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 November 30, 2020

OR

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

Commission File Number 001-39398

NURIX THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**27-0838048**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1700 Owens Street, Suite 205 San Francisco, CA	**94158**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 660-5320

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	NRIX	Nasdaq Global Market

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on July 28, 2020 as reported by the Nasdaq Global Market on such date was approximately $452 million. The Registrant has elected to use July 28, 2020, which was the closing date of its initial public offering of common stock, as the calculation date because on May 29, 2020 (the last business day of the Registrant's most recently completed second fiscal quarter) the Registrant was a privately held company. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

As of February 11, 2021 , the Registrant had 38,907,223 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the Registrant's definitive Proxy Statement to be filed in connection with the Registrant's 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such definitive Proxy Statement will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended November 30, 2020.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements contained in this Annual Report on Form 10-K other than statements of historical fact, including statements concerning our business strategy and plans, future operating results and financial position, as well as our objectives and expectations for our future operations, are forward-looking statements.

In some cases, you can identify forward-looking statements by such terminology as “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements about:

- the timing of our planned investigational new drug application (IND) submissions for our lead product candidates and other drug candidates;
- the timing and conduct of our clinical trial programs for our lead product candidates NX-2127 and NX-1607 and other drug candidates, including statements regarding the timing of initiation of the clinical trials;
- the timing of, and our ability to obtain, marketing approvals for our lead product candidates NX-2127 and NX-1607 and other drug candidates;
- our plans to pursue research and development of other product candidates;
- the potential advantages of our DELigase platform and our product candidates;
- the extent to which our scientific approach and DELigase platform may potentially address a broad range of diseases;
- the potential benefits of our arrangements with Sanofi S.A. and Gilead Sciences, Inc.;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the potential receipt of revenue from future sales of our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our estimates regarding the potential market opportunity for our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacturing of our product candidates;
- the impact of the ongoing coronavirus (COVID-19) pandemic on our business, financial condition, liquidity and results of operations;
- the potential achievement of milestones and receipt of royalty payments under our collaborations;
- our ability to enter into additional collaborations with third parties;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations; and
- our competitive position.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, prospects, and financial needs. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We disclaim any intention or obligation to publicly update or revise any forward-looking statements for any reason or to conform such statements to actual results or revised expectations, except as required by law.

PART I

Item 1. Business

When used in this report, unless otherwise indicated, "Nurix," "Company," "we," "us" and "our" refers to Nurix Therapeutics, Inc. and its wholly owned subsidiary.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of small molecule therapies designed to modulate cellular protein levels as a novel treatment approach for cancer and other challenging diseases. Leveraging our extensive expertise in E3 ligases together with our proprietary DNA-encoded libraries, we have built DELigase, an integrated discovery platform to identify and advance novel drug candidates targeting E3 ligases, a broad class of enzymes that can modulate proteins within the cell. Our drug discovery approach is to either harness or inhibit the natural function of E3 ligases within the ubiquitin-proteasome system (UPS) to selectively decrease or increase cellular protein levels. Our wholly owned pipeline comprises targeted protein degraders of Bruton's tyrosine kinase (BTK), a B-cell signaling protein, and inhibitors of Casitas B-lineage lymphoma proto-oncogene-B (CBL-B), an E3 ligase that regulates T cell activation. Our lead drug candidate from our protein degradation portfolio, NX-2127, is an orally available BTK degrader with immunomodulatory drug (IMiD) activity for the treatment of relapsed or refractory B-cell malignancies. We filed an IND for NX-2127 in December 2020 and received clearance by the U.S. Food and Drug Administration (FDA) to initiate human clinical trials. We expect to dose the first patient in a Phase 1 clinical trial for NX-2127 in the first quarter of 2021. Our second drug candidate from our protein degradation portfolio, NX-5948, is an orally bioavailable BTK degrader without IMiD activity for the treatment of relapsed or refractory B-cell malignancies and potentially autoimmune diseases. We anticipate commencing a Phase 1 trial for NX-5948 in the second half of 2021. Our lead drug candidate from our E3 ligase inhibitor portfolio, NX-1607, is an orally available CBL-B inhibitor for immuno-oncology indications. We expect to commence a Phase 1 clinical trial for NX-1607 in the second half of 2021. We are also advancing a CBL-B inhibitor NX-0255 for *ex vivo* use to enhance adoptive T-cell therapy. We anticipate commencing a Phase 1 trial for our first cell therapy candidate, DeTIL-0255, in the second half of 2021. Beyond these portfolios, we are advancing additional preclinical programs, either independently or through our established strategic collaborations with Sanofi S.A. (Sanofi) and Gilead Sciences, Inc. (Gilead).

In disease settings where currently available treatments are limited by suboptimal efficacy or safety, or where relevant protein targets are not druggable by conventional means, we believe targeted protein modulation represents a novel treatment paradigm with the potential to improve upon or become the standard of care. Recent advances in the field have highlighted the significant therapeutic potential of E3 ligases in promoting targeted protein degradation. In addition, we believe the largely unexplored area of inhibiting E3 ligases directly to increase protein levels represents an equally promising approach. Using our powerful DELigase platform, we have the ability to discover small molecule drug candidates to decrease or increase protein levels by either harnessing or inhibiting the activity of the appropriate E3 ligase, depending on the desired therapeutic effect. We have carefully selected and are progressing over 30 E3 ligases to expand the universe of E3 ligases that can be modulated beyond cereblon and von Hippel-Lindau (VHL), the two predominantly used in the field today. Our DNA-encoded library (DEL) collection consists of billions of small molecule compounds used to identify potential binders to ligases and protein targets as critical starting points in our drug discovery process. The differentiation of our protein modulation platform is in its breadth and versatility, enabling us to alter protein levels either upward or downward for both clinically validated targets, such as BTK, and for targets previously thought to be "undruggable"; that is, proteins that could not be addressed by conventional pharmacological means such as CBL-B.

Our protein degradation portfolio includes a series of chimeric targeting molecules (CTMs) that catalyze potent and specific degradation of BTK, a well validated target for B-cell malignancies. Our lead BTK degrader drug candidate, NX-2127, is an orally available CTM for the treatment of relapsed or refractory B-cell malignancies including non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL). In preclinical studies, we have demonstrated the ability of certain of our BTK CTMs to degrade BTK in tumor cell lines harboring either wild type BTK and the C481S mutation in BTK that confers resistance to currently marketed BTK inhibitors. In addition to degrading BTK, NX-2127 was also designed to have IMiD activity. Based on our preclinical data, we believe NX-2127 has the potential to demonstrate improved clinical benefit over current standard-of-care in multiple oncology

indications. We filed an IND for NX-2127 in December 2020 and received clearance by the FDA to initiate human clinical trials. We expect to dose the first patient in a Phase 1 clinical trial for NX-2127 in the first quarter of 2021. Our second BTK CTM drug program, NX-5948, is a BTK degrader designed to have limited or no IMiD activity for potential applications in indications where sparing IMiD activity may be beneficial. We expect to commence a Phase 1 clinical trial of NX-5948 in the second half of 2021.

Our E3 ligase inhibitor portfolio is comprised of a series of small molecule inhibitors of CBL-B, which functions as an intracellular checkpoint regulating activation of T cells, B-cells and NK cells. In preclinical studies, primary human T cells exposed to our lead oral CBL-B ligase inhibitor drug candidate NX-1607 demonstrated increased T cell activation in the absence of co-stimulation with CD3 and CD28, a potential advantage in a suppressive tumor microenvironment. In addition, NX-1607 has been shown in preclinical models to increase T-cell proliferation and result in increased secretion of interleukin-2 (IL-2) a key cytokine involved in immune activation. We believe that oral delivery of CBL-B inhibitors has the potential to drive immune cell activation and stimulation of localized IL-2 secretion, leading to enhanced anti-tumor response. As an intracellular immune checkpoint inhibitor, we believe NX-1607 has potential utility across a wide range of oncology indications. We expect to commence a Phase 1 clinical trial in the second half of 2021. We are also planning the development of a second CBL-B ligase inhibitor, NX-0255, for *ex vivo* use. We believe incorporating NX-0255 into adoptive cell therapy (ACT) has the potential to enhance T cell proliferation and phenotype to improve anti-tumor activity. We intend to create new drug-enhanced tumor infiltrating lymphocytes (TIL) therapies through our drug-enhanced tumor infiltrating lymphocyte (DeTIL) program and expect to commence a Phase 1 clinical trial using NX-0255 to produce an autologous cellular therapy we call DeTIL-0255 in the second half of 2021. In addition, we have established DeCART Therapeutics Inc. (DeCART), a wholly owned subsidiary, to advance new drug-enhanced chimeric antigen receptor T cell (CAR-T) therapies.

Beyond our current programs, we are extending our degrader and inhibitor portfolios both on our own and with partners by developing new CTM degraders and ligase inhibitors for a number of targets for which we believe the protein modulation modality can be clinically advantageous over existing therapies. These programs and future programs may have the potential to address diseases with significant unmet need, including autoimmune disease, viral diseases, cancer and neurodegeneration. We have entered into several revenue generating collaborations with large biopharmaceutical companies to leverage our DELigase platform for drug discovery. In December 2019, we entered into a global strategic collaboration with Sanofi, which was subsequently expanded and amended in January 2021, to discover, develop and commercialize a pipeline of innovative targeted protein degradation drugs for patients with challenging diseases in multiple therapeutic areas. In June 2019, we entered into a global strategic collaboration with Gilead to discover, develop and commercialize innovative targeted protein degradation drugs for a wide range of diseases including cancer. Both collaborations allow us to further advance our future pipeline with ten currently identified targets included in these collaborations. In aggregate, we have received $286.0 million in non-dilutive financing from our collaborators to date, and as of November 30, 2020, we are eligible to receive up to $4.8 billion in potential future fees and milestone payments, as well as royalties on future product sales. We retain options for co-development and co-commercialization rights in the United States for up to four drug candidates discovered under these collaborations.

Corporate Strategy

Our strategy is to leverage our DELigase platform to discover breakthrough therapies to improve upon existing drugs and address targets that are thought to be undruggable with current modalities. The key elements of our strategy are to:

- ***Advance our lead programs through clinical development.*** We have four targeted cancer therapy and immune modulating drug candidates that we are advancing into clinical development in 2021. We expect to dose the first patient in a Phase 1 clinical trial for our lead protein degradation drug candidate, NX-2127, in the first quarter of 2021. We expect to commence a Phase 1 clinical trial for our lead CBL-B inhibitor drug candidate, NX-1607, in the second half of 2021. We are also advancing a second BTK CTM program, NX-5948, which may be developed for oncology and graft-versus-host disease (GVHD) with the commencement of a Phase 1 clinical trial planned in the second half of 2021. In addition, we are advancing a second CBL-B inhibitor incorporated into drug-enhanced ACT, DeTIL-0255, and expect to commence a Phase 1 clinical trial in the second half of 2021.

- ***Enhance and expand our DELigase platform.*** Targeted protein modulation is a rapidly emerging therapeutic modality that can provide significant advantages over existing modalities. Our proprietary DELigase platform enables us to advance an industry-leading approach to either selectively decrease or increase protein levels. We intend to continue to invest resources in our research and development activities to expand the breadth of our DELigase platform both in terms of the number of ligases available for drug discovery and the scale of our DEL collection. We plan to leverage our platform capabilities to further enhance our position as a leader in the promising field of protein modulation.
- ***Discover and develop new targeted protein modulation drug candidates.*** We select new targets for which we have evidence that modulation of protein levels may provide a distinct therapeutic advantage over traditional small molecule inhibitors, or which have been considered undruggable by existing modalities. We have multiple additional wholly owned and partnered targets in DEL screening, lead optimization and preclinical research. We plan to use our DELigase platform to continue to explore new targets with potential applications in autoimmune, cancer, neurodegeneration and viral diseases.
- ***Explore additional strategic collaborations to fully exploit our DELigase platform.*** We have received $286.0 million in non-dilutive funding to date from our partnerships to support our research and development activities and to create new targeted protein modulation drugs with our partners. Under our Sanofi and Gilead partnerships as of November 30, 2020, we have the opportunity to receive up to $4.8 billion in potential future fees and milestone payments, as well as royalties on future sales while retaining certain commercialization options. We plan to continue evaluating additional partnership opportunities that can meaningfully enhance our platform capabilities and help expand our development pipeline, in addition to providing non-dilutive funding to support our broad research and development efforts.
- ***Maximize the commercial potential of our drug candidates.*** We currently retain worldwide development and commercialization rights to our BTK and CBL-B portfolios. In addition, we have opt-in rights to jointly commercialize certain drug candidates developed under our Sanofi and Gilead collaborations in the United States. We intend to become a fully integrated biopharmaceutical company and build a targeted sales force in the United States to support the commercialization of our drug candidates, if approved. We intend to selectively evaluate commercialization partnerships for our drug candidates with partners whose capabilities complement our own while retaining meaningful commercial rights in key geographic territories.

Role of proteins in disease and ubiquitin-proteasome system biology

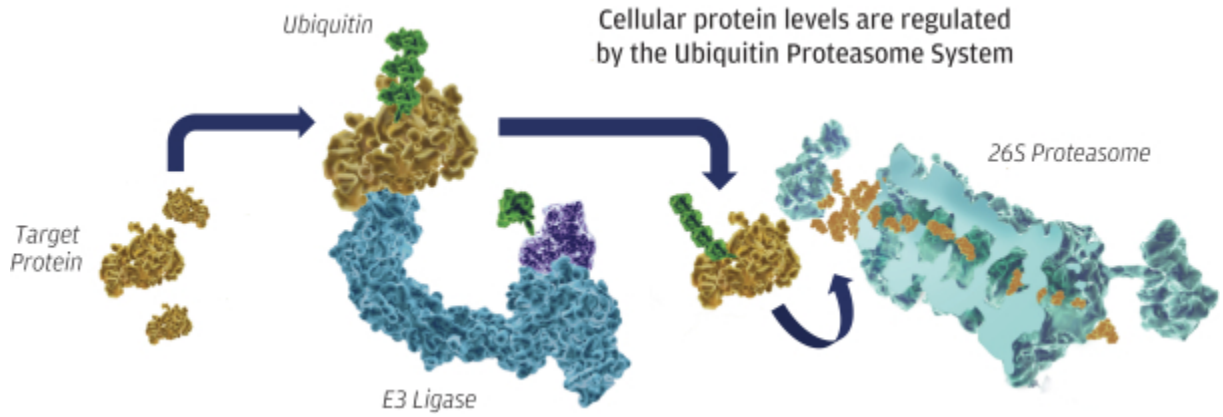
Proteins as targets in treating disease

Each cell type within the body is comprised of proteins that define its biochemistry and biological function. When proteins are expressed and regulated correctly, the health of each individual cell as well as the body as a whole is maintained. However, disease can occur when normal cellular processes are dysregulated as a result of changes in protein structure, function, expression levels, or pathway regulation. Factors such as genetic mutations, infection, exposure to toxins, diet and behavior can lead to dysregulation of cellular processes and, if unchecked, a disease process.

The traditional approach to discovering treatments for disease has involved the development of small molecule drugs that bind to a protein's surface and modulate its activity. These "druggable" proteins contain distinct structural features that mediate protein function called active sites which can be exploited when identifying and optimizing compounds that disrupt protein activity. However, the vast majority of the body's proteins do not have distinct active sites that can be targeted using traditional discovery methods. Because dysregulation and disease are not restricted to these "druggable" proteins, a significant number of therapeutically relevant proteins have not been addressed by traditional small molecule drugs. Other modalities including antibody and protein-based therapies, genetic medicines and cell therapies have emerged to address these issues but are still limited by their modes of delivery, scalability and their therapeutic applications.

Leveraging E3 ligases and the UPS as a new treatment modality

Normal cellular physiology requires highly orchestrated and regulated processes that operate at the level of individual proteins. The ability of proteins to respond to stimuli quickly and in a coordinated fashion requires protein function to be readily controllable. One of the most exquisitely ordered cellular systems governing cellular proteins is the UPS.



As depicted above, the UPS is responsible for regulating and maintaining normal protein levels in the cell. An important class of enzymes called E3 ligases mediate this process with a high degree of specificity by recognizing individual proteins and catalyzing the attachment of ubiquitin protein tags to their surface. Proteins marked with chains of ubiquitin are then shuttled to the proteasome for degradation and removal from the cell. In addition to protein degradation, E3 ligases also mediate other functions such as protein localization, receptor internalization, protein signaling and protein quality control. There are over 600 E3 ligases encoded within the human genome, representing more than 5% of genes. The prevalence of the E3 ligase class of enzymes reflects the diversity of their physiological roles and biological significance and may allow for the creation of a wide spectrum of ligase-targeted therapeutics.

Modulating protein levels through small molecule therapeutics targeting E3 ligases

Advances in our understanding of the UPS suggest broad potential for development of new therapies that modulate E3 ligases in context of diseases such as cancer, neurodegenerative disorders, and autoimmune disorders. An example are the IMiDs, which include the approved cancer drugs Revlimid (lenalidomide) and Pomalyst (pomalidomide). IMiDs exert their therapeutic effects by targeting the E3 ligase cereblon and redirecting its activity toward proteins it would not normally degrade such as Aiolos, a transcription factor regulating immune cell function. Elucidation of this mechanism led to the recognition that pharmacological control of E3 ligase activity could more generally represent a promising new paradigm for small molecule drug action. This idea has since translated into the development of targeted protein degraders, which we believe have significant therapeutic potential. In addition, the largely unexplored area of inhibiting E3 ligases directly to increase cellular protein levels may represent an equally promising approach.

- ***Harnessing E3 ligases.*** Targeted protein degradation harnesses the natural activity of ligases to remove specific proteins from the cell. Targeted protein degradation is accomplished by using bifunctional small molecules, which are composed of an E3 ligase binding element, or harness, linked to a target protein binding element. Unlike traditional small molecule inhibition, targeted protein degradation is catalytic whereby one molecule can induce the degradation of multiple copies of the protein target, enabling the efficient elimination of cellular proteins. In addition, since the effect is mediated through the binding of a small molecule drug rather than through functional inhibition, proteins lacking active sites are potentially targetable, greatly expanding the spectrum of both proteins and diseases amenable to small molecule therapeutic intervention.

- ***Inhibiting E3 ligases.*** By inhibiting the function of E3 ligases, it is possible to rapidly increase specific proteins levels to control biological pathways. Increasing the levels of distinct sets of proteins could be a powerful approach to blocking pathological processes and restoring normal physiology. While there is enthusiasm in the scientific community around the therapeutic potential of E3 ligase inhibition, the discovery of such inhibitors has been impeded by the limited understanding of this biochemically and structurally complex class of enzymes.

We believe that targeting E3 ligases to modulate protein levels represents a new therapeutic frontier that retains the favorable attributes of small molecule treatment modalities while addressing some major limitations. In addition to the points above, we believe other key differentiating attributes of our treatment modality include:

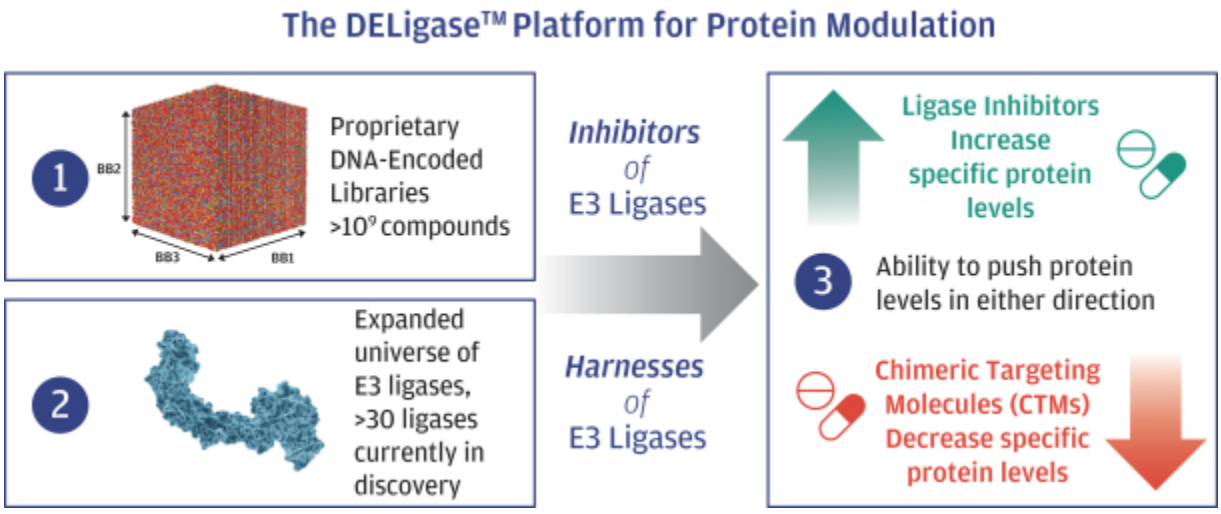
- ***Expansive therapeutic potential.*** The UPS and its associated E3 ligases function across the majority of cell types and organ systems, making it possible to modulate virtually any protein of interest for a wide range of diseases.
- ***Deliverable and Tunable.*** Oral delivery of small molecule compounds lends itself to broad medical applicability in a range of patient populations with delivery that may be readily calibrated through dosing schedule and quantity.
- ***Ease of manufacturing***. Development and manufacturing of small molecules utilizes established, cost-efficient processes that are readily scalable.

Our Approach

Our approach leverages the specificity of E3 ligases and the natural function of the UPS to regulate the cellular proteome for therapeutic effect. Development of therapies that modulate E3 ligases has been historically limited by the inherent difficulties in building biochemical and cellular assays relevant for measuring E3 ligase function, as well as by the relative lack of mechanistic understanding of this critical class of proteins. Through our focused efforts and investment over the past several years, we have developed proprietary tools, in-depth knowledge and expertise relating to E3 ligases as targets for drug discovery. In addition, we have assembled a team that has extensive experience applying DEL discovery technologies to a wide variety of proteins including targets previously considered undruggable. Together, these capabilities and insights have allowed us to develop a powerful platform technology called DELigase to identify and advance novel drug candidates that either selectively increase or decrease protein levels within the cell.

Our DELigase platform combines our proprietary DELs and E3 ligase expertise to empower efficient drug discovery. DEL technology is well suited to finding new binders for targets thought to be undruggable, which include the vast majority of proteins encoded in the human genome including E3 ligases.

