Tenant an amendment to this Lease setting forth the terms for the rental of the Available Space consistent with those set forth in the Expansion Notice and otherwise consistent with the terms of this Lease and Tenant fails to execute such Lease amendment within 10 business days following such tender, Tenant shall be deemed to have waived its right to lease such Available Space.

(c) Exceptions. Notwithstanding the above, the Expansion Right shall, at Landlord's option, not be in effect and may not be exercised by Tenant:

(i) during any period of time that Tenant is in Default under any provision of the Lease; or

(ii) if Tenant has been in Default under any provision of the Lease 3 or more times, whether or not the Defaults are cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Expansion Right.

(d) Termination. The Expansion Right shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Expansion Right, if, after such exercise, but prior to the commencement date of the lease of such Available Space, (i) Tenant fails to timely cure any default by Tenant under the Lease; or (ii) Tenant has Defaulted 3 or more times during the period from the date of the exercise of the Expansion Right to the date of the commencement of the lease of the Available Space, whether or not such Defaults are cured.

(e) Subordinate. Tenant's Expansion Rights granted pursuant to Section 41(a) above are and shall remain subject and subordinate to any expansion rights granted to tenants of the Project prior to the date of the date of this Lease.

(f) Rights Personal. The Expansion Right is personal to Tenant and is not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease, except that they may be assigned in connection with any Permitted Assignment of this Lease.

(g) No Extensions. The period of time within which any Expansion Right may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Expansion Right.

42. Miscellaneous.

(a) Notices. All notices or other communications between the parties shall be in writing and shall be deemed duly given upon delivery or refusal to accept delivery by the addressee thereof if delivered in person, or upon actual receipt if delivered by reputable overnight guaranty courier, addressed and sent to the parties at their addresses set forth above. Landlord and Tenant may from time to time by written notice to the other designate another address for receipt of future notices.

(b) Joint and Several Liability. If and when included within the term "Tenant," as used in this instrument, there is more than one person or entity, each shall be jointly and severally liable for the obligations of Tenant.

(c) Financial Information. Tenant shall furnish Landlord with true and complete copies of (i) Tenant's most recent audited annual financial statements within 90 days of the end of each of Tenant's fiscal years during the Term, (ii) Tenant's most recent unaudited quarterly financial statements within 45 days of the end of each of Tenant's first three fiscal quarters of each of Tenant's fiscal years during the Term, (iii) at Landlord's request from time to time, updated business plans, including cash flow projections and/or pro forma balance sheets and income statements, all of which shall be treated by Landlord as confidential information belonging to Tenant, (iv) corporate brochures and/or profiles prepared by Tenant for prospective investors, and (v) any other financial information or summaries that Tenant typically provides to its lenders or shareholders. So long as Tenant is a "public company" and its financial information is publicly available, then the foregoing delivery requirements of this Section 40(c) shall not apply.

(d) Recordation. Neither this Lease nor a memorandum of lease shall be filed by or on behalf of Tenant in any public record. Landlord may prepare and file, and upon request by Landlord Tenant will execute, a memorandum of lease. Nothing contained in this Lease is intended to prohibit Tenant from filing this Lease with the Securities and Exchange Commission ("SEC") to the extent that Tenant is required to do so pursuant to applicable SEC requirements. Prior to any such filing of this Lease, Tenant shall redact the Base Rent and other economic terms to the extent permitted by the applicable SEC regulators.

(e) Interpretation. The normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any exhibits or amendments hereto. Words of any gender used in this Lease shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, unless the context otherwise requires. The captions inserted in this Lease are for convenience only and in no way define, limit or otherwise describe the scope or intent of this Lease, or any provision hereof, or in any way affect the interpretation of this Lease.

(f) Not Binding Until Executed. The submission by Landlord to Tenant of this Lease shall have no binding force or effect, shall not constitute an option for the leasing of the Premises, nor confer any right or impose any obligations upon either party until execution of this Lease by both parties.

(g) Limitations on Interest. It is expressly the intent of Landlord and Tenant at all times to comply with applicable law governing the maximum rate or amount of any interest payable on or in connection with this Lease. If applicable law is ever judicially interpreted so as to render usurious any interest called for under this Lease, or contracted for, charged, taken, reserved, or received with respect to this Lease, then it is Landlord's and Tenant's express intent that all excess amounts theretofore collected by Landlord be credited on the applicable obligation (or, if the obligation has been or would thereby be paid in full, refunded to Tenant), and the provisions of this Lease immediately shall be deemed reformed and the amounts thereafter collectible hereunder reduced, without the necessity of the execution of any new document, so as to comply with the applicable law, but so as to permit the recovery of the fullest amount otherwise called for hereunder.

(h) Choice of Law. Construction and interpretation of this Lease shall be governed by the internal laws of the state in which the Premises are located, excluding any principles of conflicts of laws.

(i) Time. Time is of the essence as to the performance of Tenant's obligations under this Lease.

(j) OFAC. Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

(k) Incorporation by Reference. All exhibits and addenda attached hereto are hereby incorporated into this Lease and made a part hereof. If there is any conflict between such exhibits or addenda and the terms of this Lease, such exhibits or addenda shall control.