Our DELigase platform



DEL technology taps enormous chemical space to overcome "druggability" limits

Our DEL collection comprises several billion compounds whereas typical screening collections contain less than a few million. This increased scale provides the necessary chemical diversity to identify chemical starting points for more challenging protein targets that have been considered undruggable by other approaches. DEL technology evaluates each library compound simultaneously in a single experiment, enabling a more accurate assessment of compound function. In addition, because DEL drug discovery is performed by measuring compound binding rather than biochemical activity it allows inclusion of proteins for which biochemical assays are lacking or not feasible. Further, the relative ease with which binding screens can be performed and interpreted provides sufficient flexibility to allow evaluation of structurally complicated proteins like E3 ligases, which display distinct conformations and activity states and are often part of large multi-protein complexes. Lastly, a chemical linker attaches each DEL compound to a strand of DNA, which functions as a structure barcode allowing screening hits to be easily identified. DEL's built in chemical linker is also an advantage in the context of identifying bifunctional degraders, as it allows the discovery of compounds that can effectively bind proteins when linked to a partner molecule.

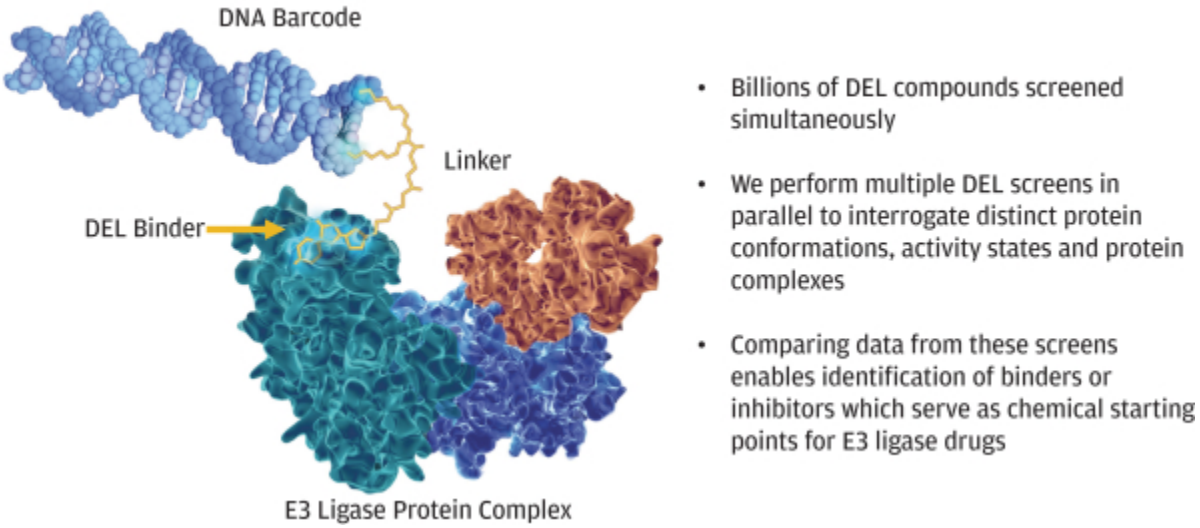
Our DELigase platform was designed for E3 ligase discovery

Our integrated DELigase platform relies on proprietary DELs we have specifically engineered to identify and select binders against a diverse group of target protein classes, including some considered to be undruggable, as well as binders to E3 ligases. Key features of our DELigase platform include:

- ***Custom-synthesized scaffold-based DELs.*** Our custom-synthesized chemical scaffolds impart desirable, drug-like chemical properties, like solubility, into each library compound in a manner that cannot be achieved when building DEL collections solely from commercial inputs. In addition, these scaffolds are ideally suited for binding to the shallow binding pockets on the surfaces of proteins like E3 ligases.
- ***Covalent small molecule discovery using DELs.*** Our expertise in aqueous synthetic chemistry and affinity screening technology has allowed us to integrate covalent drug discovery into our DELigase platform through the introduction of covalent DELs. The formation of a covalent bond enables more efficient identification of binders to transient or cryptic binding pockets on a protein's surface, making covalent DELs an ideal discovery tool for challenging protein targets like E3 ligases. In addition, covalent and reversible covalent compounds have begun to show promise in augmenting performance of targeted protein degraders, suggesting that our covalent DELs may have additional utility.

- ***Proprietary data analysis and hit confirmation technologies.*** We have built a suite of custom analytical tools including machine learning for interpretation and prioritization of our DEL binder outputs, which routinely contain thousands of productive hits. We have also developed high throughput methods for nanoscale hit resynthesis and affinity selection mass spectroscopy that allow a more comprehensive and industrialized process for identifying the best chemical starting points for future pipeline programs.
- ***Many screens, one protein target.*** E3 ligases can exist in multiple potential conformation states. Our approach uses comprehensive parallel screening campaigns to interrogate numerous states and surfaces of the target protein. An illustration of how we probe the surface of an E3 ligase by DEL screening is depicted in the graphic below.

An E3 Ligase protein complex bound to a DEL molecule representing just one of several possible protein conformations



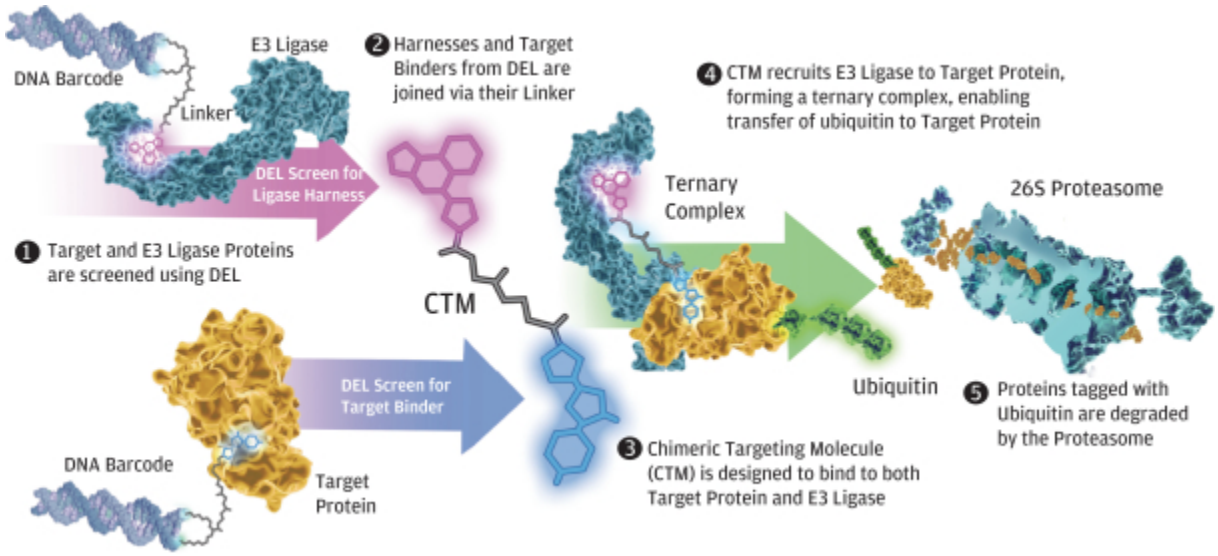
Our DELigase discovery platform enables us to address multiple therapeutic applications

We have expanded the universe of E3 ligases available for therapeutic manipulation from the two predominantly used in the field, cereblon and VHL, by screening over 30 additional E3 ligases to date. We have carefully selected these E3 ligases for use in drug discovery across our four core areas of therapeutic expertise: oncology, immuno-oncology, ACT and immune disorders. We consider the unique biological function of each ligase and the therapeutic requirements of the disease state for inhibitor programs. For ligases that direct targeted protein degradation, we take into account the biochemical specificity of the E3 ligase as well as tissue specificity of action and cellular localization of the target protein. E3 ligases that are required for cancer cell survival are also of high interest for cancer indications to reduce the risk of intrinsic resistance to degrader action. We are growing our set of E3 ligases for use in our DELigase platform tailored to our core therapeutic areas.

DELigase for E3 ligase harnesses

We apply our platform to utilize the ubiquitination function of E3 ligases for targeted protein degradation. Our DELigase platform enables us to identify binders to E3 ligases, which we refer to as harnesses, as well as binders to degradation targets. We use these molecular starting points to design compounds using a modular approach that connects an E3 ligase harness to a target protein binder with a linker. We refer to these bifunctional molecules as CTMs, which function by bringing the E3 ligase into proximity of the target protein to catalyzing its ubiquitination and degradation. The process of designing CTMs and their activity is shown in the graphic below.

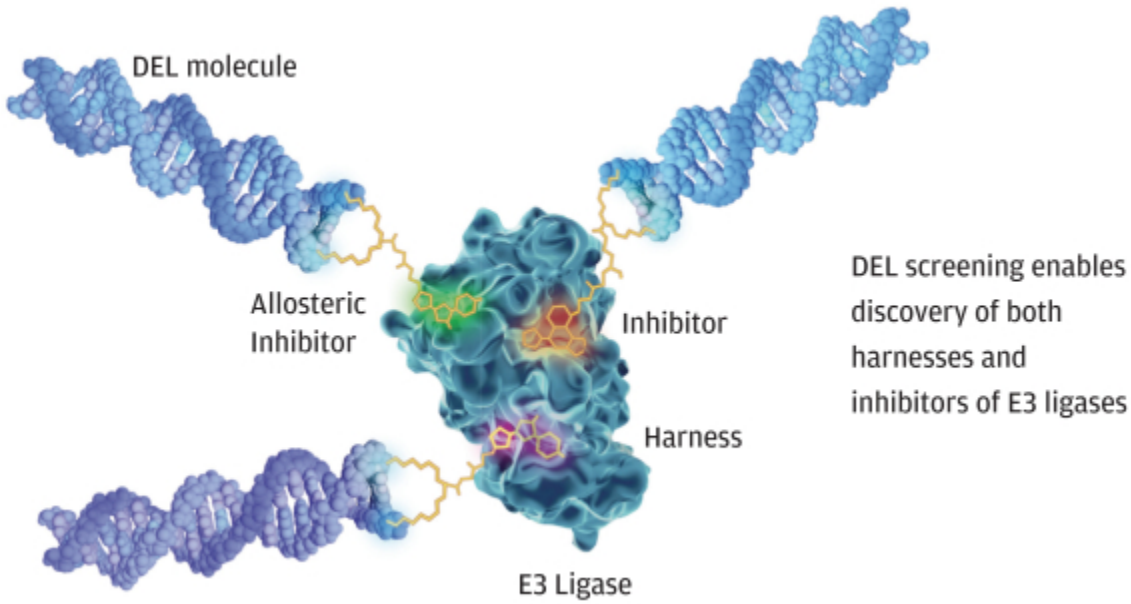
DELigase allows the discovery of small molecule binders in the context of a chemical linker, enabling CTM design



DELigase for E3 ligase inhibitors

By inhibiting the function of E3 ligases, it is possible to rapidly increase specific protein levels to control biological pathways. Increasing the levels of distinct sets of proteins could be a powerful approach to blocking pathological processes and restoring normal physiology. Our DELigase platform enables the identification of inhibitors through parallel screening of distinct E3 ligase activity states using chemical matter tailored specifically for binding to E3 ligases. Our substantial expertise in E3 ligase biochemistry and biology has allowed us to identify and develop potent inhibitors of E3 ligases that play pivotal roles in T cell signaling and immune cell function.

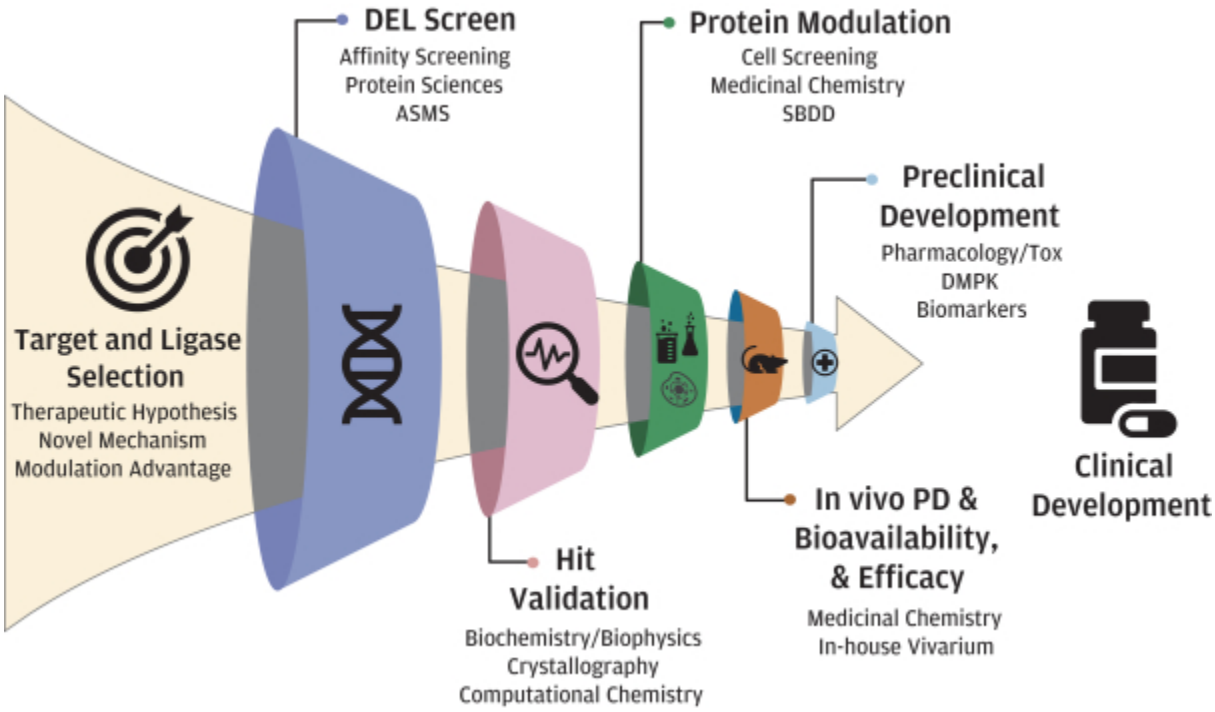
DELs allow access to a spectrum of binders across the protein surface, some of which inhibit protein function.



Drug candidate identification and selection process

We employ a series of processes and studies from target validation to preclinical development for selection of the appropriate candidate for further development. We have invested in an integrated drug development infrastructure that enables us to perform every step of the drug discovery and early preclinical development process within our research facility. Each of our primary areas of core expertise and technology are highlighted in the below illustration.

Our integrated drug discovery and development system and core technical expertise



Our Drug Candidates

Our pipeline consists of a protein degradation portfolio of CTM drug candidates that degrade target proteins and our ligase inhibitor portfolio of drug candidates that raise substrate protein levels. These two portfolios demonstrate our ability to both increase and decrease protein levels in cells through the modulation of E3 ligases.

Drug Candidate	Target / Delivery	Therapeutic Area	Discovery	Lead Optimization	Preclinical	Phase 1	Phase 2	Phase 3
Protein Degradation Chimeric Targeting Molecule (CTM) Portfolio								
NX-2127	BTK + IMiD activity *Oral*	B-cell malignancies						
NX-5948	BTK *Oral*	B-cell malignancies and autoimmune disease				Phase 1 in H2 2021		
KINASE-CTM3	Undisclosed	T-cell malignancies and autoimmune disease						
COVID-CTMs	3 targets	Anti-viral						
Ligase Inhibitor Portfolio								
NX-1607	CBL-B *Oral*	Immuno-oncology				Phase 1 in H2 2021		
DeTIL-0255	CBL-B *ex vivo*	Tumor infiltrating lymphocytes				Phase 1 in H2 2021		
LIGASE-INH2	Undisclosed	Immuno-oncology						
Partners and Subsidiaries								
DeCART	CBL-B and others *ex vivo*	Chimeric antigen receptor T-cells (CAR T)						
Gilead Sciences	5 targets	Undisclosed						
Sanofi	5 targets	Undisclosed						

* Expected commencement of Phase 1 clinical trial timing based on calendar year quarters.

In addition to our CBL-B and BTK portfolios, our wholly owned drug discovery pipeline includes several CTM programs that are at DEL discovery, cell-based screening and lead optimization stages. Our CTM drug discovery programs include KINASE-CTM3, a kinase involved in T cell growth and activation that we are pursuing to treat T cell malignancies and autoimmune disease, and which is in lead optimization. We have also initiated three programs that are at DEL discovery and cell-based screening stages that are designed to apply targeted protein degradation to SARs CoV2 targets. COVID-CTM1, COVID-CTM2 and COVID-CTM3 have been selected based on their multi-functional nature at critical points within the viral life cycle. We believe targeted protein degradation may offer an advantage over existing anti-viral agents, which largely focus on a limited set of viral targets that can be inhibited by small molecules. The fundamentally different pharmaco-kinetic and pharmaco-dynamic action of CTMs, due to the catalytic nature of ligase-mediated degradation, may allow for the rapid removal of viral proteins and successful interruption of the viral life cycle. In addition, we have over 30 ligase programs at various stages of DEL discovery, cell-based screening and lead optimization, including LIGASE-INH2, with potential applications in immuno-oncology, which is in lead optimization. LIGASE-INH2 is differentiated from our CBL-B program in that we believe its primary mode of action is through natural killer cells.

Although we believe our product candidates have the potential to improve upon existing drugs and address targets that are thought to be undruggable with current modalities, we will need to complete additional preclinical studies and clinical trials to determine the safety and efficacy of our product candidates. The results of these future studies and trials may be different than the results of our earlier studies and trials. We have not received regulatory approval for any of our product candidates, and in order to obtain regulatory approval and commercialize our product candidates, the FDA or foreign regulatory agencies will need to determine that our product candidates are safe and effective.

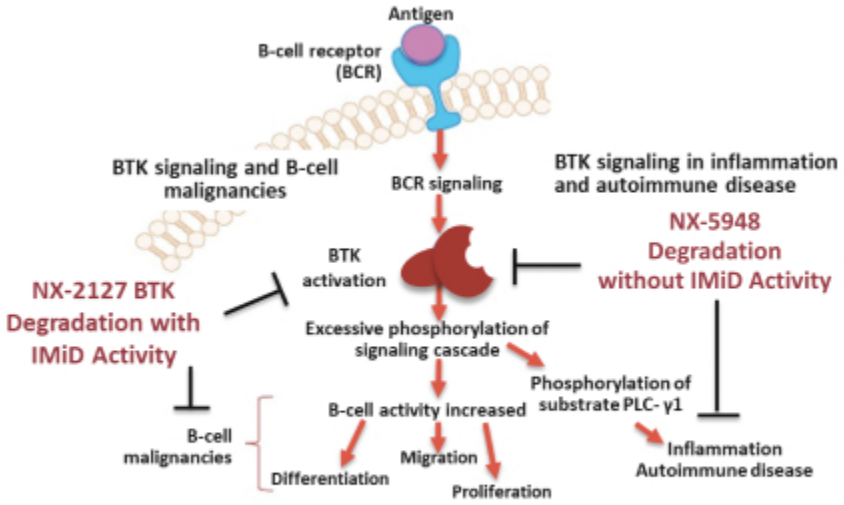
Protein degradation portfolio: Bruton's Tyrosine Kinase degraders

We have developed a series of CTMs that are potent degraders of the BTK protein, a genetically validated signaling factor that drives B-cell activation and proliferation. Our BTK degraders use the E3 ligase cereblon and may be engineered to include IMiD activity, a well validated mechanism to treat hematologic malignancies. Our lead BTK CTM development candidate, NX-2127, is a dual degrader of both BTK and Aiolos, a protein target of IMiD drugs. In certain B-cell malignancy indications, we believe dual activity may provide therapeutic advantages that could result in improved outcomes. We expect to dose the first patient in a Phase 1 clinical trial for NX-2127 in the first quarter of 2021. Our second BTK CTM drug program, NX-5948, is a BTK degrader designed to have limited or no IMiD activity for potential applications in indications where sparing IMiD activity may be beneficial. We expect to commence a Phase 1 clinical trial of NX-5948 in the second half of 2021.

BTK's role in B-cell malignancy

BTK is a key component of the B-cell receptor signaling pathway and has been clinically validated as a target in the treatment of B-cell malignancies. It is estimated that approximately 77,000 people in the United States will be diagnosed with NHLs in 2020. Approximately 85% of NHLs are a result of B-cell malignancies. The natural progression of NHL varies widely and takes multiple forms, ranging from aggressive subtypes such as diffuse large B-cell lymphoma (DLBCL), to more indolent forms such as follicular lymphoma (FL), which account for approximately 30% and 22% of all NHL cases respectively.

- BCR signaling through BTK can be excessive in both B-cell malignancies and autoimmune disease
- Degradation of BTK may be a superior approach to conventional enzyme inhibition
- NX-2127 is a BTK degrader drug candidate with IMiD activity for B-cell malignancies
- NX-5948 has been designed to degrade BTK without IMiD activity for certain B-cell malignancies, autoimmune diseases and related diseases such as GVHD



Background on BTK inhibitors and IMiDs for B-cell malignancies

BTK inhibitor Imbruvica (ibrutinib) is approved for the treatment of CLL and various forms of NHLs, including mantle cell lymphoma (MCL), Waldenstrom's macroglobulinemia (WM), and marginal zone lymphoma (MZL). Calquence, or acalabrutinib, is approved for use in CLL and MCL, and Brukinsa, or zanubrutinib, is approved for use in MCL. In 2020, global sales of BTK inhibitors were approximately $7.1 billion. These BTK inhibitors bind covalently to cysteine C481 of the BTK protein and irreversibly inhibit BTK; however, all have some off-target binding to other kinases, which leads to unwanted side effects. In addition, acquired resistance, most commonly through mutations in C481, may limit long term efficacy of these first generation BTK inhibitors. A number of noncovalent BTK inhibitors are currently being investigated in clinical trials as potential therapies for patients with relapsed and refractory disease. We believe targeted protein degradation of BTK may be a superior approach to existing covalent or noncovalent BTK inhibitors that only inhibit enzyme activity, particularly in the relapsed and refractory setting.

IMiDs are analogs of Thalomid, or thalidomide, including Revlimid, or lenalidomide, and Pomalyst, or pomalidomide, which possess several anti-tumor properties, including anti-angiogenic and anti-proliferative effects. IMiDs also have multiple effects on the immune system, including enhancement of T cell mediated and NK cell mediated immunity. Revlimid, the market leading IMiD by global sales, was first approved in 2006 for the treatment of multiple myeloma. In May of 2019, Revlimid in combination with Rituxan received a supplemental indication approval for previously treated FL, MZL and MCL, and in August of 2020, Revlimid in combination with Monjuvi received a supplemental indication in DLBCL, thus validating the importance of the IMiD activity in these indications. In 2020, global sales of Revlimid were approximately $12 billion. Subsequent to their approval and successful commercialization, studies demonstrated that IMiDs exert their therapeutic effect by triggering the degradation of specific proteins including Aiolos through the E3 ligase activity of cereblon and hence were identified retrospectively as the first approved drugs to target an E3 ligase.

Published studies have recently reported early clinical data showing that combining a BTK inhibitor with an IMiD may have the potential to augment clinical activity of certain standard of care agents in some hematologic malignancies such as DLBCL. Further, scientific publications have previously described synthetic lethality in a DLBCL cell line treated with both ibrutinib and lenalidomide. By targeting both BTK and IMiD pathways simultaneously, it is believed that the redundant survival mechanisms driven by accumulated mutations within certain cancers can be overcome, thereby preventing escape and disease relapse. This may be especially effective if each pathway has not only different functions but also if they share certain critical parts in common. Specifically, the two mechanisms of BTK inhibition and IMiD activity are thought to intersect through the suppression of interferon regulatory factor 4, a member of a family of transcription factors leading to a cell lethal increase in interferon production. The early clinical study cited above was particularly noteworthy since few combinations have previously produced promising results in DLBCL. This may suggest that simultaneous degradation of BTK combined with IMiD activity by a single agent could produce a synergistic or additive effect in certain B-cell malignancies.

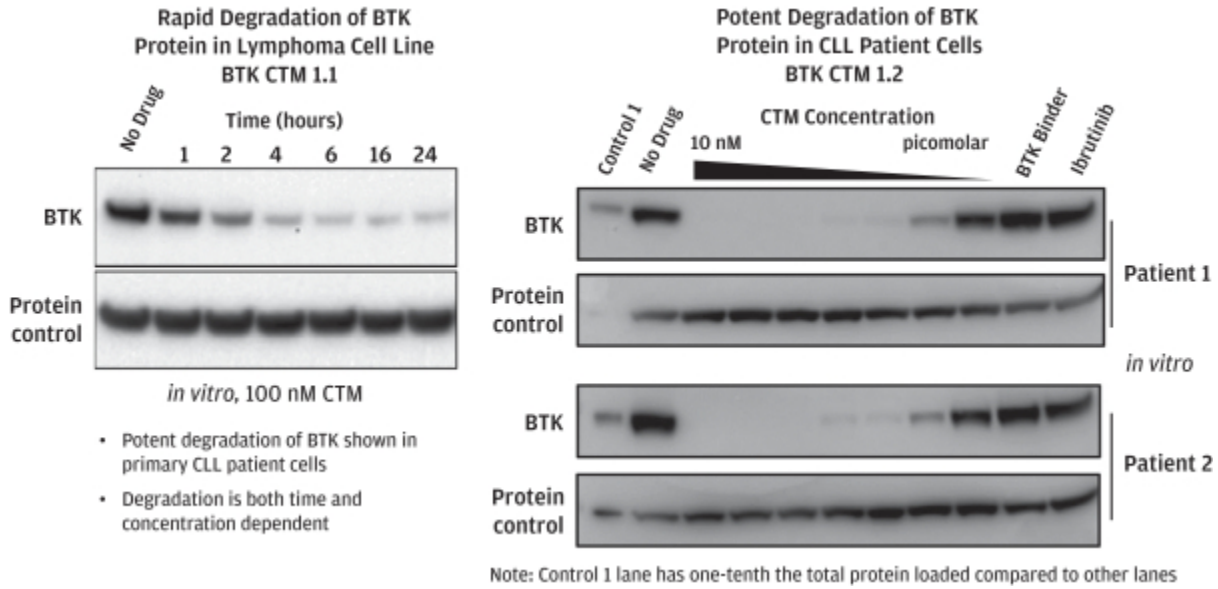
BTK in autoimmune disease and related disorders

B-cell responses to foreign antigens are mediated through BTK interaction with B-cell receptors, initiating a signaling cascade central in the production of antibodies, proinflammatory cytokines and chemokines, as illustrated in the figure above on the right side. BTK is also expressed at high levels in certain myeloid cells, such as macrophages and granulocytes, in which receptor activation by immune complexes promotes BTK mediated expression of proinflammatory cytokines and cell adhesion molecules. Collectively, these actions contribute to the selective elimination of foreign antigens by the immune system. However, the immune system can mistakenly identify self-proteins as foreign antigens leading to autoimmunity, and the role of BTK in promoting the inflammatory process has been implicated in a number of autoimmune disorders. GVHD is one such autoimmune-like disorder that can occur as a result of an allogeneic bone marrow or hematopoietic stem cell transplant (HSCT). In GVHD, the donated bone marrow or peripheral blood stem cells view the recipient's host cells as foreign, and the donated cells attack the host's normal healthy cells. There are two forms of GVHD—an acute form mediated primarily by T cells, and a chronic form which involves T cells, B-cells, dendritic cells, monocytes and macrophages. Transplant recipients may experience either or both forms. The condition is estimated to occur in 30% to 70% percent of all patients who receive an HSCT. The BTK inhibitor ibrutinib is approved for chronic GVHD in patients that do not have an adequate response to steroids. There are a number of other BTK inhibitors which are currently being investigated in clinical trials as potential therapies for autoimmune disorders.

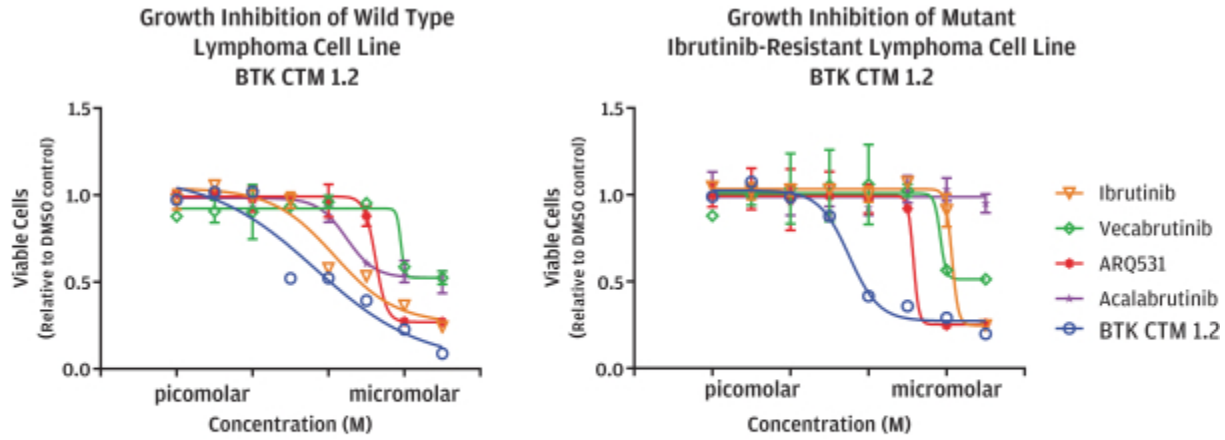
Preclinical development of BTK degraders

We have conducted preclinical studies to select BTK CTMs for clinical development. We have demonstrated that certain of our BTK CTMs can induce BTK degradation and inhibit tumor growth with oral administration in xenograft mouse models implanted with both wild type and ibrutinib-resistant lymphoma cell lines. As our BTK CTM portfolio advanced, we also explored the potential clinical utility of dual degraders of BTK and Aiolos, a target protein of IMiDs. Our preclinical research has suggested the feasibility of developing an oral, small molecule drug candidate such as NX-2127 with favorable properties and the ability to potently and selectively degrade these target proteins.

We have demonstrated that certain of our BTK CTMs induce rapid BTK degradation over time in a lymphoma cell line as compared to a control protein, with nearly complete loss of BTK within four hours of administration as shown in the figure below on the left. In addition, we have demonstrated that certain of our BTK CTMs can potently induce BTK degradation in cells from CLL patients in a concentration dependent manner *ex vivo*, as shown in the figure below on the right. The precursor compound BTK CTM 1.2 shown in the figure and graph below led to the optimization and selection of NX-2127 as a development candidate.

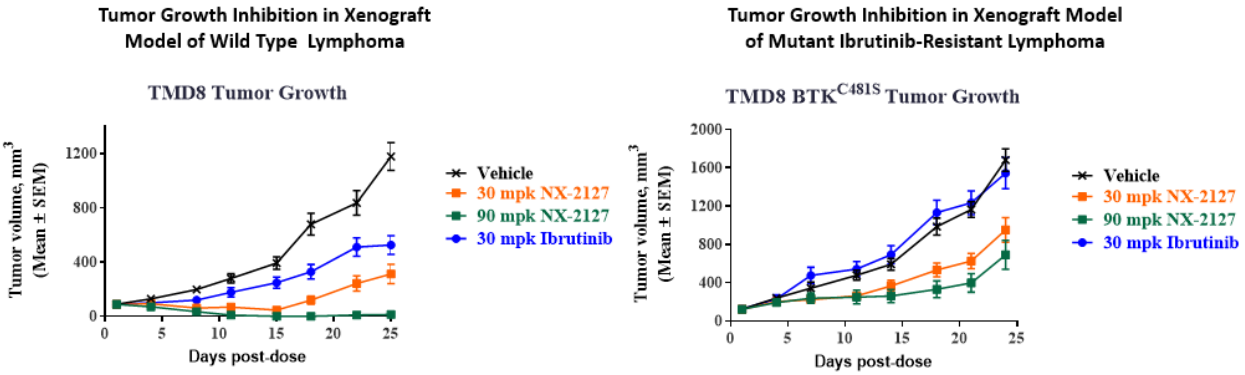


We have optimized our CTMs to be able to degrade both wild type BTK and the C481S variant of BTK that has been identified as the most common mutation in patients who have become resistant to ibrutinib therapy over time. Using a human lymphoma cell line, we have demonstrated that certain of our BTK CTMs have an ability to degrade BTK and inhibit growth of tumor cell lines that are resistant to ibrutinib. As shown in the charts below, our BTK CTM can inhibit both wild type and ibrutinib-resistant tumor cell line growth at lower concentrations compared to ibrutinib and other non-covalent inhibitors of BTK such as vecabrutinib and acalabrutinib, and we believe it could prove superior to other BTK inhibitors in treating resistance mutations. The precursor compound BTK CTM 1.2 shown in the graphs below led to the optimization and selection of NX-2127 as a development candidate.



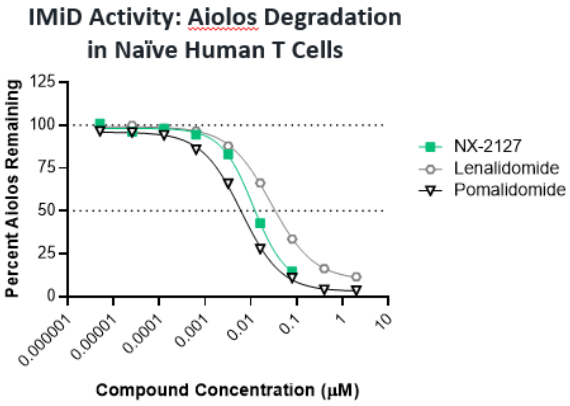
- BTK CTM 1.2 demonstrates comparable growth inhibition as ibrutinib of a tumor cell line with a wild type (normal) BTK target protein and more potent effects compared to other BTK inhibitors
- BTK CTM 1.2 retains potent growth inhibition activity relative to BTK inhibitors in a tumor cell line carrying the C481S mutation, one of the most common known human resistance mutations in the BTK target protein

Potent tumor growth inhibition was achieved at varying doses of orally administered NX-2127 in mouse xenograft tumor models with a wild type BTK protein, as shown in the figure below on the left, as well in a tumor containing the C481S ibrutinib-resistance mutations, as shown in the figure below on the right. The activity of NX-2127 in the figure below is compared to a similar dose of the approved BTK inhibitor ibrutinib.

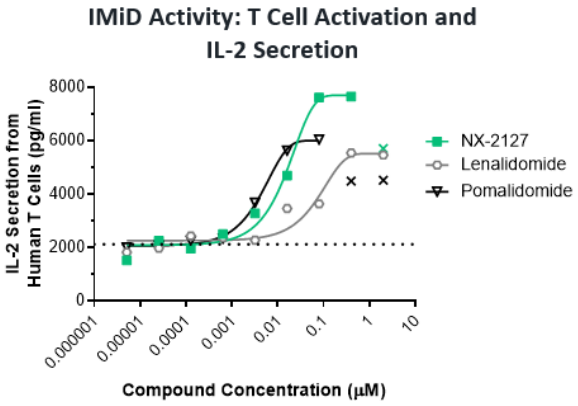


- NX-2127 demonstrates comparable tumor growth inhibition to ibrutinib in a xenograft mouse model containing tumors with a wild type BTK
- NX-2127 shows more potent tumor growth inhibition compared to ibrutinib in a xenograft mouse model containing tumors with the most common human resistance mutation (C481S) in BTK target protein

In addition to BTK degradation, we have also demonstrated the ability of certain of our BTK CTMs to degrade Aiolos, a protein target of IMiD drugs in preclinical studies, as shown in the figure below on the left. Studies in human T cells comparing NX-2127 to the IMiD drugs lenalidomide and pomalidomide have shown comparable Aiolos degradation and resultant T cell activation, as shown in the figure below on the right. Based on the clinical data of both ibrutinib and the IMiDs in B-cell malignancies, we believe that this strategy of targeting both BTK and Aiolos in a single oral treatment may improve anti-tumor activity. We have also designed a second clinical candidate, NX-5948, to degrade BTK with limited or no IMiD activity for potential applications in indications where sparing IMiD activity may be beneficial.



- NX-2127 degrades Aiolos with similar potency to that of pomalidomide and lenalidomide

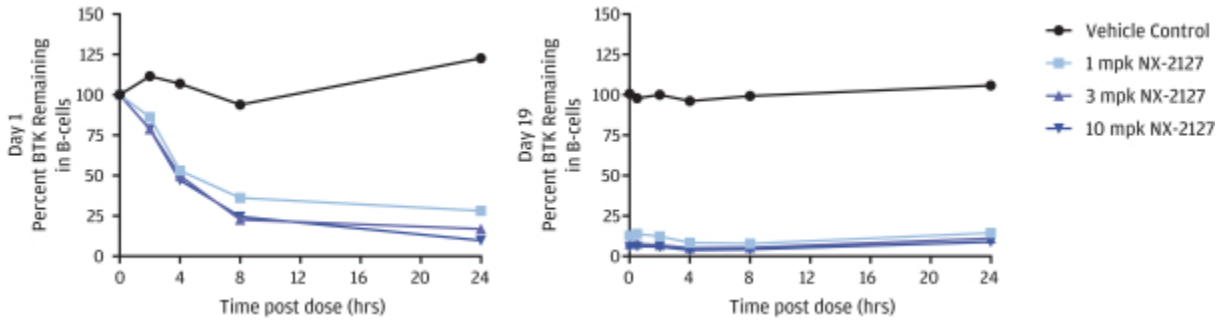


- NX-2127 exhibits IMiD-like activity by activation and IL-2 production following CD3/CD28 stimulation

NX-2127, a development candidate for the treatment of B-cell malignancies

Despite the increasing number of approved treatments for B-cell malignancies, significant unmet need remains for patients with relapsed, refractory disease. We believe that NX-2127, a novel agent with a dual BTK and Aiolos degradation mechanism of action, could address such patient populations. We have conducted a preclinical program to characterize NX-2127 as our lead development candidate. NX-2127 has demonstrated promising activity in multiple *in vitro* and *in vivo* models using human cancer cell lines. Oral administration of NX-2127 demonstrated dose proportional degradation of BTK proteins in mouse models and showed potent anti-tumor activity against C481S ibrutinib-resistant lymphoma in a xenograft mouse tumor model. NX-2127 demonstrated favorable drug-like characteristics in our *in vitro* and *in vivo* studies performed through our preclinical development candidate selection process. Taken together, these data suggest that NX-2127 could have a favorable efficacy profile against both wild type and ibrutinib-resistant BTK alleles in CLL as well as in other indications including DLBCL and FL where ibrutinib or IMiDs alone do not provide sufficient clinical benefit. However, the FDA has not yet approved NX-2127 and we will need to complete clinical trials to determine whether it is safe and effective. We expect to dose the first patient in a Phase 1 clinical trial in the first quarter of 2021.

We have conducted exploratory oral dose range-finding (DRF) studies with NX-2127 in mice and non-human primates (NHPs) to identify appropriate dose levels for evaluation in good laboratory practice (GLP) compliant 28-day IND-enabling toxicology studies. In addition to standard safety and toxicology assessments, in NHP studies, we included clinically relevant pharmacodynamic measures of BTK protein levels in the blood as measured by flow cytometry. BTK levels were measured at various time points after dose administration on the first (Day 1) and last (Day 19) day of once daily dosing; the results are shown in the graphs below. As illustrated in the figures below, a single oral dose as low as 1 mg per kg (mpk) of NX-2127 degraded BTK as early as 4 hours post administration, to more than 90% degradation through 24 hours post administration on Day 1. BTK protein levels remained suppressed throughout the 19-day duration of the study.

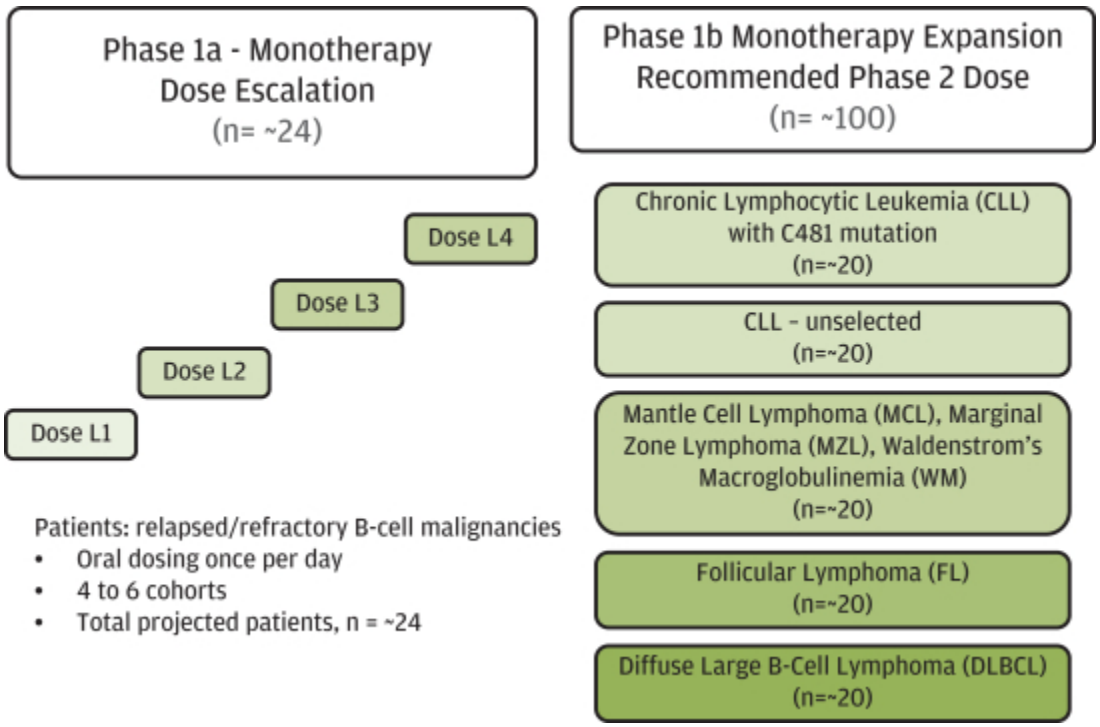


Safety observations in the 14-day non-GLP exploratory oral DRF toxicity study in NHPs noted slight to severe bruising of the skin on various parts of the body, mild degeneration of muscle, localized swelling of the face and mild hemorrhage in certain internal organs at the two highest dose levels evaluated (30 and 100 mpk), but were absent or mild in animals in the two lower, clinically relevant, doses (1 and 10 mpk) and vehicle-treated control groups. In the 19-day non-GLP exploratory oral DRF toxicity study in NHPs, these safety observations were absent in animals in the three lower clinically relevant dose groups (1, 3 and 10 mpk) and vehicle-treated control groups. All animals survived through the studies with no effects on body weight or food consumption. Such findings may be associated with BTK or related targets, and increased bleeding risk has been a reported side effect of approved BTK inhibitors. We have completed the in-life phases of GLP-compliant 28-day oral toxicity studies with NX-2127 in mice and NHPs.

Clinical development plans for NX-2127

We plan to study the pharmacology of NX-2127 in multiple subtypes of relapsed and refractory B-cell malignancies, including those in which ibrutinib has shown only modest effects or is ineffective, as in the case of CLL patients with the C481 mutation. Furthermore, indications in which IMiD activity could augment responses are of high interest. These indications include DLBCL, MZL and FL. We anticipate testing NX-2127 in additional B-cell malignancies, such as CLL, WM and MCL, where IMiDs are not approved but may have shown modest responses, including in patients who have acquired ibrutinib-resistance or are ibrutinib intolerant. We plan to expedite development in indications where NX-2127 shows evidence of compelling clinical activity and where there is high unmet need.

As illustrated in the diagram below, we have designed a two-part Phase 1 clinical trial of NX-2127 in patients with relapsed or refractory NHL and CLL. The Phase 1a portion will be designed as a monotherapy dose escalation trial to investigate the safety and tolerability of NX-2127 and to identify a maximum tolerated dose for further evaluation. The Phase 1b portion of the trial will be designed as a monotherapy expansion trial in five cohorts of up to 20 patients each. The five cohorts include CLL patients, CLL patients with the C481 mutation, patients with MCL, MZL or WM, patients with FL and patients with DLBCL



Clinical development plans for NX-5948

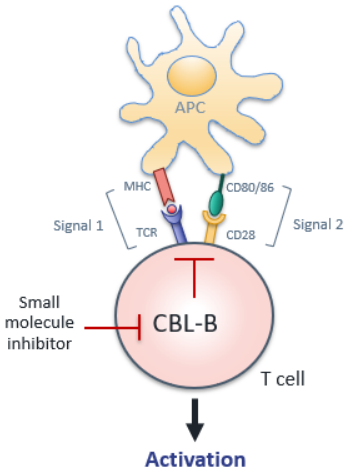
NX-5948 is an orally bioavailable, potent degrader of BTK that is differentiated from NX-2127 in possessing limited or no IMiD activity. NX-5948 has demonstrated potent anti-tumor activity in mouse xenograft models of B-cell malignancies as well as degradation of BTK after oral dosing of NHPs as determined by flow cytometry measuring BTK protein levels in the blood. NX-5948 has potential utility for certain B-cell malignancies where IMiD activity may be less important in achieving a therapeutic benefit and also in autoimmune disease such as GVHD. We expect to commence a Phase 1 clinical trial in the second half of 2021 in patients with relapsed or refractory NHL and CLL.