(l) Entire Agreement. This Lease, including the exhibits attached hereto, constitutes the entire agreement between Landlord and Tenant pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, understandings, letters of intent, negotiations and discussions, whether oral or written, of the parties, and there are no warranties, representations or other agreements, express or implied, made to either party by the other party in connection with the subject matter hereof except as specifically set forth herein.

(m) No Accord and Satisfaction. No payment by Tenant or receipt by Landlord of a lesser amount than the monthly installment of Base Rent or any Additional Rent will be other than on account of the earliest stipulated Base Rent and Additional Rent, nor will any endorsement or statement on any check or letter accompanying a check for payment of any Base Rent or Additional Rent be an accord and satisfaction. Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or to pursue any other remedy provided in this Lease.

(n) Hazardous Activities. Notwithstanding any other provision of this Lease, 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 acceptable to Landlord, in Landlord's reasonable discretion, for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Tenant's Share of Operating Expenses in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

(o) Counterparts. This Lease may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Lease and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

(p) Shuttle Services. Landlord and affiliates of Landlord plan to provide a campus shuttle service for the Project and other buildings in the vicinity of the Project that are owned by affiliates of Landlord (the "Shuttle Service"); provided, however, that neither Landlord nor any affiliate of Landlord shall be obligated to provide the Shuttle Service (or, once the Shuttle Service has commenced, to continue providing the Shuttle Service for any specific period of time) or to cause the Shuttle Service to follow any specific route, make any specific stops, or adhere to any specific schedule or hours of operation. If Landlord and affiliates of Landlord actually commence operation of the Shuttle Service, (i) Landlord shall give Tenant written notice of the date such operation will commence ("Shuttle Services Commencement Date") and the planned route, stops, schedule, and hours of operation, (ii) Landlord shall permit Tenant's employees actually employed at the Project to use the Shuttle Service, and (iii) regardless of whether Tenant's employees use the Shuttle Services, commencing on later to occur of (x) the Shuttle Services Commencement Date, or the Rent Commencement Date, through the earlier of the expiration of the Term or the date that Landlord permanently ceases to provide Shuttle Service, Operating Expenses shall include the cost of provision the Shuttle Service (the "Shuttle Service Costs"). Tenant acknowledges and agrees that Landlord has not made any representations or warranties regarding the commencement or continued availability of the Shuttle Service and that Tenant is not entering into this Lease with an expectation that the Shuttle Service shall commence or continue to be available to Tenant throughout the Term.

[Signatures are on the next page]

TENANT:

NEOLEUKIN THERAPEUTICS, INC.,
a Delaware corporation

By: _____
Its: _____

LANDLORD:

ARE-EASTLAKE AVENUE NO. 3, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: _____
Its: _____

LANDLORD'S ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA)

) §

County of)

On _____, 201_____, before me, _____, a Notary Public, personally appeared _____ who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature of Notary

(Affix seal here)

TENANT'S ACKNOWLEDGMENT

STATE OF _____
COUNTY OF _____ | ss.

On this ____ day of _____, 20____, before me personally appeared _____, to me known to be the _____ of _____, a _____, that executed the within and foregoing instrument, and acknowledged the said instrument to be the free and voluntary act and deed of said corporation for the uses and purposes therein mentioned, and on oath stated that they were authorized to execute said instrument.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal the day and year first above written.

(Signature of Notary)

(Legibly Print or Stamp Name of Notary)

Notary public in and for the State of

_____,
residing at _____

My appointment expires _____

LIST OF SUBSIDIARIES OF NEOLEUKIN THERAPEUTICS, INC.

Subsidiaries

Neoleukin Corp.

Aquinox Pharmaceuticals (Canada) Inc.

Incorporation

State of Delaware

Canada

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements Nos.333-194490, 333-203179, 333-210172, 333-216572, 333-223589 and 333-234734 on Form S-8 and Nos. 333-215457 and 333-223584 on Form S-3 of our report dated March 12, 2020, relating to the financial statements of Neoleukin Therapeutics, Inc. appearing in this Annual Report on Form 10-K of Neoleukin Therapeutics, Inc. for the year ended December 31, 2019.

/s/ Deloitte LLP

Chartered Professional Accountants
Vancouver, Canada
March 12, 2020

CERTIFICATIONS

I, Jonathan G. Drachman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Neoleukin 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 12, 2020

/s/ Jonathan G. Drachman
Jonathan G. Drachman
Chief Executive Officer

CERTIFICATIONS

I, Kamran Alam, certify that:

1. I have reviewed this Annual Report on Form 10-K of Neoleukin 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:
 1. 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;
 2. 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 12, 2020

/s/ Kamran Alam

Kamran Alam
Interim Chief Financial Officer

NEOLEUKIN THERAPEUTICS, INC.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Neoleukin Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan G. Drachman, Chief Executive Officer of the Company, certify, pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jonathan G. Drachman

Jonathan G. Drachman
Chief Executive Officer

March 12, 2020

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 Neoleukin 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.

NEOLEUKIN THERAPEUTICS, INC.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Neoleukin Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kamran Alam, Interim Chief Financial Officer of the Company, certify, pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Kamran Alam

Kamran Alam

Interim Chief Financial Officer

March 12, 2020

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 Neoleukin 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.