Ligase inhibitor portfolio: CBL-B ligase inhibitors

Background on CBL-B

T cells play a key role in cell-mediated adaptive immune response. Activation, expansion and function of antigen-specific T cells is a multistep process and its outcome depends on the balance of positive and negative feedback mechanisms controlling each step. Many factors can hamper the development of an efficient anti-tumor immune response, such as insufficient expression of tumor antigens, defective antigen presentation, inhibitory molecular interactions including those effected by immune checkpoints, immune suppressive factors or suppressor cells and T cell exhaustion.

- CBL-B is an E3 ligase that regulates the immune system by specifically degrading proteins involved in shutting off T-cell signaling
- Blocking CBL-B removes a brake on the immune system
- CBL-B function is supported by mouse and human genetics
- CBL-B inhibitors have remarkable effects on T cells
  - CBL-B inhibitors induce immune cells to secrete IL-2
  - Skewing T cells to a central memory phenotype
  - *Ex vivo* and *in vivo* administration of CBL-B inhibitors demonstrate anti-tumor effects in animal models of cancer



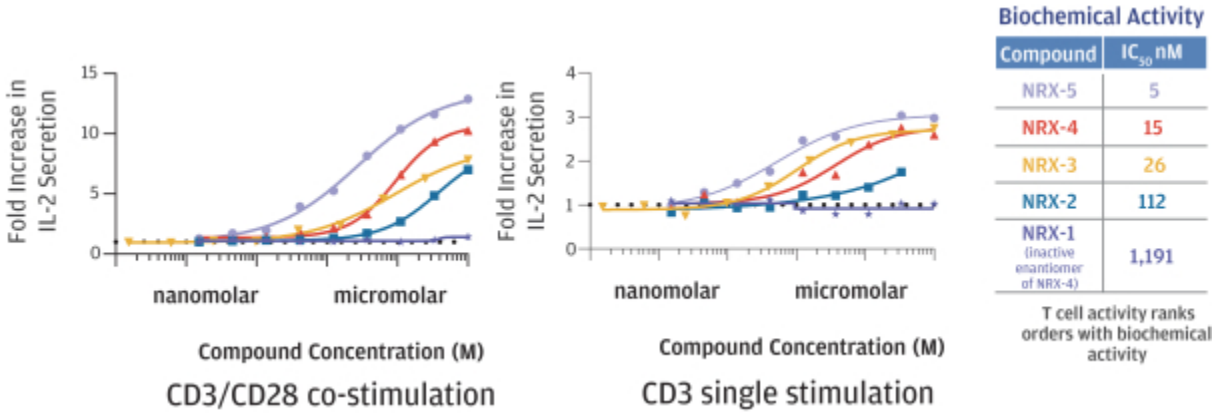
CBL-B, an E3 ligase expressed in immune cell lineages, functions as an intracellular immune checkpoint that negatively regulates T cell activation and immune response, as illustrated above. CBL-B deficient animal models demonstrate enhanced signal dependent T cell activation and robust T cell dependent anti-tumor immunity. We believe that our oral, small molecule CBL-B inhibitors have several potential immunotherapy applications through enhancing T cell mediated anti-tumor activity by lowering the activation threshold of T cells in a suppressive tumor microenvironment where CBL-B plays a key role in the downregulation of T cells. We are planning to develop our lead oral CBL-B inhibitor, NX-1607, in multiple solid tumors as monotherapy or in combination with other mechanistically complementary therapies. Solid tumors represent approximately 90% of adult human cancers, with estimated new cases in 2020 ranging from approximately 14,000 for cervix uteri cancer to 275,000 for breast cancer. Various immunotherapy strategies have been developed in order to increase the efficiency of anti-tumor immune response, including the use of antibody checkpoint inhibitors such as anti-PD-1, anti-PD-L1, and anti-CTLA-4, which block the “brakes” of immune response. These immune-stimulating antibodies have a more favorable clinical outcome than traditional treatment modalities on a growing list of tumor types. However, most patients fail to respond or experience only transient responses.

CBL-B is highly expressed in human CD4+ and CD8+ T cells, with expression tightly regulated by CD28 and CTLA-4 and other co-stimulatory and inhibitory signals. T cells typically require two signals for activation, the first provided by interaction of the T cell receptor (TCR), with a peptide presented by an MHC molecule, and the second through co-stimulatory molecules on antigen-presenting cells. CBL-B plays an essential role in the negative

regulation of T cell activation by regulating the activity of the TCR through substrate proteins that require a costimulatory signal to mount a productive immune response upon TCR engagement. Studies have found that CBL-B deficient T cells display lower thresholds for activation by antigen recognition receptors and co-stimulatory molecules such as CD28. For example, loss of CBL-B in T cells results in T cells that can be activated upon TCR engagement without co-stimulation by CD28, although to a lesser extent than with co-stimulation. Importantly, our CBL-B inhibitors do not appear to activate T cells in the absence of TCR engagement. Such CBL-B deficient T cells are resistant to T cell anergy, a tolerance mechanism in which T cells are functionally inactivated and T cell proliferation is greatly impaired. Notably, CBL-B deficient T cells show increased rates of proliferation as well as elevated cytokine secretion including IL-2. The increased secretion of IL-2 is of particular importance in the optimization and development of our CBL-B inhibitors, serves as a key cellular biomarker for measuring successful T cell activation and is a known therapeutic cytokine in oncology.

Pre-clinical development of CBL-B inhibitors

We have developed a series of potent small molecule inhibitors of CBL-B activity that have demonstrated biochemical activity and effects *in vitro* on human immune cells as well as in mouse tumor models. Consistent with studies cited above, CBL-B inhibitors enhanced *ex vivo* T cell activation as measured by induction of IL-2, a key cytokine required for immune cell activation and proliferation. Induction of IL-2 secretion occurs at low nanomolar concentrations in primary human and mouse T cells stimulated with anti-CD3/anti-CD28 antibodies or anti-CD3 antibodies alone. As illustrated below, we demonstrated several fold increases in IL-2 production in tandem with increasing biochemical activity of our CBL-B inhibitors. In addition, certain of our CBL-B inhibitors reduced anergy and exhaustion in an *ex vivo* model of T cell exhaustion using human donor T cells and further, this effect was additive to that achieved with an anti-PD-1 antibody. Based on our findings to date, we believe that CBL-B inhibitors may induce an immune cell localized IL-2 secretion that in combination with other immune activation effects will enhance anti-tumor responses. The precursor compounds shown in the graphs below led to the optimization and selection of NX-1607 and NX-0255 as development candidates in our CBL-B portfolio.

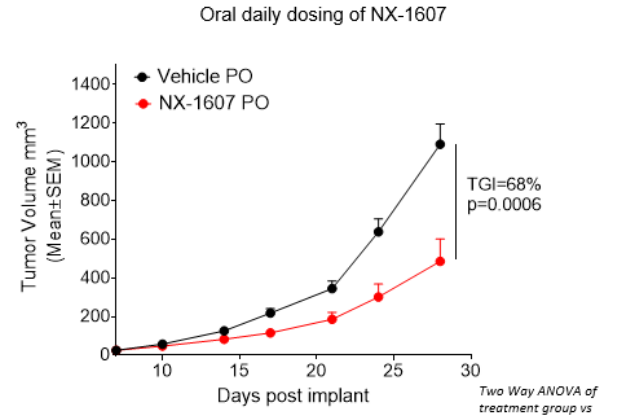


Development strategy of CBL-B inhibitors

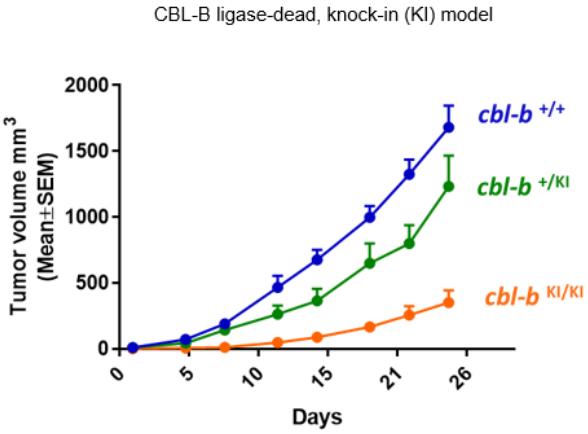
We are focused on three major immunotherapy applications for our CBL-B inhibitors in oncology. In these applications, our overall strategy is to maximize an anti-tumor effect and clinical benefit of our CBL-B inhibitors by enhancing T cells *in vivo* or *ex vivo*. In the first application, NX-1607, an oral small molecule immunotherapy drug candidate, is intended to be used as a single agent or in combination with other mechanistically complementary oncology therapies. The second application is the *ex vivo* use of NX-0255 to create drug-enhanced ACT products, initiatives we refer to as DeTIL and DeCART. DeTIL-0255, is a drug-enhanced investigational ACT product that uses NX-0255 *ex vivo* to enhance TIL propagation and phenotypic characteristics. We have entered into agreements with contract manufacturing organizations (CMOs) for the development of DeTIL-0255. We have established DeCART, a wholly owned subsidiary, to advance new drug enhanced CAR-T therapies. The third application is the use of orally dosed NX-1607 in combination with potentially any ACT, such as DeTIL-0255, to promote engraftment and anti-tumor activity of the transplanted cells.

NX-1607, an oral CBL-B inhibitor for immuno-oncology

NX-1607 is an investigational, orally bioavailable, potent inhibitor of CBL-B. *In vitro*, NX-1607 has been demonstrated to increase T cell activation in primary human T cells in the absence of co-stimulation with CD3 and CD28, a potential advantage in a suppressive tumor microenvironment. *In vivo*, oral administration of NX-1607 in mice has demonstrated notable tumor growth inhibition in a tumor model as illustrated in the figure below on the left. The tumor growth inhibition with oral administration of NX-1607 recapitulates the genetic experiment in mice with a ligase-inactive version of CBL-B which also shows tumor growth inhibition as illustrated in the figure below on the right.



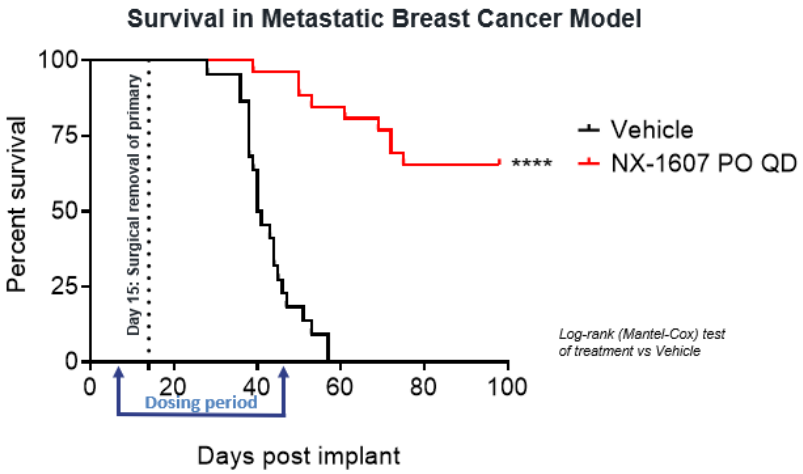
Tumor growth inhibition (TGI) with NX-1607 treatment; tumors implanted at Day 0; once daily oral dosing of NX-1607 was given from Day 9 to Day 28



Anti-tumor effects in ligase-inactive, knock-in (KI) mutation model

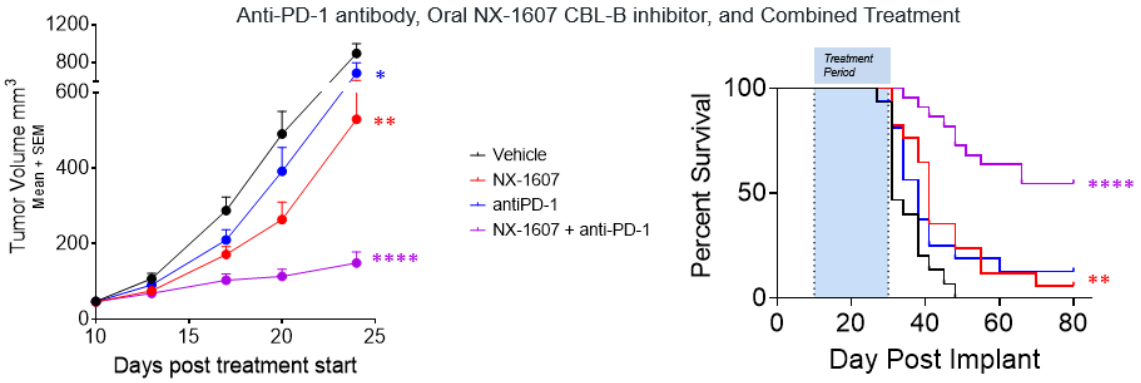
The *in vivo* effects of orally administered NX-1607 were further evaluated as a single agent in an animal mouse model of triple-negative breast cancer. In this experiment shown in the figure below, tumors were implanted in a mouse and removed 15 days later. Without further treatment, all mice in the vehicle group (black line) died by day 60 as a result of tumor metastases in the lung, liver, and brain. By contrast, animals treated with NX-1607 (red line) administered as a daily oral dose starting at day 7 and continuing through day 46 demonstrated a highly significant prolongation of survival.

- Once daily oral dosing of NX-1607
- Tumors implanted at Day 0
- Surgical removal of primary tumor at Day 15
- NX-1607 was given before the surgery from day 7 to day 15 (neo-adjuvant phase) and continued after surgery until day 46



Triple negative breast carcinoma cells metastasize from subcutaneous space to distant sites

The *in vivo* effects of orally administered NX-1607 were evaluated in combination with an antibody to PD-1 as shown in the figure below. In this model, tumor-bearing mice were treated with NX-1607 (red line), anti-PD-1 (blue line), or the combination (purple line) and compared to animals who received no treatment. Either single agent alone showed only modest inhibition of tumor growth (figure below on the left) and prolongation of survival (figure below on the right). However, the combination of NX-1607 with the anti-PD-1 antibody demonstrated enhanced activity for both tumor growth inhibition and overall survival.



Combination of NX-1607 and anti-PD-1 treatment significantly improves anti-tumor response and survival in mice bearing two tumors relative to vehicle or anti-PD-1 alone

Tumors from both flanks plotted
Two-way ANOVA of treatment group vs vehicle control

Log-rank (Mantel-Cox) test of vehicle vs treatment

Clinical development of NX-1607

We are conducting a preclinical program to characterize NX-1607 as our lead oral CBL-B inhibitor development candidate and expect to commence a Phase 1 clinical trial in the second half of 2021. Our Phase 1 clinical trial is planned as a single agent, dose-escalation study of NX-1607 in patients with solid tumors who are resistant to standard of care, which may include checkpoint inhibitors. The Phase 1 clinical trial will investigate the safety and tolerability of NX-1607 and identify a maximum tolerated dose for further evaluation. Secondary objectives of the study may include preliminary assessment of the pharmacokinetic and pharmacodynamic profile of NX-1607, as well as preliminary assessment of anti-tumor activity of NX-1607. We are planning to complete the preclinical characterization, DRF studies and IND-enabling activities for NX-1607 in the first half of 2021.

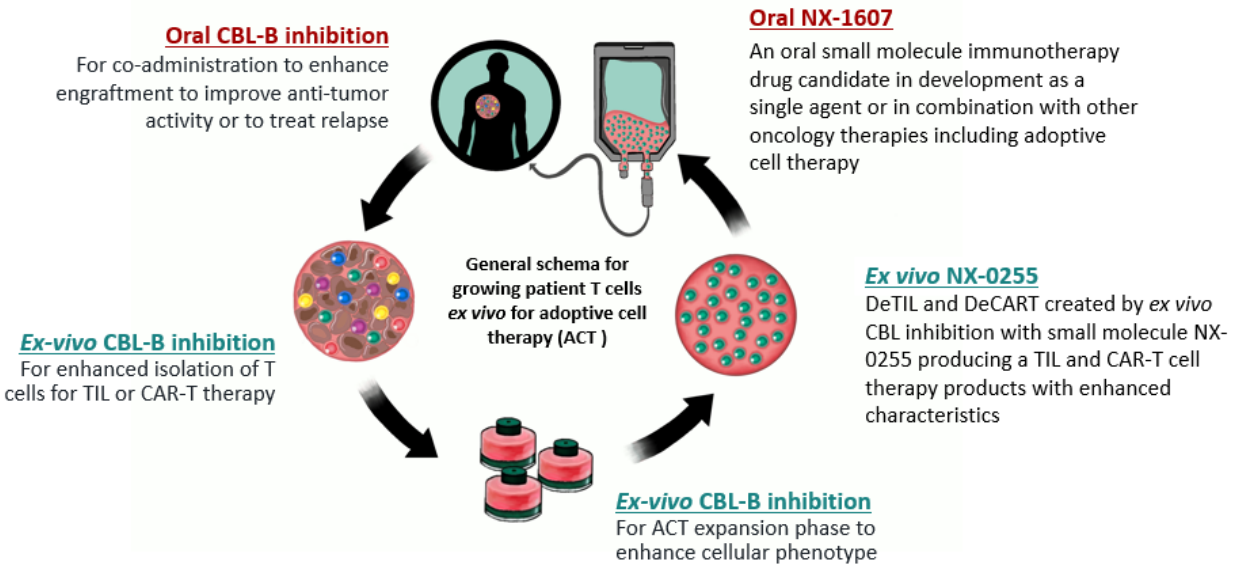
CBL-B inhibitors for Adoptive Cell Therapies

Background on Adoptive Cell Therapies

ACTs represent another class of immunotherapy in which T cells are isolated directly from patient tumors, as with TIL, or from patient blood with subsequent genetic modification to recognize specific antigens present on cancer cells, as with CAR-T therapies. Tumor-reactive T cells are then expanded and infused back into the patient. Currently, the only FDA-approved ACTs are anti-CD19 CAR-T therapies that are approved for treatment of acute B-cell leukemia and acute B-cell lymphoma. CAR-T therapies have not yet proven to be effective in solid tumors. This is due to a number of factors within the tumor microenvironment unique to solid tumors such as the presence of immune checkpoint molecules and suppressive cytokines, and the heterogeneous nature of tumor cells themselves, preventing the identification of uniformly expressed targets for CAR design. Another ACT is TIL therapy. TIL are an expanded collection of lymphocytes that have penetrated the stroma of a tumor and contain host T cells that have recognized a variety of tumor antigens. *Ex vivo* expanded TIL can be infused into the patient as a therapeutic to amplify the patient's own immune response to the tumor. Although existing ACT have delivered encouraging results in certain hematologic malignancies and some solid tumors, most patients fail to respond due to three main issues: (i) failure to obtain sufficient quantity and/or quality of T cells from the tumor samples or from the blood for a successful production process, (ii) poor engraftment of T cells upon reinfusion to the patient and (iii) lack of a persistent anti-tumor response or relapse.

CBL-B Inhibitors for Adoptive Cell Therapies

The opportunities to address the above limitations are substantial and our results to date support the concept that CBL-B inhibitors may address some or all of the current limitations of ACT. We are advancing several lines of experimentation to refine our understanding of the clinical and commercial opportunities in this area. We have consolidated these efforts under an initiative we call the Nurix Adoptive Cell Therapy program (NxACT) as illustrated in the figure below. Our NxACT initiative includes a drug-enhanced TIL program known as DeTIL, and a drug-enhanced CAR-T therapy known as DeCART, which is being advanced by our wholly owned subsidiary, DeCART Therapeutics Inc. The broader conceptual framework for NxACT is convergence of targeted protein modulation with ACT. In addition to CBL-B, we expect to explore additional targets for protein modulation that may be useful in the NxACT program. We expect to develop NxACT product opportunities through CMOs.



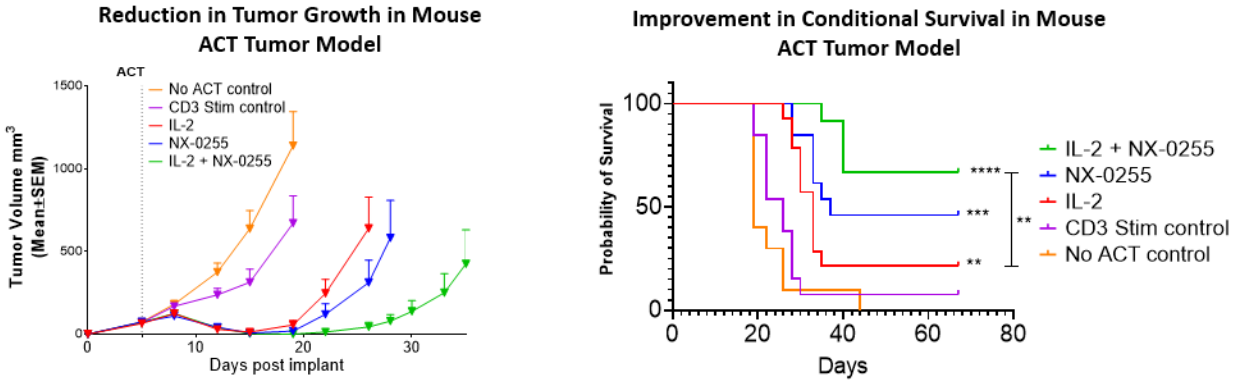
Based on our preclinical findings to date, we believe CBL-B inhibition using NX-0255 *ex vivo* during the isolation and expansion of TIL can address some of the issues that have limited the success of existing ACT. We believe the use of NX-0255 *ex vivo* can address these limitations by producing not only more T cells, but also T cells with favorable characteristics including greater numbers of CD8+ T cells with an enhanced central memory phenotype, a profile that has been associated with better clinical outcomes. In our preclinical ACT research program, we expanded TIL from human tumor samples *ex vivo* and measured the effects of drug enhancement by NX-0255 on TIL production. The central memory T cell population was increased in human TIL expanded *ex vivo* in the presence of NX-0255, as compared to the effector memory T cell population in TIL that had been isolated and propagated from tumor fragments in the presence of recombinant IL-2.

The DeTIL-0255 investigational product under development is an autologous cell therapy consisting of T cells derived from a patient's tumor expanded in culture with NX-0255. Although NX-0255 has limited oral bioavailability, we have demonstrated inhibition of CBL-B both biochemically and in *ex vivo* T cell culture, making it well suited for the *ex vivo* creation of new ACT products. DeTIL-0255 is designed to be a single administration autologous TIL therapy infused following non-myeloablative chemotherapy. We believe DeTIL-0255 could allow a broader application of TIL therapy, potentially providing long term benefit to patients with multiple types of cancer.

Preclinical development of DeTIL-0255

We have tested NX-0255 in a mouse model of ACT shown below to determine if culture of tumor specific T cells *ex vivo* in the presence of a potent CBL-B inhibitor can confer a superior anti-tumor effect as compared to standard culture conditions using IL-2 alone. We have demonstrated that even a short, 3-day *ex vivo* exposure of T cells to NX-0255, either alone or in combination with IL-2, conferred a lasting anti-tumor phenotype upon transfer of the cells into a tumor-bearing animal as compared to controls. We have also demonstrated that those cells

cultured under standard conditions with IL-2 alone resulted in superior conditional survival of the mice relative to controls, but not as good as either group treated with NX-0255 as shown in the figure below.



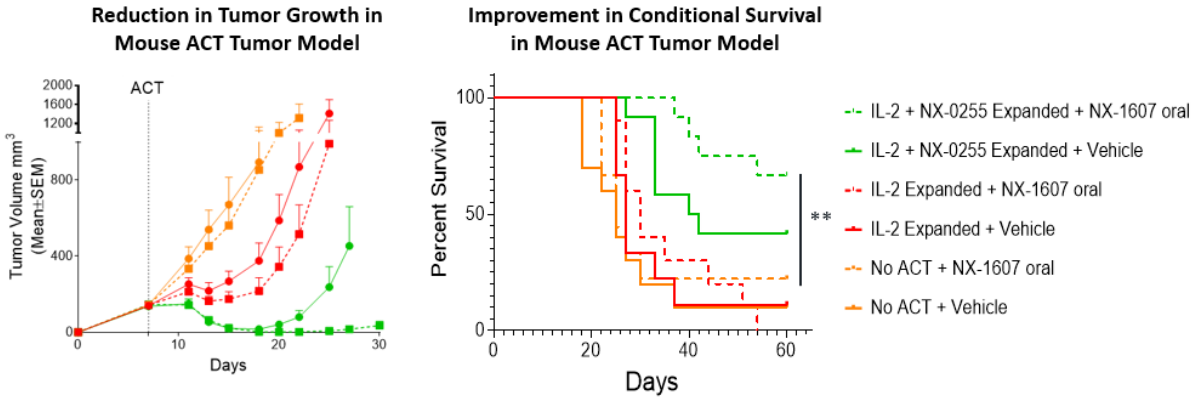
- CD8+ cells exposed to NX-0255 alone *ex vivo* resulted in superior conditional survival compared to using IL-2 alone
- CD8+ cells exposed to NX-0255 and IL-2 combined *ex vivo* exert a deeper anti-tumor response
- NX-0255 *ex vivo* exposure period is only three days, anti-tumor effects persist for over a month after engraftment
- Animals that rejected tumor were rechallenged 80 days post ACT. All animals rejected tumor, demonstrating immunological memory

Clinical development plans for DeTIL-0255

We are planning to complete the preclinical characterization and IND-enabling activities for DeTIL-0255 and expect to commence a Phase I clinical trial in the second half of 2021. We are currently working with CMOs with experience in TIL product development for the development of the DeTIL-0255 process and manufacturing. We expect the Phase 1 clinical trial will be conducted at multiple sites in the United States that have experience in conducting TIL and other ACT trials. We expect to include patients with a spectrum of advanced solid tumors who have failed standard of care. The primary objective of the study will be to evaluate safety and tolerability of DeTIL-0255 autologous cell therapy. Secondary objectives may include an exploratory evaluation of efficacy. Other exploratory objectives may include characterization of DeTIL-0255 phenotypes utilizing a variety of T cell markers, identification of potential mechanisms of response or resistance to DeTIL-0255 including repertoire analysis and persistence of the autologous cell therapy in the patient. The specific study design and protocol are currently under development and will include plans regarding selection of the patient population, eligibility criteria and safety monitoring.

Oral CBL-B inhibitors combined with ex vivo CBL-B inhibition in a mouse model of ACT

We have further explored ACT by including an oral dosing regimen of NX-1607 in combination with NX-0255 *ex vivo* treated T cells. Preliminary results shown below illustrate that the combination with NX-1607 yields more substantial anti-tumor effect and subsequent conditional survival than with *ex vivo* NX-0255 ACT alone. Pending trial results using each therapy alone, we also intend to evaluate the combination of oral NX-1607 and *ex vivo* NX-0255 ACT in a future clinical trial.



- Oral NX-1607 treatment once daily further enhances conditional survival and anti-tumor activity of T cells expanded for three days with recombinant IL-2 plus NX-0255 *ex vivo* in adoptive cell therapy mouse model

Formation of DeCART Therapeutics Inc.

We have established DeCART Therapeutics Inc. (DeCART) a wholly owned subsidiary incorporated in Delaware, with an investment of $3.0 million and granted DeCART a license to three of our compounds, including NX-0255, for drug-enhanced isolation of T cells nonexclusively with respect to one CAR-T therapy target and exclusively with respect to three novel CAR-T therapy targets. The founding team of DeCART includes Carl H. June, M.D., Joseph A. Fraietta, Ph.D., Xian Hua, M.D., Ph.D., and Dana M. Hammill, M.S., M.B.A. Dr. June, the Richard W. Vague Professor in Immunotherapy and Director of the Center for Cellular Immunotherapies in the Abramson Cancer Center of the University of Pennsylvania, will lead the founding team and will serve as the chairman of DeCART's scientific advisory board. DeCART expects to combine our protein modulation technologies with novel CAR-T therapies to address current immunotherapy limitations and improve outcomes for patients with cancer. Dana Hammill serves as DeCART's Chief Operating Officer. Over time, we intend for DeCART to seek equity financing from third parties and to become an independent operating entity. DeCART has granted to its founders stock options to purchase shares of DeCART's common stock equal to 14% of the fully diluted capitalization of DeCART. Following either the third-party funding or the exercise of the contemplated stock option grants, DeCART will no longer be a wholly owned subsidiary.

Collaborations

Sanofi Collaboration and License Agreement

In December 2019, we entered into a global strategic collaboration with Genzyme Corporation, a subsidiary of Sanofi, which became effective in January 2020, and was subsequently expanded and amended in January 2021 (the Sanofi Agreement), to discover, develop and commercialize a pipeline of targeted protein degradation drugs for patients with challenging diseases in multiple therapeutic areas using our DELigase platform to identify small molecules designed to induce degradation of three specified initial drug targets. In January 2021, Sanofi exercised its option to expand the number of targets in the collaboration agreement from three to a total of five targets. Over time and subject to certain limitations, Sanofi may elect to replace the drug targets with other reserved targets.

Under the Sanofi Agreement, Sanofi has exclusive rights and is responsible for the clinical development, commercialization and manufacture of product candidates resulting from the collaboration while we retain the option to co-develop, co-promote and co-commercialize up to two targets, one of which must be selected from a list of targets designated at the execution of the Sanofi Agreement and one of which must be selected from targets identified by Sanofi as part of their recent expansion. Our right to exercise our option to co-develop, co-promote and co-commercialize a given target is dependent on our ability to demonstrate, within a given timeframe, that we have sufficient cash resources and personnel to commercialize the product. The collaboration excludes our current internal protein degradation programs for which we retain all rights, and also excludes our future internal programs, provided that we have distinguished future programs as excluded from the scope of the collaboration.

For drug targets that are subject to the collaboration, we have primary responsibility for conducting preclinical research activities (including target validation, drug discovery, identification or synthesis) in accordance with the applicable research plan agreed to by the parties and established on a target-by-target basis. We are obligated to use commercially reasonable efforts to identify relevant target binders and CTMs in order to identify development candidates. Subject to certain exceptions, each party will bear its own costs in the conduct of such research. Sanofi will be responsible for any development and commercialization activities unless we exercise our co-development and co-promotion option. For those programs that we exercise our option to co-develop, co-promote and co-commercialize, we will be responsible for a portion of the U.S. development costs, and the parties will split U.S. profits and losses evenly and we will be eligible to receive royalties on ex-U.S. net sales and reduced milestone payments on such optioned products.

Upon signing the Sanofi Agreement, Sanofi paid us an upfront payment of $55.0 million in January 2020. Subsequently in January 2021, Sanofi paid us an additional $22.0 million to exercise its option to expand the number of targets beyond the initial targets included in the collaboration. As of November 30, 2020, we are eligible to receive up to approximately $2.5 billion in total payments, including payments of up to $500.0 million upon the achievement of specified development milestones, up to $625.0 million upon the achievement of specified regulatory milestones and up to $1.3 billion upon the achievement of certain sales milestones, as well as up to $163.1 million in certain additional fees related to target licensing and reservation. In addition, we are eligible to receive tiered royalties ranging from mid-single digit to low teen percentages on annual net sales of any commercial products that may result from the collaboration, subject to certain reductions and excluding sales in the United States of any products for which we exercise our option to co-develop and co-promote, for which we share profits and losses evenly.

Subject to earlier expiration in certain circumstances, the Sanofi Agreement expires on a licensed product-by-licensed product or profit-shared licensed product-by-profit-shared licensed product basis and country-by-country basis upon on the later of the expiration of (i) the last-to-expire patent with a valid claim covering the applicable licensed product in the applicable country, (ii) the expiration of any regulatory exclusivity for the applicable licensed product in the applicable country or (iii) ten years after the first commercial sale of the applicable licensed product in the applicable country covered by the Sanofi Agreement.

Gilead Collaboration, Option and License Agreement

In June 2019, we entered into a global strategic collaboration agreement with Gilead, which was amended in August 2019 (the Gilead Agreement), to discover, develop and commercialize a pipeline of targeted protein degradation drugs for patients with cancer and other challenging diseases using our DELigase platform to identify novel agents that utilize E3 ligases to induce degradation of five specified drug targets.

Under the Gilead Agreement, Gilead has the option to license drug candidates directed to up to five targets resulting from the collaboration and is responsible for the clinical development and commercialization of product candidates resulting from the collaboration. We retain the option to co-develop and co-promote, under a profit share structure, up to two product candidates in the United States, provided that we may only exercise such option once per licensed product and Gilead retains the right to veto our option selection for any one product candidate of its choice. The collaboration excludes our current internal protein degradation programs for which we retain all rights, and also excludes our future internal programs, provided that we have distinguished future programs as excluded from the scope of the collaboration.

Over time, Gilead may elect to replace the initial drug targets with other drug targets. For drug targets that are subject to the collaboration, we are obligated to use commercially reasonable efforts to undertake a research program in accordance with a research plan agreed to by the parties and established on a target-by-target basis. We have primary responsibility under the agreement for performing preclinical research activities (including target validation, drug discovery, identification or synthesis) pursuant to a research plan. Each party will bear its own costs in the conduct of research activities. Gilead will be responsible for any development, commercialization and manufacturing activities, unless we exercise our co-development and co-promotion option. For those programs that we exercise our option to co-develop and co-promote, we and Gilead will split U.S. development costs as well as U.S. profits and losses evenly, and we will be eligible to receive royalties on ex-U.S. net sales and reduced milestone payments.

Upon signing the Gilead Agreement, Gilead paid us an upfront payment of $45.0 million, plus $3.0 million in additional fees. As of November 30, 2020, we are eligible to receive up to approximately $2.3 billion in total additional payments, including up to $697.5 million upon the achievement of specified development milestones, up to $1.5 billion upon the achievement of specified sales milestones, subject to reduction for any product for which we exercise our option to co-develop and co-promote, and up to $139.8 million in certain additional fees related to target licensing, reservation and selection and research term extensions. In addition, we are eligible to receive tiered royalties from mid-single digit to low tens percentages on annual net sales from any commercial products directed to the optioned collaboration targets, subject to certain reductions and excluding sales in the United States of any products for which we exercise our option to co-develop and co-promote, for which we share profits and losses evenly.

Subject to earlier expiration in certain circumstances, the Gilead Agreement expires on a licensed product-by-licensed product and country-by-country basis upon on the later of (i) the expiration of the last-to-expire patent with a valid claim covering the applicable licensed product in the applicable country, (ii) the expiration of any regulatory exclusivity for the applicable licensed product in the applicable country or (iii) ten years after the first commercial sale of the applicable licensed product in the applicable country covered by the Gilead Agreement, provided that the term for any profit-shared licensed product in the United States will expire upon the expiration or termination of the applicable profit-share term as set forth in an applicable profit-share agreement to be negotiated upon our exercise of our option to co-develop and co-promote such licensed product. If Gilead does not exercise an option to license a drug candidate, then the Gilead Agreement will terminate at the end of the last-to-expire option period.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any facilities for product manufacturing, packaging, storage and distribution, or testing. We rely on and expect to continue to rely on CMOs for both drug substance and finished drug product, and ACT product. We have personnel or engaged consultants with extensive technical, manufacturing, analytical and quality experience and good project management to oversee contract manufacturing and testing activities. We have engaged third-party manufacturers to supply the drug substance for NX-2127 and to develop and manufacture finished drug product for NX-2127 that we plan to use in our Phase 1 clinical trial. We have also engaged a third-party manufacturer to supply the drug substance for NX-1607. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. Because TIL and CAR-T therapies are manufactured on a patient-by-patient basis, they involve complex manufacturing and we anticipate that we will have to rely on third-party manufacturers to manufacture our ACT products for pre-clinical studies and clinical trials. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

All of our drug candidates are organic compounds of low molecular weight, generally called small molecules, but which are larger than traditional small molecule therapeutics. We have selected these compounds not only on the basis that they could have potentially favorable efficacy and safety profiles, but also for their ease of synthesis and reasonable cost of their starting materials. In particular, our lead product candidates are manufactured using reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale up and does not require unusual equipment in the manufacturing process. We expect to continue to develop drug candidates that can be produced cost-effectively at contract manufacturing facilities.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property and proprietary products. While we believe that our technology, development experience, scientific knowledge and intellectual property portfolio provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and commercialization. Not only must we compete with other companies that are focused on protein modulation, but any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Moreover, our industry is characterized by the existence of large numbers of patents and frequent allegations of patent infringement.

Our platform and product focus is the discovery and development of protein modulation therapies using our chimeric small molecules and ligase inhibitors. Other companies researching chimeric small molecules for protein degradation include Arvinas, Inc., C4 Therapeutics, Inc., Cullgen Inc. and Kymera Therapeutics, Inc., all of which are currently in preclinical development with the exception of Arvinas which has initiated clinical trials. Further, several large pharmaceutical companies have disclosed preclinical investments in this field, including Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Genentech, Inc., GlaxoSmithKline plc and Novartis International AG. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. In addition to competition from other protein modulation therapies, any products that we develop may also face competition from other types of therapies, such as small molecule, antibody, vaccine or gene therapies.

Our lead product candidates target hematologic cancers and immune-mediated diseases including immuno-oncology and cell-based therapeutics for cancer. The most common methods of treating patients in oncologic indications are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy. A new class of therapies for treatment of oncology patients are ACTs including CAR-T cell therapies and TIL cell therapies. There are a variety of available drug therapies marketed for cancer, including hematologic cancers. In many cases, these drugs are administered in combination to enhance efficacy. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. In general, although there has been considerable progress over the past few decades in the treatment of cancer and the currently marketed therapies provide benefits to many patients, these therapies all are limited to some extent in their efficacy and frequency of adverse events, and none of them are successful in treating all patients. As a result, the level of morbidity and mortality from cancer remains high.

In addition to currently marketed drugs, there are also several product candidates in late stage clinical development for the treatment of oncologic indications and immune-mediated diseases. These products in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval.

If any of our product candidates are approved for the indications for which we expect to conduct clinical trials, they will compete with the foregoing therapies and the currently marketed drugs and potentially any drugs in development. It is also possible that we will face competition from other biologic or pharmaceutical approaches as well as from other types of therapies.

Many of our current or potential competitors, either alone or with strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. 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 reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

The key competitive factors affecting the success of all our programs, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition and availability of reimbursement.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, platforms, product candidates and improvements thereof that are commercially important to our business, including obtaining, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among, other methods, pursuing patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and product candidates that are important to the development and implementation of our business. Our patent portfolio, including pending priority applications and Patent Cooperation Treaty (PCT) applications, is intended to cover, but is not limited to, our technology platforms, product candidates and components thereof and their methods of use, and any other inventions that are commercially important to our business. However, the portfolio covering our product candidates is at an early stage and is currently comprised of only applications and we do not currently own or license any issued patents.

We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates and continuing innovation to develop, strengthen, and maintain our position in our DELigase platform and product candidates. Trade secrets are difficult to protect and provide us with only limited protection. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned or controlled by third parties; to defend and enforce our proprietary rights, including our patent applications; to defend against challenges and assertions by third parties of their purported intellectual property rights; and to operate without infringement of valid and enforceable patents and other proprietary rights of third parties. For risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

We believe that we have a strong global intellectual property position and substantial know how and trade secrets relating to our DELigase platform and product candidates. As of February 1, 2021, we have nine U.S. utility patent applications, seven PCT applications and two foreign applications that we own, and two provisional applications that we co-own with Gilead. NX-2127 and NX-5948 are covered by one U.S. utility application and one PCT application claiming the compound, formulation, synthetic methods, and uses thereof. Should patents issue claiming NX-2127 or NX-5948, these patents are expected to expire between 2039-2040. NX-1607 is covered by three U.S. utility applications and three PCT applications claiming the compound, formulation, synthetic methods and uses thereof. Should patents issue claiming NX-1607, these patents are expected to expire between 2040-2041. DeTIL-0255 is covered by three U.S. utility applications, two PCT applications and two foreign applications. Should patents issue claiming DeTIL-0255, these patents are expected to expire in 2040.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing of a non-provisional patent application in the applicable country. However, the patent term of United States patents may, in certain cases, be adjusted for administrative delays by the United States Patent and Trademark Office (the USPTO) in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In addition, the term of a patent may be extended as compensation for the patent term lost during the FDA regulatory review process. For example, for drugs that are regulated by the FDA under the Hatch-Waxman Act, it is permitted to extend the term of a patent that covers such drug for up to five years beyond the normal expiration date of the patent. For more information on patent term extensions, see “Business—Government Regulation: The Hatch-Waxman Act—Patent term extension.” In the future, if and when our pharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents, if issued, covering those product candidates. We intend to seek patent term extensions to any of our patents, if issued, in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

The actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We also rely on trade secret protection for our know-how, confidential and proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, competitors or other third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements under the commencement of employment or consulting relationships with us. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in relation to the resulting know-how or inventions. For more information, please see the sections titled "Risk Factors—Risks Related to Our Intellectual Property" and "Risk Factors—Risks Related to Regulatory Approval and Marketing of Our Product Candidates."

Government Regulation

FDA approval process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The processes for obtaining approval in the United States, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. The Federal Food, Drug, and Cosmetic Act (the FDCA) and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, quality control, packaging, storage, recordkeeping, approval, labeling, promotion, advertising and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (NDAs) withdrawal of an approval, imposition of a clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice (DOJ) or other governmental entities.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as *in vitro* and animal trials to assess the characteristics and potential safety and efficacy of the product for initial testing in humans and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. 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 animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, a sponsor must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. The sponsor may be a company seeking to develop the drug or, as in the case of an investigator-initiated trial, the sponsor may be an investigator who is conducting the trial. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. 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 new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (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 detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness 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, as a clinical hold or partial clinical hold, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol, or part of a protocol, is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, the FDA has promulgated regulations governing the acceptance of foreign clinical trials not conducted under an IND, establishing that such studies will be accepted as support for an IND or application for marketing approval if the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA’s regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies. If a marketing application is based solely on foreign clinical data, the FDA requires that the foreign data be applicable to the U.S. population and U.S. medical practice; the studies must have been performed by clinical investigators of recognized competence; and the FDA must be able to validate the data through an onsite inspection or other appropriate means, if the FDA deems such an inspection to be necessary.

The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) representing each institution participating in the clinical trial. The IRB must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. 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.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on its ClinicalTrials.gov website. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or in certain indications such as cancer, patients with the target disease or condition, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are conducted. In a Phase 3 trial, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk benefit profile of the product, and to provide adequate information for the labeling of the product.

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, such as where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible. Post-approval studies, or Phase 4 trials, are often required following initial approval and are intended to gain additional experience and data from treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse effects occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with current good manufacturing practices

(cGMP) requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,942,965 for fiscal year 2020, and the manufacturer and sponsor under an approved NDA are also subject to annual program fees, currently $325,424 for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

The FDA has 60 days from its receipt of an NDA 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. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. Applications for standard review drug products are meant to be reviewed within ten months; applications for priority review drugs are meant to be reviewed in six. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and accompanying information and the manufacturing facilities, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, 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. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a 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.

If the FDA approves a product, it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA 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 NDA supplements as it does in reviewing NDAs.

Expedited approval pathways

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life threatening disease or condition. These programs are referred to as Fast Track designation, Breakthrough Therapy designation and Priority Review designation. In addition, accelerated approval offers the potential for approval based on a surrogate or intermediate clinical endpoint. In May 2014, the FDA published a final Guidance for Industry titled "Expedited Programs for Serious Conditions Drugs and Biologics," which provides guidance on the FDA programs that are intended to facilitate and expedite development and review of new product candidates as well as threshold criteria generally applicable to concluding that a product candidate is a candidate for these expedited development and review programs.

The FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a product for Priority Review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case by case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A Priority Review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated approval pathway

The FDA may grant accelerated approval to a drug for a serious or life threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (IMM) and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan Drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and an exemption from the NDA application user fee.

Pediatric studies and exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant

pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (the FDASIA) sponsors must also submit pediatric study plans prior to the assessment data.

Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Post-approval requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often 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 the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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

- Restrictions on the marketing or manufacturing of the product, including total or partial suspension of production, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or holds on post-approval clinical trials;

- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products; or
- Injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

In addition, the distribution of prescription drug products is subject to the Prescription Drug Marketing Act (the PDMA) which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription drug product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for generic drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme allowing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA) to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are “abbreviated” because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD).

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form and the strength of the drug. An applicant may submit an ANDA suitability petition to request the FDA’s prior permission to submit an abbreviated application for a drug that differs from the RLD in route of administration, dosage form, or strength, or for a drug that has one different active ingredient in a fixed combination drug product (i.e., a drug product with multiple active ingredients). At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.” Upon approval of an ANDA, the FDA indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists may consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity (NCE). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years from the date the NDA is approved, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; it does, however, block the FDA from approving ANDAs during the period of exclusivity. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

505(b)(2) New Drug Applications

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Hatch-Waxman patent certification and the 30-month stay

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Orange Book.

When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent, known as a Section VIII statement. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Patent term extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between the effective date of an IND application and the submission date of a NDA, plus the time between NDA submission date and the NDA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of product approval. Only one patent applicable to an approved drug is eligible for extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

Foreign regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Other healthcare laws

Although we do not currently have any products on the market, in addition to FDA restrictions on marketing of pharmaceutical products, we are also subject to healthcare statutory and regulatory requirements and enforcement by the U.S. federal and state governments. Even though we are not in a position to make patient referrals and do not bill Medicare, Medicaid, or other government or commercial third-party payers, our relationships with healthcare providers, physicians and third-party payors will subject us to healthcare statutory and regulatory requirements and enforcement by federal and state governments. These laws include anti-kickback statutes, false claims statutes and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce, or in return for, purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federal health care program. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) amended the intent element of the federal Anti-Kickback Statute to clarify that a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to commit a violation. Among others, this statute applies to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other, including, for example, consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions and patient support offerings. A conviction for violation of the federal Anti-Kickback Statute can result in criminal fines and/or imprisonment and requires mandatory exclusion from participation in federal health care programs. Exclusion may also be imposed if the government determines that an entity has committed acts that are prohibited by the federal Anti-Kickback Statute. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions under the law, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. The federal Anti-Kickback Statute safe harbors are the subject of possible regulatory reforms. Any changes to the safe harbors may impact our future contractual and other arrangements with pharmacy benefit managers, group purchasing organizations, third party payors, wholesalers and distributors, healthcare providers and prescribers, and other entities, as well as our future pricing strategies.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false record or statement material to a false claim. The False Claims Act, which covers claims made to programs where the federal government reimburses (directly or indirectly) individuals and entities, such as under the Medicare and Medicaid programs, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. The law also prohibits avoiding, decreasing or concealing an obligation to pay money to the federal government. The government can bring claims directly or through a civil whistleblower or *qui tam* action, and potential liability includes mandatory treble damages and significant per claim penalties, currently set at up to $23,332 per false claim or statement for penalties assessed after January 29, 2018, with respect to violations occurring after November 2, 2015. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. There is also the Federal Criminal False Claims Act, which is similar to the Federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular provider, practitioner, or supplier (although pharmaceutical manufacturers are not considered suppliers for purposes of this law), and contracting with an individual or entity that the person knows or should know is excluded from participation in a federal health care program. In addition, federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, requirements to facilitate certain patient rights, requirements to safeguard the privacy, security, and transmission of individually identifiable health information, and requirements to provide notice to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect. These laws are rapidly evolving and may impose additional regulatory compliance burden and legal risks on our operations.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services (CMS) has promulgated regulations to implement what is commonly known as the federal Physician Payment Sunshine Act, which, among other things, requires manufacturers of prescription drugs, among others, to collect and report information on certain payments or transfers of value they make to U.S.-licensed physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reports must be submitted on an annual basis, and the reported data is made available in searchable form on a public website. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives will also be required.

In addition, several states require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. healthcare reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which intended to substantially change the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iii) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs (iv) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer what are now 70% point of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (v) expanded 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 138% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vi) expanded the entities eligible for discounts under the 340B Public Health program, (vii) required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to licensed practitioners, (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research, and (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

The prior U.S. presidential administration and Congress sought to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. From January 2017 through January 2021, the Trump administration issued three executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on January 22, 2018, the Trump administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain

high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act (TCJA) among other things, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment, or penalty, 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." In December 2018, a federal district court in Texas ruled that the ACA's individual mandate, without the penalty that was repealed effective January 1, 2019, was unconstitutional and could not be severed from the ACA. As a result, the court ruled the remaining provisions of the ACA were also invalid. The Fifth Circuit Court of Appeals affirmed the district court's ruling that the individual mandate was unconstitutional, but it remanded the case back to the district court for further analysis of whether the mandate could be severed from the ACA (i.e., whether the entire ACA was therefore also unconstitutional). The Supreme Court of the United States granted certiorari on March 2, 2020, and the case is expected to be decided in 2021.

Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." There is uncertainty with respect to the impact the new U.S. presidential administration and Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent statutory amendments, will remain in effect through 2030 unless additional Congressional action is taken. In 2020, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) temporarily suspended the 2% cut in Medicare payments from May 1, 2020 through December 31, 2020, and it extended the cut through fiscal year 2030 to offset the cost of such temporary suspension. The American Taxpayer Relief Act of 2012 made other changes, including reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the NIH to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities which may delay our ability to develop, market and sell any products we may develop.

More recently the cost of prescription pharmaceuticals has been the subject of considerable discussion in the United States. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the cost of prescription drugs under Medicare and reform government program reimbursement methodologies for drug products. Any proposed measures will require authorization through additional legislation to become effective, and it is uncertain whether Congress or the new Biden administration will seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are

undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

Human Capital

As of November 30, 2020, we had 135 full-time employees, of which 115 are engaged in research and development. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain, and motivate selected employees, consultants, and directors through the granting of stock-based compensation awards.

Corporate Information

We were incorporated under the laws of the State of Delaware in August 2009 under the name Kura Therapeutics, Inc. We subsequently changed our name to Nurix, Inc. in February 2012 and then to Nurix Therapeutics, Inc. in October 2018. Our principal executive offices are located at 1700 Owens Street, Suite 205, San Francisco, California 94158, and our telephone number is (415) 660-5320.

The mark “Nurix” is our registered trademark in Canada, France, Germany, Italy, Japan, Mexico, Spain and the United Kingdom and for which we have a pending trademark application in the United States. The marks “DELigase,” “DeCART” and “DeTIL” are our trademarks for which we have a pending trademark application in the United States. The Nurix logo is our common law trademark. All other service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this Annual Report on Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Additional Information

Nurix's Internet website address is http://www.nurixtx.com. On our website, the company makes available, free of charge, its annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after the company electronically files such material with, or furnishes such material to, the Securities and Exchange Commission (SEC). The SEC maintains a website at www.sec.gov that contains reports as well as other information regarding us and other companies that file materials with the SEC electronically.

Also available on our website is information relating to corporate governance at Nurix and our Board of Directors, including our Corporate Governance Guidelines; our Code of Business Conduct and Ethics (for our directors, officers and employees); and our Board Committee Charters. We will provide any of the foregoing information without charge upon written request to our Corporate Secretary, Nurix Therapeutics, Inc., 1700 Owens Street, Suite 205, San Francisco, CA 94158.

We use our Investor Relations website (http://ir.nurixtx.com) as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures are included in the “News” and “Events and Presentations” sections of our website. Accordingly, investors should monitor these portions of our website, in addition to following our press releases, SEC filings and public conference calls and webcasts.

The information contained on our website does not constitute, and shall not be deemed to constitute, a part of this Annual Report on Form 10-K, or any other report we file with, or furnish to, the SEC. Our references to the URLs for websites are intended to be inactive textual references only.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the accompanying notes and the information contained in our other public filings before deciding whether to invest in shares of our common stock. We cannot assure you that any of the events described below will not occur. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks occur, our business, financial condition, operating results, and future prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length below. These risks include, among others, the following:

- We have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.
- We have never generated revenue from product sales and may never be profitable.
- We will need substantial additional funding. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development programs or future commercialization efforts.
- We are very early in our development efforts. We only recently initiated clinical development of our first product candidate and all of our other product candidates are in preclinical development. If we are unable to advance to clinical development, develop, obtain regulatory approval for and commercialize our product candidates or experience significant delays in doing so, our business may be materially harmed.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we may develop, we may need to abandon or limit our further clinical development of those product candidates.
- We only recently initiated testing of our lead product candidate in clinical trials, and we have not tested any of our other product candidates in clinical trials. The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.
- We face substantial competition in an environment of rapid technological change, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We expect to depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.
- We rely on CMO for the manufacture of both drug substance and finished drug product for our product candidates for preclinical testing and expect to continue to do so for our clinical trials and commercialization. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.
- Our commercial success and ability to effectively compete in the market depends, in part, upon our ability and the ability of our collaborators to obtain and maintain adequate patent protection for our technology, current product candidates and any future product candidates that we may develop and our

ability to develop, manufacture, market and sell our product candidates and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property of others.

- Our business, operations, clinical development plans, the timing of regulatory filings and regulatory approvals and the achievement of milestones could be adversely affected by the current COVID-19 pandemic.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.

Our net loss was $43.2 million and $21.7 million for the fiscal years ended November 30, 2020 and 2019, respectively. As of November 30, 2020, we had an accumulated deficit of $103.7 million. To date, we have not generated any revenue from product sales and have financed our operations primarily through our collaborations and sales of our equity interests. We are in the early stages of development of our product candidates. We filed an IND for NX-2127 in December 2020 and received clearance by the FDA to initiate human clinical trials. We expect to dose the first patient in a Phase 1 clinical trial for NX-2127 in the first quarter of 2021 and expect our four most advanced product candidates to enter clinical trials in 2021. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our operating expenses and capital expenditure requirements will increase substantially if and as we:

- conduct a Phase 1 clinical trial of our product candidate NX-2127;
- file INDs elsewhere and initiate clinical trials of our other lead product candidates NX-1607, NX-5948, DeTIL-0255 and other drug candidates;
- enter advanced clinical development and scale up external manufacturing capabilities to supply clinical trials;
- expand the capabilities of our DELigase platform and apply our DELigase platform to advance additional product candidates into preclinical and clinical development;
- conduct process development for manufacturing of our DeTIL cell therapy products;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory, manufacturing, quality assurance and scientific personnel; and
- add operational, financial and management information systems and personnel to support our research, product development and future commercialization efforts and support our operations as a public company.

Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency (EMA) or other regulatory authorities to perform trials in addition to those we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our planned clinical trials or the development of any of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never be profitable.

We only recently commenced clinical development of our first product candidate NX-2127, and we are currently only in the preclinical testing stages for our other most advanced product candidates and research programs. We expect that it will be many years, if ever, before we have a product candidate ready for commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing approval for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, establishing and maintaining arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing approval for our product candidates and manufacturing, marketing, selling and obtaining reimbursement for any products for which we may obtain marketing approval.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will need substantial additional funding. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development programs or future commercialization efforts.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we conduct our Phase 1 clinical trial of NX-2127, and work to prepare for IND submissions and initiate planned Phase 1 clinical trials of our other lead product candidates NX-1607, NX-5948, DeTIL-0255 and other drug candidates, grow our pipeline of product candidates, expand the breadth of our DELigase platform, continue research and development, and initiate additional clinical trials of and potentially seek marketing approval for our lead programs and other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, reimbursement, and sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we otherwise would prefer to develop and market ourselves.

We had cash, cash equivalents and investments of $372.0 million as of November 30, 2020. We believe that our existing cash, cash equivalents and investments, will be sufficient to fund our operations through at least the next 12 months. However, our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect, and we may need to seek additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our Phase 1 clinical trial for NX-2127 and our planned Phase 1 clinical trials for our other lead product candidates NX-1607, NX-5948, DeTIL-0255 and other drug candidates, and any future clinical development of such product candidates;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- the number and development requirements of other product candidates that we pursue;
- the scope of, and costs associated with, future advancements to our DELigase platform;
- the scope of, and costs associated with, future preclinical development of our DeTIL cell therapy products;
- the success of our collaborations with Sanofi, Gilead and any other collaborations we may establish;

- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our ability to establish additional collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates.

We will need to raise substantial additional capital to complete the development and commercialization of our product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. Adequate additional funds may not be available to us on acceptable terms, or at all.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future milestone payments under our collaborations with Sanofi and Gilead, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

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

We commenced operations in 2009, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates. All of our product candidates are either in preclinical development or have only recently entered clinical development, and their risk of failure is high. We have not yet demonstrated our ability to successfully: complete any clinical trials, including large-scale, pivotal clinical trials; obtain marketing approvals; manufacture a commercial-scale product or arrange for a third party to do so on our behalf; or conduct market access, sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to the Discovery and Development of Our Product Candidates

We are very early in our development efforts. All of our product candidates are either in preclinical development or have only recently entered clinical development. If we are unable to advance to clinical development, develop, obtain regulatory approval for and commercialize our product candidates or experience significant delays in doing so, our business may be materially harmed.

We are very early in our development efforts. All of our product candidates are either in preclinical development or have only recently entered clinical development, and their risk of failure is high. We have invested substantially all of our efforts and financial resources in building our DELigase platform, in the identification and preclinical development of our current product candidates, and in the initiation of Phase 1 clinical trials for our lead product candidate, NX-2127. Our ability to generate revenue from product sales, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- sufficiency of our financial and other resources;
- successful completion of preclinical studies;
- successful submission of INDs and initiation of clinical trials;
- successful patient enrollment in, and completion of, clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- establishing a continued acceptable safety profile of the products and maintaining such a profile following approval; and
- effectively competing with other therapies.

If we do not successfully achieve 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 could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations.

One of our approaches to the discovery and development of product candidates based on our targeted protein degradation platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products.

Treating diseases using targeted protein degradation is a new treatment modality. Our future success depends on the successful development of this novel therapeutic approach. Very few small molecule product candidates

designed to control cellular protein levels, such as our BTK CTMs, have been tested in humans, none has been approved in the United States or Europe, and the data underlying the feasibility of developing these therapeutic products is both preliminary and limited. Discovery and development of CTMs that harness ligases to degrade protein targets have been impeded largely by the complexities and limited understanding of the functions, biochemistry and structural biology of E3 ligases as well as by challenges of engineering compounds that promote protein-protein interactions.

We believe that our CTM product candidates may offer an improved therapeutic approach by removing the disease-causing proteins instead of simply inhibiting their activities. However, the scientific research that forms the basis of our efforts to develop our CTM product candidates is ongoing and the scientific evidence to support the feasibility of developing CTM-based therapeutic treatments is both preliminary and limited. Further, certain patients have shown inherent primary resistance to approved BTK inhibitors and other patients have developed acquired secondary resistance to these inhibitors. Although we believe NX-2127 may have the ability to degrade the BTK mutation that confers resistance to currently marketed BTK inhibitors, any inherent primary or acquired secondary resistance to our BTK CTMs in patients would prevent or diminish their clinical benefit.

We only recently initiated clinical development of NX-2127, and we have not yet initiated a clinical trial of any other CTM product candidate, nor have we assessed the safety of any CTM product candidate in humans. Although some of our product candidates have produced observable results in animal studies, there is a limited safety data set for their effects in animals. These product candidates may not demonstrate the same chemical and pharmacological properties in humans, and may interact with human biological systems in unforeseen, ineffective or harmful ways. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

Additionally, 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. Although other companies are also developing therapeutics based on targeted protein degradation, no regulatory authority has granted approval for any such therapeutic. As a result of these factors, it is more difficult for us to predict the time and cost of CTM product candidate development, and we cannot predict whether targeted protein degradation will result in the development and marketing approval of any products. Any development problems we experience in the future related to any of our CTM research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate, or from commercializing any CTM product candidates we may develop on a timely or profitable basis, if at all.

Drug development is a lengthy and expensive process, with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

All of our product candidates are either in preclinical development or have only recently entered clinical development, and their risk of failure is high. We are unable to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or similar regulatory authorities outside the United States will accept our proposed clinical programs or if the outcome of our preclinical testing and studies ultimately will support the further development of our programs.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical trials, that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may experience delays in reaching, or may fail to reach, a consensus with regulators on trial design;

- 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, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators or IRB 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 difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the selection of certain clinical endpoints may require prolonged periods of clinical observation or analysis of the resulting data;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRB to suspend or terminate the trials;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- 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;
- regulators or IRB may require that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements or changes in the way the product is administered; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials

will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, or could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, results of operations, financial condition and prospects.

Further, cancer therapies sometimes are characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line or later use, meaning for use after two or more other treatments have failed. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, immunotherapy, radiation therapy, surgery, targeted 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. Our planned clinical trials for our lead product candidates NX-2127 and NX-1607 and other drug candidates will be with patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but any product candidates we develop, even if approved, may not be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we may develop, we may need to abandon or limit our further clinical development of those product candidates.

We have not evaluated any product candidates in human clinical trials, and there have been very few clinical trials to date involving small molecule product candidates designed to control cellular protein levels through targeted protein degradation. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There is a limited safety data set for the effects of NX-2127, NX-1607, NX-5948 and DeTIL-0255 in animals and our product candidates have not been tested on humans at all. There can be no assurance that our current product candidates or any future product candidate will not cause undesirable side effects. Unforeseen side effects from our product candidates could arise at any time during preclinical or clinical development.

A potential risk in any protein modulation product is that healthy proteins or proteins not targeted for modulation will be modulated or that the modulation of the targeted protein in itself could cause adverse events, undesirable side effects or unexpected characteristics. It is possible that healthy proteins or proteins not targeted for modulation could be modulated by our product candidates in any of our planned or future clinical studies. There also is the potential risk of delayed adverse events following treatment with our product candidates.

If any product candidates we develop are associated with serious adverse events, or undesirable side effects, or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. In our preclinical studies, we may observe undesirable characteristics of our product candidates. This may prevent us from advancing them into clinical trials, delay these trials or limit the extent of these trials. For example, increased bleeding risk and cardiac arrhythmia such as atrial fibrillation have been reported side effects of approved BTK inhibitors. NX-1607 could activate the immune response to unsafe levels and may have the potential to induce hypercytokinemia, or cytokine storm, which is the overstimulation of immune cells and subsequent overproduction of their activating compounds. Many product candidates that initially showed promise in early-stage testing for treating cancer or other diseases later have been found to cause side effects that prevented further clinical development of the product candidates or limited their competitiveness in the market.

We expect to dose the first patient in our first clinical trial in the first quarter of 2021 and have not tested any of our other product candidates in clinical trials. The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. In

addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. In particular, the small number of patients in our planned early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of our initial clinical trial for NX-2127 and of our planned Phase 1 clinical trials of our other lead product candidates NX-1607, NX-5948 and DeTIL-0255 and other drug candidates may not be predictive of the results of further clinical trials of these product candidates or any of our other product candidates. Moreover, preclinical and clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain marketing approval of their products. Our future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business, results of operations, financial condition and prospects.

Interim top-line and preliminary data from our planned 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 top-line or preliminary data from our planned 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 top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. In particular, we are preparing to dose the first patient in a Phase 1 clinical trial for NX-2127 in patients with CLL and other B-cell malignancies and we are preparing to begin Phase 1 clinical trials for NX-1607 in immune-oncology indications. We cannot predict how difficult it will be to enroll patients for trials in these indications. Therefore, our ability to identify and enroll eligible patients for our NX-2127 clinical trial and our planned NX-1607 clinical trial may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who otherwise would be eligible for our planned clinical trials instead may enroll in clinical trials of our competitors' product candidates. Moreover, the size of the relevant patient populations for the diseases that our lead product candidates target are small and as more companies begin to focus attention and resources on product candidates to treat the same indications as our product candidates we may experience delays or be unable to successfully recruit and enroll a sufficient number of eligible patients in our clinical trials. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the size of the patient population and process for identifying patients;
- the availability and efficacy of approved medications for the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- physicians' attitudes and practices with respect to clinical trial enrollment;
- the burden on patients due to inconvenient procedures;

- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the impact of the current COVID-19 pandemic, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials.

Our inability to enroll a sufficient number of patients for our current or planned clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our current or planned clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

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

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

The manufacture of drugs is complex and we and our third-party manufacturers are early in our manufacturing efforts.

We have established manufacturing relationships with a limited number of suppliers to manufacture raw materials and the drug substance of any product candidate for which we now are pursuing, or may in the future pursue, preclinical or clinical development. Our current cGMPs, manufacturing process development with our third-party manufacturers and scale-up is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Our third-party manufacturers may encounter difficulties in production, including 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 any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our current or future product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

We have limited experience with the development and manufacturing of adoptive cellular therapeutics, which is a relatively new and expanding category of therapeutics with unique development, manufacturing and regulatory risks.

We are exploring the use of T cell-enhancing compounds to improve the current industry-standard methods and technology for adoptive cellular therapies (ACTs) in both hematologic cancers and solid tumors. ACTs represent a class of immunotherapy in which T cells are isolated directly from patient tumors, as with TIL, or from patient blood with subsequent genetic modification to recognize specific antigens present on cancer cells, as with CAR-T therapies. These tumor-reactive T cells are then expanded and infused back into the patient. These cell therapy technologies are a relatively new and expanding category of therapeutics, with which we have limited experience. We may observe undesirable characteristics such as cytokine storm, immunogenicity, infection or other adverse events. Additionally, because TIL and CAR-T therapies are manufactured on a patient-by-patient basis, they require extensive research and development and involve complex and costly manufacturing. Moreover, we anticipate that we will have to rely on third-party manufacturers to manufacture our ACT products for pre-clinical

studies and clinical trials and if they fail to commence or complete, or experience delays in, manufacturing ACT products, our pre-clinical studies and clinical trials will be delayed. The FDA and other regulatory bodies also have limited experience with ACTs, which may result in regulatory delays. The regulatory pathway is complex and may take more time and be more expensive to pursue than the regulatory pathway for other established product candidates. Moreover, the FDA regulatory pathway for our DeTIL and CAR-T programs is not clear and may require us to file a Biologics License Application or an application for a Combination Product, and will be subject to further discussion with regulators. Because this is a relatively new and expanding area, there are many uncertainties related to the appropriate regulatory pathway, development, manufacturing, marketing, reimbursement, and the commercial potential for these product candidates, and we may never be successful in developing these therapeutics.

We may not be successful in our efforts to identify or discover additional potential product candidates.

A key element of our strategy is to apply our DELigase platform to address a broad array of targets and new therapeutic areas. The therapeutic discovery activities we are conducting may not be successful in identifying product candidates that are useful in treating hematologic cancers, immune-mediated diseases or any other diseases. Our research programs initially may show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable product candidates for preclinical and clinical development, we will not be able to obtain revenues from sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

We may not be successful in our efforts to expand the breadth of our DELigase platform.

A key element of our strategy is to expand the capabilities of our DELigase platform and leverage our platform to discover, develop and potentially commercialize additional product candidates beyond our current portfolio to target diseases in a wide range of organ systems and tissues and treat various disease states. These enhancements require substantial technical, financial and human resources, and may not result in the discovery or development of additional product candidates or therapies. We may pursue what we believe is a promising opportunity to leverage our platform only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that individual products or our science in general has technology or biology risks that were previously unknown or underappreciated. Our strategy of pursuing the value of our DELigase platform over a long time horizon and across a broad array of human diseases may not be effective. In the event material decisions in any of these areas turn out to be incorrect or sub-optimal, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize what we believe is the potential of our DELigase platform.

We face substantial competition in an environment of rapid technological change, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. Moreover, the biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from third parties that use protein modulation, antibody therapy, ACT, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and other public

and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are aware of several biotechnology companies focused on developing small molecules that degrade target proteins including Arvinas, Inc., C4 Therapeutics, Inc., Cullgen Inc. and Kymera Therapeutics, Inc., all of which currently are in preclinical or clinical development. Further, several large pharmaceutical companies have disclosed preclinical investments in this field, including Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Genentech, Inc., GlaxoSmithKline plc and Novartis International AG.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies also may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

If we do not achieve our projected development goals in the time frames 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 and may be associated with payments from collaborators such as Sanofi or Gilead. 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, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Our estimated market opportunities for our product candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited.

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot be assured of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may prove not to be accurate. Although we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this report. If this third-party or internally generated data prove to be inaccurate or if we make

errors in our assumptions based on that data, our actual market may be more limited than we estimate it to be. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business.

Risks Related to Dependence on Third Parties

We expect to depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We have sought third-party collaborators for the research, development, and commercialization of some of our CTM programs. For example, in June 2019 we entered into a collaboration with Gilead and in December 2019 we entered into a collaboration with Sanofi, which was subsequently expanded and amended in January 2021. Both collaborations require us to conduct certain research activities. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, biotechnology companies and universities. These and any future arrangements with third parties limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. 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. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any product candidates we may develop, including our collaborations with Sanofi and Gilead, 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 any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition or business combination that diverts resources or creates competing priorities.
- Sanofi and Gilead have broad option rights to select up to five targets each for exclusive CTM development, so long as not excluded by us under the terms of each collaboration, and may select targets we are considering but have not taken sufficient action to exclude under each collaboration.
- 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 develop independently, or develop with third parties, products that compete directly or indirectly with our products or 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 obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Sanofi and Gilead have the first right to enforce or defend certain intellectual property rights under the applicable collaboration arrangement with respect to particular licensed programs, and although we may have the right to assume the enforcement and defense of such intellectual property rights if the collaborator does not, our ability to do so may be compromised by their actions.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.

- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control. For example, Sanofi may terminate its agreement with us if we undergo a change of control.
- 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. For example, each of Sanofi and Gilead can terminate its agreement with us in its entirety or with respect to a specific target for convenience upon written notice or in connection with a material breach of the agreement by us that remains uncured for a specified period of time.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, marketing approval, and commercialization described in this report apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute the ownership interest of our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the proposed collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, 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 may seek to establish additional collaborations. If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

We plan to continue to selectively pursue collaborations with leading biopharmaceutical companies with development and commercial expertise and capabilities. We face significant competition in attracting appropriate collaborators to advance the development of any product candidates for which we may seek a collaboration. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical studies and clinical trials, the likelihood of approval by the FDA or other 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, 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), the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator also may have the opportunity to collaborate on other product candidates or technologies for similar indications and will have to evaluate whether such a collaboration could be more attractive than one with us.

Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical companies has reduced the number of potential future collaborators, and

we may not be able to locate a suitable collaborator. Any collaboration we enter into may limit our ability to enter into future agreements on particular terms or covering similar target indications with other potential collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue from product sales, which could have an adverse effect on our business, prospects, financial condition and results of operations.

We expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials.

We will rely on third-party clinical research organizations (CROs) to conduct our Phase 1 clinical trial program for NX-2127, our planned Phase 1 clinical trial programs for NX-1607, NX-5948 and DeTIL-0255, and any other clinical trials for other drug candidates. We currently do not plan to conduct any clinical trials independently. Agreements with these CROs might terminate for a variety of reasons, including for their failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities.

Our reliance on these CROs for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

If these CROs do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We rely on third-party contract manufacturing organizations for the manufacture of both drug substance and finished drug product for our product candidates for preclinical testing and expect to continue to do so for our clinical trials and commercialization. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on and expect to continue to rely on CMOs for both drug substance and finished drug product, and ACT product. This reliance on CMOs, particularly where one CMO is the sole source of the drug substance or finished drug product, or ACT product, may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish agreements with CMOs or to do so on acceptable terms. Even if we are able to establish agreements with CMOs, reliance on them entails additional risks, including:

- reliance on the CMO for regulatory, compliance and quality assurance;
- the possible breach of the manufacturing agreement by the CMO;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and

- the possible termination or nonrenewal of the agreement by the CMO at a time that is costly or inconvenient for us.

We have only limited technology transfer agreements in place with respect to our product candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our product candidates and other materials. If we receive marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party.

The CMOs we retain may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to suitable manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Some of our suppliers may experience disruption to their respective supply chain due to the effects of the COVID-19 pandemic, which could delay, prevent or impair our development or commercialization efforts.

We obtain certain chemical or biological intermediates in the synthesis of our product candidates and NHPs for toxicology testing in countries affected by the COVID-19 pandemic. If we are unable to obtain these chemical or biological intermediates or NHPs in sufficient quantity and in a timely manner, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Our CMOs may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. Quality issues may arise during scale-up activities. Our reliance on a limited number of CMOs, the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Furthermore, if our CMOs fail to deliver the required commercial quality and quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement CMOs capable of production in a timely manner at a substantially equivalent cost, then testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, a product candidate may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, ibrutinib is a well-established current treatment for CLL and other B-cell malignancies, and doctors may continue to rely on this and other treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from product sales and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals; and
- any restrictions on the use of our products together with other medications.

If we are unable to establish sales and marketing capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biopharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either by ourselves or through collaboration or other arrangements with third parties.

We currently expect that we may build our own focused, specialized sales and marketing organization to support the commercialization in the United States of product candidates for which we receive marketing approval and that can be commercialized with such capabilities. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales and marketing capabilities and enter into arrangements with third parties to perform these services, our revenue from product sales and our profitability, if any, are likely to be lower

than if we ourselves were to market and sell any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to market and sell our product candidates or may be unable to do so on terms that are acceptable to us. Any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. 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, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that 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.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and 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. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to 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 similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, also may not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate 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.

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

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

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- withdrawal of marketing approval, recall, restriction on the approval or a "black box" warning or contraindication for an approved drug;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- injury to our reputation and significant negative media attention;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our product liability insurance coverage as we initiate our clinical trials, as we expand our clinical trials and if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain or increase our insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology, current product candidates and any future product candidates that we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology and product candidates similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired, and we may not be able to compete effectively in our market.

Our commercial success depends, in large part, on our ability to obtain and maintain patent and other intellectual property and proprietary protection in the United States and other countries with respect to our product candidates and proprietary technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. However, the portfolio covering our product candidates is at an early stage and comprised only of patent applications and we do not currently own or license any issued patents covering our product candidates. If we are unable to obtain or maintain patent protection with respect to our proprietary product candidates and technology or do not otherwise adequately protect our intellectual property, competitors and other third parties may be able to use our product candidates and technologies and erode or negate any competitive advantage that we may have, which could have a material adverse effect on our business. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors and other third parties to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the patent applications we own, co-own or license may fail to result in issued patents that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the

technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology. If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could have a material adverse effect on our ability to commercialize our product candidates and our business.

To protect our proprietary positions, we file patent applications in the United States and other countries related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive, complex and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in all potential jurisdictions 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 be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in the public domain. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors and other third parties may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the protections offered by laws of different countries vary and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, whether owned or in-licensed, are highly uncertain. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the U.S. Patent and Trademark Office (USPTO), the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions typically are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first inventors to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications, whether owned or in-licensed, may not result in patents being issued that protect our technology or product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. 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. Moreover, we may be subject to a third-party preissuance submission of prior art to the USPTO challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or other post-grant proceedings, in the United States or elsewhere, challenging our or our licensors' 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, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, exclusivity, freedom to operate, or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, any threat to the breadth or strength of protection provided by our patents and patent applications could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents and are unchallenged, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors and other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors and other third parties may be able to design around or circumvent our patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable. If the patent protection provided by the patents and patent applications we own or license is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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 patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our business.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and therefore is costly, time-consuming and inherently uncertain. Past or future patent reform legislation in the United States and other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, may diminish the value of our patents or narrow the scope of our patent protection and may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Under the Leahy-Smith America Invents Act, (the America Invents Act), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings.

Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any of the foregoing, including any similar adverse changes in the patent laws of other jurisdictions, could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we are able to obtain patent protection for our product candidates, the life of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non provisional filing date. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Upon the expiration of patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and other third parties, which would materially adversely affect our business, financial condition, results of operations and prospects.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or product candidates, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, also may be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates we may seek to acquire.

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

Our commercial success depends, in part, upon our ability, and the ability of our collaborators to develop, manufacture, market and sell our product candidates and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties.

Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of CTMs and including patents owned or controlled by our competitors. There is considerable and complex intellectual property litigation in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and *inter partes* review proceedings before the USPTO and oppositions and other comparable proceedings in foreign jurisdictions. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, future product candidates and technology, including interference, derivation, reexamination or *inter partes* review proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future and claims may also come from competitors or other third parties against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringe patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization.

As we continue to develop and, if approved, commercialize our current and future product candidates, competitors or other third parties may claim that our technology infringes, misappropriates or otherwise violates their intellectual property rights. There are and may in the future be additional U.S. and foreign-issued patents and pending patent applications owned by third parties in the fields in which we are pursuing product candidates. For example, we are aware of a patent owned by a third party with a claim that covers many potential CTMs. This patent may be alleged to cover one or more of our CTM product candidates, including our NX-2127 product candidate. While we believe that we have valid defenses against any assertion of such patent against us, such defenses may be unsuccessful. If we are unsuccessful and any of our CTM product candidates is found to infringe this patent, we could be required to obtain a license to such patent or forced to permanently cease developing, manufacturing, marketing and commercializing the infringing CTM product candidate. We may not be able to obtain any required license on commercially reasonable terms or at all, and even if we were able to obtain a license, it could be non-exclusive, thereby giving the licensor and other third parties the right to use the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing the product candidate. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willingly infringed any such patent. Even if we were ultimately to prevail, any litigation could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Moreover, as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Patent and other types of the intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, by a court of competent jurisdiction to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our products

and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty or other payments. Without such a license, we could be forced, including by court order, to cease commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or future product candidates or force us to cease some of our business operations, which could materially harm our business. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. If we lose a foreign patent lawsuit alleging our infringement of a competitor's patents, we could be prevented from marketing our therapeutics in one or more foreign countries and/or be required to pay monetary damages for infringement or royalties in order to continue marketing. Claims that we have misappropriated the confidential information, trade secrets or other intellectual property of third parties could have a similar negative impact on our business. Any of these outcomes would have a material adverse effect on our business.

Further, we do not know which processes we will use for commercial manufacture of our future products, or which technologies owned or controlled by third parties may prove important or essential to those processes. Many companies have filed, and continue to file, patent applications related to novel protein modulation therapies that target disease-causing proteins and many companies have filed and continue to file patent applications related to ACT. Some of these patent applications have already been allowed or issued and others may issue in the future. Because this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there likely will be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending that we are not aware of that may later result in issued patents that may be infringed by the manufacture, use, sale or importation of our product candidates or future products. If a patent holder believes the manufacture, use, sale, offer for sale or importation of one of our product candidates or future products infringes its patent, the patent holder may sue us even if we have licensed other patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our licensed patent portfolio may therefore have no deterrent effect.

It is also possible that we have failed to identify all relevant third-party patents or applications. Patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale, importation or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, later be amended in a manner that could cover our technologies, our future products or the manufacture or use of our future products.

Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of our product candidates or future product candidates or manufacture or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This burden is a high one and in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity or enforceability by invalidating the claims of any such U.S. patent or finding that our product candidates or technology did not infringe any such claims.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may be time-consuming, cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities and ongoing business operations. If we are unable to avoid infringing

the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our future products or processes. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Unlike some of our larger competitors and other third parties, we may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. Uncertainties resulting from the litigation of patent litigation and other proceedings could delay our research development efforts, adversely affect our ability to raise additional funds, and could limit our ability to continue our operations. Any of the foregoing could have a material adverse effect on our business.

We may be subject to claims by third parties asserting that we or our employees, consultants, contractors or advisors have misappropriated, wrongfully used or disclosed alleged trade secrets or other intellectual property, or claiming ownership of what we regard as our own intellectual property.

We employ individuals who were previously employed at universities as well as other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We also may in the future be subject to claims that we have caused such individual to breach the terms of his or her non-competition or non-solicitation agreement or from former employers or other third parties claiming to have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees.

In addition, although it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, such assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such litigation or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors, or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, the patents of our licensors, or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which, regardless of merit, can be expensive, time-consuming, unpredictable and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their patents or other intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or proceeding involving our patents or patent applications may put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Even if we successfully assert our patents or other intellectual property rights, a court may not award remedies that sufficiently compensate us for our losses. The impact of public announcements of the results of hearings related to such awards on the price of our common stock may be uncertain. If securities analysts or investors perceive such results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel for significant periods of time during such litigation could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology and product candidates outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors or other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in various foreign governmental require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application process. Although 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 a patent or 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. In such an event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our business.

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 product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, and confidentiality agreements to maintain our competitive position. However, trade secrets can be difficult to protect. We seek to protect our trade secrets, proprietary technology and processes, 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, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. 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 inside and outside of the United States are less willing or unwilling to protect trade secrets. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our product candidates and technology.

We cannot guarantee that we have entered into such agreements with each party that may have or had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and

electronic security of our information technology systems; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach.

Moreover, our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third parties, our competitive position would be harmed.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future;
- we, or our current or future license partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license now or in the future;
- we, or our current or future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we may hold rights to in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities 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; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Regulatory Approval and Marketing of Our Product Candidates

The regulatory approval process of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future, will ever obtain marketing approval.

Our product candidates could be delayed or fail to receive marketing approval for many reasons, including the following:

- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may disagree with the design or implementation of our planned clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of a NDA to the FDA or other submissions necessary to obtain marketing approval in the United States;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, financial condition and prospects. The FDA has substantial discretion in the approval process, and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, or they may impose significant limitations in the form of narrow indications, warnings or REMs. In addition, regulatory authorities may not approve the price we intend to charge for our products, may require precautions or contra-indications with respect to conditions of use, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We, as a company, do not have experience in filing for and obtaining regulatory approval to initiate a clinical trial or in manufacturing or in quality assurance in order to market a new drug in the United States or in any other jurisdiction.

As a company, we do not have experience in filing for or obtaining regulatory approval to initiate clinical trials or in manufacturing or in quality assurance in order to market a new drug and expect to rely on CROs or other third-party consultants or vendors to assist us in this process. Our inexperience may result in failure to or delays in obtaining the required regulatory approvals to initiate clinical trials and to obtain marketing approval for our product candidates. If we are unable to obtain regulatory and marketing approval for our product candidates or experience significant delays in our efforts to do so, our business could be substantially harmed.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad and may limit our ability to generate revenue from product sales.

To market and sell our product candidates in jurisdictions outside the United States, 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, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals on a timely basis or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. 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. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any jurisdiction, which would materially impair our ability to generate revenue.

The United Kingdom's recent exit from the European Union (EU), commonly referred to as "Brexit," continues to create political and economic uncertainty, particularly in the United Kingdom and the EU. Because a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the withdrawal of the United Kingdom from the EU could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU.

If we fail to comply with the regulatory requirements in international markets and thus receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Even if we, or any collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we, and any collaborators, will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation and reporting requirements. We, our third-party manufacturers, and any collaborators and their third-party manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any collaborators, receive marketing approval for one or more of our product candidates, we, any collaborators, and our respective third-party manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any collaborators, are not able to comply with post-approval regulatory requirements, we, and any collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition and prospects.

Any product candidate for which we, or any collaborators, obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we, or any collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products when and if any of them are approved.

Any product candidate for which we, or any collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REM. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The FDA also may impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of REMs. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products only for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown side effects or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;

- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can lead to significant penalties and sanctions.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our collaborators and their contract manufacturers also will be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, such as the requirement to implement a REM.

Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, exclusions from government programs, contractual damages and reputational harm, and could diminish our future profits and earnings.

Our future arrangements with third-party payors, physicians, and other customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.

Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, a criminal law, prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease or order of any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil False Claims Act, which may be enforced through civil whistleblower or *qui tam* actions and is often used to enforce the federal Anti-Kickback Statute and other healthcare laws and regulations, imposes civil penalties and potential exclusion from federal healthcare programs, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;
- federal criminal statutes created by HIPAA impose criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private insurance plans, or, in any matter involving a healthcare benefit program, for knowingly and willfully making materially false, fictitious or fraudulent statements in connection with the delivery of or payment for health care benefits;
- HIPAA, as amended by HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Food, Drug, and Cosmetic Act which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

- the federal and state laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report payments and other transfers of value to physicians, teaching hospitals, and, beginning in 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives as well as certain ownership and investment interests held by physicians and their immediate families, which includes annual data collection and reporting obligations; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant compliance guidance promulgated by the federal government. State laws also require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

The efforts of the Trump Administration to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

The Trump Administration took several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking and the issuance of guidance. On January 30, 2017, former President Trump issued an executive order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and on February 2, 2017, the Trump Administration indicated that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, the extent to which they will impact the FDA's ability to exercise its regulatory authority and the impact that the new Biden Administration could have on these requirements. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

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 product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

Healthcare reform measures that may be adopted in the future, may result in reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Any proposed measures will require authorization through additional legislation to become effective, and it is uncertain whether Congress or the new Biden Administration will seek new legislative and/or administrative measures to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. These include legislation and regulations regarding price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, legislative action designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of drugs, if any.

In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Risks Related to Employees, Managing our Growth and Other Legal Matters

The outbreak of COVID-19 may adversely affect our business and the market price of our common stock.

The recent global pandemic of COVID-19 is impacting worldwide economic activity and 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 shutdowns that may be requested or mandated by governmental authorities. Although 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, cause diversion of healthcare resources away from the conduct of preclinical and clinical trial matters to focus on pandemic concerns, limit travel in a manner that interrupts key trial activities, such as trial site initiations and monitoring, delay regulatory filings with regulatory agencies in affected areas or adversely affect our ability to obtain regulatory approvals. The COVID-19 outbreak and mitigation measures also may have an adverse impact on global economic conditions, which could adversely impact our business, financial condition or results of operations. Additionally, the COVID-19 outbreak has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past as a result of the COVID-19 outbreak could have an adverse effect on our ability to access capital and on the market price of our common stock. It is currently not possible to predict how long the COVID-19 outbreak will last or the time that it will take for economic activity to return to prior levels. 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 taken to contain its impact. See also the section titled "—Risks Related to Dependence on Third Parties."

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

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including our President and Chief Executive Officer, Arthur T. Sands, M.D., Ph.D., and our Chief Scientific Officer, Gwenn Hansen, Ph.D. The loss of the services of Drs. Sands and Hansen or other members of our senior leadership team could impede, delay or prevent the successful development of our product pipeline, completion of our current and planned clinical trials, commercialization of our products or in-licensing or acquisition of new assets, and could negatively impact our ability to successfully implement our business plan. If we lose the services of such individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

Moreover, we might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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

As of November 30, 2020, we had 135 full-time employees. As our development and commercialization plans and strategies develop, and as we continue our transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. We filed our first IND for NX-2127 December 2020 and received clearance by the FDA to initiate human clinical trials. We expect our four most advanced product candidates to enter clinical trials in 2021. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these 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.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading laws.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include:

- intentional, reckless or negligent conduct or disclosure to us of unauthorized activities that violate the regulations of the FDA or similar foreign regulatory authorities;
- healthcare fraud and abuse in violation of U.S. and foreign laws and regulations;
- violations of U.S. federal securities laws relating to trading in our common stock; and
- failures to report financial information or data accurately.

In particular, 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 regulate a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. While we have adopted a code of conduct and implemented other internal controls applicable to all of our employees, 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. Additionally, we are subject to the risk that a person could allege 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, including the imposition of civil, criminal and administrative penalties, damages, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, diminished profits and future earnings, any of which could adversely affect our ability to operate our business or cause reputational harm.

We depend on our information technology systems, and any failure of these systems, or those of our CROs, third-party vendors, collaborators or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or other personal information, prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems, infrastructure and data to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including but not limited to intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

Despite the implementation of security measures, our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet (including harmful attachments to emails, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), persons inside our organization, or persons with access to systems inside our organization. Any of the foregoing may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants or lead to data leakage.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be material, and although we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If such an event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption or delay 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. Furthermore, significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could 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), which could result in financial, legal, business, and reputational harm to us. If any such event, including a computer security breach, results in the unauthorized access, use or release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws (and other similar non-U.S. laws), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. For example, the California Consumer Privacy Act (the CCPA), provides for a private right of action for security breaches that is expected to increase security breach litigation that could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences. Such actions could result in significant legal and financial exposure and reputational damages that could have a material adverse effect on our business, results of operations, prospects and financial condition.

We are or may become subject to a variety of stringent privacy and data security laws, regulations, policies and contractual obligations related to data privacy and security, and changes in such laws, regulations, policies and contractual obligations and our failure, or any failure by our third-party vendors, collaborators, contractors or consultants, to comply with them could harm our business.

We maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, a large quantity of sensitive information, including confidential business, personal and patient health information in connection with our preclinical and clinical studies and our employees, and are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and the legislative landscape is constantly evolving. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. The U.S. Department of Health and Human Services (HHS) has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect. For example, the CCPA, which came into effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020, along with related regulations which came into force on August 14, 2020. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act (the CPRA), which expands upon the CCPA, was passed in the recent election on November 3, 2020. The CCPA gives (and the

CPRA will give) California residents expanded privacy rights, including the right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed. Additionally, the CCPA requires companies that process personal information of California residents to make disclosures to consumers about their data collection, use and sharing practices, allow consumers to opt out of certain data sharing with third parties and provide a private right of action for data breaches, as described above. Although the CCPA includes limited exceptions, including exceptions for personal health information collected by covered entities or business associates subject to HIPAA, among others, the CCPA may regulate or impact our processing of personal information depending on the context. Additionally, the CPRA expands on the requirements of the CCPA by granting California residents expanded privacy rights and additional requirements for businesses. The CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and could have a material adverse effect on our business, including how we use personal information, financial condition, results of operations or prospects.

Additionally, the CCPA has prompted a number of proposals for new federal and state-level privacy legislation, such as in Nevada, Virginia, New Hampshire, Illinois and Nebraska. Such new privacy laws add additional complexity, requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, and could impact business strategies and the availability of previously useful data. The interplay of federal and state laws (e.g., in addition to California, Massachusetts and Nevada have adopted laws requiring the implementation of certain security measures to protect personal information, and all 50 states and the District of Columbia, Puerto Rico, the U.S. Virgin Islands and Guam have adopted breach notification laws) may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy, security and data use issues in the U.S. continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to products and services could intensify.

In addition, in May 2018, the General Data Protection Regulation (the GDPR) took effect in the European Economic Area (EEA). The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons, replacing data protection laws issued by each EU member state based on the Directive 95/46/EC (the Directive). The GDPR imposes additional compliance burdens, including by mandating burdensome documentation requirements and granting certain privacy rights to individuals to control how companies collect, use, disclose, retain and process information about them and changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. For example, on July 16, 2020, the Court of Justice of the EU (the Court of Justice) invalidated the European Union-United States (EU-U.S.) Privacy Shield on the grounds that the EU-U.S. Privacy Shield failed to offer adequate protections to EU personal information transferred to the United States. While the Court of Justice upheld the use of other data transfer mechanisms, such as the Standard Contractual Clauses, the decision has led to some uncertainty regarding the use of such mechanisms for data transfers to the United States, and the court made clear that reliance on Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. The use of Standard Contractual Clauses for the transfer of personal information specifically to the United States also remains under review by a number of European data protection supervisory authorities. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. The European Data Protection Board issued additional guidance regarding the Court of Justice’s decision on November 11, 2020 which imposes higher burdens on the use of data transfer mechanisms, such as the Standard Contractual Clauses, for cross-border data transfers. To comply with this guidance, we may need to implement additional safeguards to further enhance the security of data transferred out of the EEA, which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, the European Commission published new versions of the Standard Contractual Clauses for comment. While the comment period ended in December 2020, the European Commission is expected to finalize and implement the new Standard Contractual Clauses in early 2021. Additionally, other countries (e.g., Australia and Japan) have adopted certain legal requirements for cross-border transfers of personal information. These obligations may be interpreted and

applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our global turnover). The GDPR allows data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Further, the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit. In addition to the fines imposed by the GDPR, the Data Protection Act also imposes fines of up to £17 million or 4% of global turnover. Further, since the transition period for Brexit ended December 31, 2020, there remains some uncertainty regarding cross-border data transfers from the EEA to the UK. The EU is expected to either issue an adequacy decision for such transfers in early 2021, or an adequacy mechanism such as the Standard Contractual Clauses will be required for transfer of personal data from the EEA to the UK. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services. If we are required to implement additional measures to transfer data from the EEA, this could increase our compliance costs, and could adversely affect our business, financial condition and results of operations.

It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face regulatory investigations, significant fines and penalties, reputational damage or be required to change our business practices, all of which could adversely affect our business, financial condition and results of operations. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

U.S. federal income tax reform and changes in other tax laws could adversely affect us.

In December 2017, U.S. federal tax legislation commonly referred to as the TCJA was signed into law, significantly reforming the Internal Revenue Code of 1986, as amended (the Code). The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of business interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a partial "territorial" system, and modifies or repeals many business deductions and credits.

In March 2020, U.S. federal tax legislation named the CARES Act, was signed into law. Such legislation modified the TCJA by, among other things, eliminating the limitation on the deduction of NOLs to 80% of current year taxable income for tax years beginning before January 1, 2021, and increasing the amount of interest expense that may be deducted from 30% to 50% of adjusted taxable income for tax years beginning in 2019 or 2020.

The TCJA is a far-reaching and complex revision to the U.S. federal income tax laws with disparate and, in some cases, countervailing impacts on different categories of taxpayers and industries. The long-term impact of the TCJA, as modified by the CARES Act, on the overall economy, the industries in which we operate and our and our partners' businesses still cannot be reliably predicted. There can be no assurance that the TCJA, as modified by the CARES Act, will not negatively impact our future operating results. The estimated impact of the TCJA, as modified by the CARES Act, is based on our management's current knowledge and assumptions, following consultation with

our tax advisors. Because of our valuation allowance in the United States, ongoing tax effects of the TCJA, as modified by the CARES Act, are not expected to materially change our effective tax rate in future periods.

In addition, new legislation or regulations that could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments that could negatively impact our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial condition.

Our ability to utilize our net operating loss carryforwards may be subject to limitations.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. As of November 30, 2020, we had federal and state net operating loss (NOL) carryforwards of approximately $55.7 million and $153.3 million, respectively. To the extent we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, subject to the restrictions and exceptions described below. Federal NOLs generated in tax years beginning on or before December 31, 2017 may be carried forward 20 tax years and expire on various dates beginning in 2029. Under the TCJA, as modified by the CARES Act, NOLs arising in tax years beginning on or before December 31, 2017 may be carried back two tax years, NOLs arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back five tax years and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. In 2020, we filed a refund claim of $15.7 million to carryback our NOLs generated in the fiscal year ended November 30, 2018, and we filed a refund claim to carryback our NOLs generated in the fiscal year ended November 30, 2019 to recover an additional $3.9 million of income tax. NOLs arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried forward indefinitely but are limited to 80% of our taxable income in tax years beginning after December 31, 2020. State NOLs can be carried forward 20 years and begin expiring in 2029.

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have identified two ownership changes since our inception that have triggered a limitation on pre-change NOLs under Section 382. A majority of our pre-change NOLs remain available within the carryforward period provided by the Code, subject to availability of taxable income. We may have experienced additional ownership changes that have not yet been identified that could result in the expiration of our NOL and credit carryforwards before utilization and we may experience subsequent shifts in our stock ownership, some of which are outside our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations that potentially could result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Future acquisitions, joint ventures, spin outs or strategic alliances or transactions could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot be certain that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;

- retention of key employees from the acquired company;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, or cause us to incur unanticipated liabilities and harm the business generally. There also is a risk that future acquisitions will result in our incurring debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Additionally, we may not realize the expected value of out-licensing, joint ventures, spin outs or other strategic transactions. For example, in July 2020, we established DeCART, a wholly owned subsidiary, with an investment of $3.0 million and granted DeCART a license to three of our compounds, including NX-0255, for drug-enhanced isolation of T cells nonexclusively with respect to one CAR-T therapy target and exclusively with respect to three novel CAR-T therapy targets. Over time, we intend for DeCART to seek equity financing from third parties and to become an independent operating entity. However, we cannot assure you that DeCART will be able to obtain financing on attractive terms or at all. We may lose all or part of our investment in DeCART. Our license agreement to DeCART does not require DeCART to pay any milestone payments or royalties or other payments to us, and to the extent that DeCART is successful, we would benefit exclusively through our ownership of shares of DeCART's capital stock. If DeCART raises additional funds through further issuances of equity or convertible debt securities, including to its service providers pursuant to its equity incentive plan, our ownership interest could be significantly diluted, and any new equity securities issued by DeCART may have rights, preferences, and privileges superior to ours. We cannot assure you that we will retain significant influence over the management of DeCART, and the directors or management of DeCART may make decisions or take actions that we disagree with. Conflicts of interest may arise from time to time in connection with this transaction, DeCART may not successfully develop CAR-T or any other therapies and we may not realize the expected value from this strategy.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, or other remedial measures and legal expenses, any of which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act (the FCPA), the Bribery Act and other anticorruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also are subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, United Kingdom and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, which we collectively refer to as Trade Control Laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act, or other legal requirements including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, legal expenses, and disgorgement and other sanctions and remedial measures, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by U.S., U.K. or other authorities also could have an adverse impact on our reputation, our business, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. Although we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis of 2007-2008 caused extreme volatility and disruptions in the capital and credit markets. Similarly, the recent volatility associated with the COVID-19 outbreak has caused significant instability and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Our current operations are in the San Francisco Bay Area, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters as to which our business continuity and disaster recovery plans may not be adequate to protect us.

Our current operations are located in our facilities in San Francisco, California. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or man-made accident or incident that result in our being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations, and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates, DELigase platform, DeTIL or future development programs;
- results of preclinical and clinical trials, or the addition or termination of clinical trials or funding support by us or by existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our stock price may be volatile and you could lose all or part of your investment.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following:

- results of preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our collaboration partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or in those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning our current or future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may provide to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;

- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- effects of public health crises, pandemics and epidemics, such as COVID-19;
- natural disasters and other calamities; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk factors" section, could have a dramatic and adverse impact on the market price of our common stock.

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

Based on the beneficial ownership of our common stock as of November 30, 2020, our executive officers, directors and affiliates beneficially owned approximately 55.2% of our outstanding voting stock. As a result, these stockholders, if acting together, could have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market before or after the lock-up and other legal restrictions on resale lapse in connection with our initial public offering (IPO), the market price of our common stock could decline significantly. Each of our officers, directors and substantially all of our stockholders entered into lock-up agreements with the underwriters in connection with our IPO that restricted their ability to sell or transfer their shares. These lock-up agreements pertaining to our IPO expired on January 19, 2021. Due to the expiration of the lock-up agreements, a substantial number of shares of our common stock recently became eligible for sale in the public market.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to 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.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is and will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital.

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent additional capital is raised through the sale and issuance of shares or other securities convertible into shares, the ownership interest of our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" (EGC) as defined in the JOBS Act. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements applicable to other public companies that are not EGCs, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), (ii) reduced disclosure obligations regarding executive compensation in our periodic reports, registration statements and proxy statements, and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. We could be an EGC for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior May 31, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we no longer would be an EGC as of the following November 30, or if we issue more than $1.0 billion in non-convertible debt during the prior three-year period before that time, in which case we no longer would be an EGC immediately. Even after we no longer qualify as an EGC, we still may qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act of 1934, as amended (the Exchange Act), which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our 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 share price may be more volatile.

Under the JOBS Act, EGCs also may delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the Securities Act), upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-EGCs and the date on which we will adopt the recently issued accounting standard.

We also are a "smaller reporting company," and 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 million as of the prior May 31, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of the prior May 31. If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company 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 EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions also could make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or to take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only our board of directors to establish the number of directors and fill vacancies on our board;
- provide that directors may be removed only "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws, unless such amendments are approved by two-thirds of our board of directors, in which case stockholders can approve by a simple majority;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law (the DGCL) may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Our restated certificate of incorporation and our restated bylaws contain exclusive forum provisions for certain claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder

and our restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (a Federal Forum Provision). Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation and/or restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we no longer are an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market (Nasdaq) and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements also could make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations often are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

We are not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and therefore are not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which process is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over

financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

In the course of preparing our financial statements for fiscal years 2018 and 2019, we identified a material weakness in our internal control over financial reporting. Specifically, we did not design and maintain formally documented controls and accounting policies and procedures, including information technology general controls, segregation of duties over the review and approval of account reconciliations and manual journal entries, and the period-end financial reporting process. The existing material weakness resulted in a revision to the basic and diluted weighted-average number of shares outstanding and basic and diluted net loss per share calculations for the three- and nine-month periods ended August 31, 2020. The material weakness has not been remediated as of November 30, 2020 and could result in a misstatement of substantially all of our account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. To address our material weakness, we have implemented new financial systems and controls. We intend to continue to take steps to remediate the material weakness through formalizing documentation of policies and procedures and further evolving our accounting processes.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. We cannot assure you that we have identified all material weaknesses. Moreover, our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods, which could cause the price of our common stock to decline. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

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. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The market price of our common stock may 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties and Facilities

Our principal executive office is located in San Francisco, California, where we lease a total of 49,991 square feet of office and laboratory space that we use for our administrative, research and development and other activities. The lease expires in April 2025. Additionally, we have a sublease for a total of 2,500 square feet of laboratory space in Pittsburgh, Pennsylvania that expires in May 2021. We believe that our existing facilities are suitable and adequate for our current requirements and operations.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information for Common Stock

Our common stock has been listed on the Nasdaq Global Market under the symbol "NRIX" since July 24, 2020. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of close of business on February 11, 2021, there were 92 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to finance the growth and development of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends will fall within the discretion of our Board of Directors, and will depend on various factors, including our operating results, financial condition, and capital requirements, restrictions that may be imposed by applicable law, and other factors deemed relevant by our Board of Directors.

Stock Price Performance Graph

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Use of Proceeds from Registered Securities

In the third fiscal quarter of 2020, we completed our IPO and sold 12,550,000 shares of common stock at an offering price of $19.00 per share. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-239651), which was declared effective by the SEC on July 23, 2020. No additional shares were registered.

There has been no material change in the planned use of proceeds from our IPO as described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on July 24, 2020.

Securities Authorized for Issuance under Equity Compensation Plans

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth in Part III, Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities

From December 1, 2019 through November 30, 2020, we sold and issued the following unregistered securities:

- Prior to filing our registration statement on Form S-8 in July 2020, we issued and sold to our directors, officers, employees, and consultants an aggregate of 447,177 unregistered shares of common stock upon exercise of stock options under our 2012 Equity Incentive Plan at per share exercise prices ranging from $0.24 to $9.57.

- In March 2020, we issued 9,431,364 shares of Series D redeemable convertible preferred stock that resulted in gross proceeds of $120.2 million.

The offers, sales and issuances of the securities described in paragraph (1) above were deemed to be exempt from registration under the Securities Act under Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

The offers, sales and issuances of the securities described in paragraph (2) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act. The recipients of securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction. Each of the recipients of securities in this transaction was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

Purchases of Equity Securities by Issuers and Affiliated Purchasers

The table below provides information with respect to recent repurchase of unvested shares of our common stock:

Period	Total Number of Shares Purchased[(1)]	Average Price Paid per Share	Total Number of Shares Purchased as part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Program
September 1 – September 30, 2020	—	—	—	—
October 1 – October 31, 2020	3,020	$1.62	—	—
November 1 – November 30, 2020	—	—	—	—

(1) All of the shares repurchased, as reflected in the table above, were repurchases of unvested shares of our common stock that had been issued upon early exercise of stock options. Upon termination of employment of a person holding unvested shares, we are entitled to repurchase the unvested shares.

Item 6. Selected Financial Data

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide this information.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. As discussed in the section titled "Special Note Regarding Forward Looking Statements," the following discussion and analysis contains forward looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

A discussion regarding our financial condition and results of operation for the year ended November 30, 2020 compared to the year ended November 30, 2019 is presented below. A discussion regarding our financial condition and results of operations for the year ended November 30, 2019 compared to the year ended November 30, 2018 is included under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our prospectus for our IPO, which was filed with the SEC pursuant to Rule 424(b) on July 24, 2020.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of small molecule therapies designed to modulate cellular protein levels as a novel treatment approach for cancer and immune disorders. Leveraging our extensive expertise in E3 ligases together with our proprietary DNA-encoded libraries, we have built DELigase, an integrated discovery platform to identify and advance novel drug candidates targeting E3 ligases, a broad class of enzymes that can modulate proteins within the cell. Our drug discovery approach is to either harness or inhibit the natural function of E3 ligases within the UPS to selectively decrease or increase cellular protein levels. Our wholly owned pipeline comprises targeted protein degraders of BTK, a B-cell signaling protein, and inhibitors of CBL-B, an E3 ligase that regulates T cell activation. Our lead drug candidate from our protein degradation portfolio, NX-2127, is an orally available BTK degrader for the treatment of relapsed or refractory B-cell malignancies. We expect to dose the first patient in a Phase 1 clinical trial for NX-2127 in the first quarter of 2021. Our second drug candidate from our protein degradation portfolio, NX-5948, is also an orally bioavailable BTK degrader for the treatment of relapsed or refractory B-cell malignancies and potentially autoimmune diseases. We anticipate commencing a Phase 1 trial for NX-5948 in the second half of 2021. Our lead drug candidate from our E3 ligase inhibitor portfolio, NX-1607, is an orally available CBL-B inhibitor for immuno-oncology indications. We expect to commence a Phase 1 clinical trial in the second half of 2021. We have two additional clinical candidates, NX-5948, an orally available BTK degrader, and DeTIL-0255, a drug-enhanced tumor infiltrating lymphocyte adoptive cellular therapy, for which we anticipate commencing Phase 1 clinical trials in the second half of 2021. All expected Phase 1 clinical trial commencements are based on calendar years. Beyond these preclinical programs, we are advancing additional drug discovery programs, either independently or through our established strategic collaborations with Sanofi and Gilead.

Collaboration and license agreements

Sanofi Collaboration and License Agreement

In December 2019, we entered into a strategic collaboration with Sanofi, which became effective in January 2020, and was subsequently expanded and amended in January 2021 (the Sanofi Agreement), to discover, develop and commercialize a pipeline of targeted protein degradation drugs for patients with challenging diseases in multiple therapeutic areas using our DELigase platform to identify small molecules designed to induce degradation of three specified initial drug targets. In January 2021, Sanofi exercised its option to expand the number of targets in the collaboration agreement from three to a total of five targets. Over time and subject to certain limitations, Sanofi may elect to replace the drug targets with other reserved targets.

Under the Sanofi Agreement, Sanofi has exclusive rights and is responsible for the clinical development, commercialization and manufacture of product candidates resulting from the collaboration while we retain the option to co-develop, co-promote and co-commercialize all product candidates in the United States directed to up to two targets under certain conditions. The collaboration excludes our current internal protein degradation programs

for which we retain all rights, and also excludes our future internal programs, provided that we have distinguished future programs as excluded from the scope of the collaboration.

For drug targets that are subject to the collaboration, we have primary responsibility for conducting preclinical research activities (including target validation, drug discovery, identification or synthesis) in accordance with the applicable research plan agreed to by the parties and established on a target-by-target basis. We are obligated to use commercially reasonable efforts to identify relevant target binders and CTMs in order to identify development candidates. Subject to certain exceptions, each party will bear its own costs in the conduct of such research. Sanofi will be responsible for any development and commercialization activities unless we exercise our co-development and co-promotion option. For those programs that we exercise our option to co-develop, co-promote and co-commercialize, we will be responsible for a portion of the U.S. development costs, and the parties will split U.S. profits and losses evenly and we will be eligible to receive royalties on ex-U.S. net sales and reduced milestone payments on such optioned products.

Upon signing the Sanofi Agreement, Sanofi paid us an upfront payment of $55.0 million, which was received in January 2020. Subsequently in January 2021, Sanofi paid us an additional $22.0 million to exercise its option to expand the number of targets beyond the initial targets included in the collaboration or exercises an option to extend the license term with respect to a particular target. As of November 30, 2020, we are eligible to receive up to approximately $2.5 billion in total payments based on certain additional fees, payments and the successful completion of certain research development, regulatory and sales milestones, as well as tiered royalties ranging from mid-single digit to low teen percentages on annual net sales of any commercial products that may result from the collaboration, subject to certain reductions and excluding sales in the United States of any products for which we exercise our option to co-develop and co-promote, for which we share profits and losses evenly.

We recognized collaboration revenue from the Sanofi Agreement of $5.7 million during the year ended November 30, 2020. As of November 30, 2020, there was $49.3 million of deferred revenue related to payments received by us under the Sanofi Agreement.

Gilead Collaboration, Option and License Agreement

In June 2019, we entered into a global strategic collaboration agreement with Gilead, which was amended in August 2019 (the Gilead Agreement), to discover, develop and commercialize a pipeline of targeted protein degradation drugs for patients with cancer and other challenging diseases using our DELigase platform to identify novel agents that utilize E3 ligases to induce degradation of five specified drug targets.

Under the Gilead Agreement, Gilead has the option to license drug candidates directed to up to five targets resulting from the collaboration and is responsible for the clinical development and commercialization of product candidates resulting from the collaboration. We retain the option to co-develop and co-promote, under a profit share structure, up to two product candidates in the United States under certain conditions. The collaboration excludes our current internal protein degradation programs for which we retain all rights, and also excludes our future internal programs, provided that we have distinguished future programs as excluded from the scope of the collaboration.

Over time, Gilead may elect to replace the initial drug targets with other drug targets. For drug targets that are subject to the collaboration, we are obligated to use commercially reasonable efforts to undertake a research program in accordance with a research plan agreed to by the parties and established on a target-by-target basis. We have primary responsibility under the agreement for performing preclinical research activities (including target validation, drug discovery, identification or synthesis) pursuant to a research plan. Each party will bear its own costs in the conduct of research activities. Gilead will be responsible for any development, commercialization and manufacturing activities, unless we exercise our co-development and co-promotion option. For those programs that we exercise our option to co-develop and co-promote, we and Gilead will split U.S. development costs as well as U.S. profits and losses evenly, and we will be eligible to receive royalties on ex-U.S. net sales and reduced milestone payments.

Pursuant to the Gilead Agreement, we received an upfront payment of $45.0 million, plus $3.0 million in additional fees As of November 30, 2020, we are eligible to receive up to approximately $2.3 billion in total additional payments based on certain additional fees, payments and the successful completion of certain preclinical,

clinical, development and sales milestones. In addition, we are eligible to receive tiered royalties from mid-single digit to low tens percentages on annual net sales from any commercial products directed to the optioned collaboration targets, subject to certain reductions and excluding sales in the United States of any products for which we exercise our option to co-develop and co-promote, for which we share profits and losses evenly. In February 2020, we achieved a research milestone, resulting in a $2.5 million additional payment, which we received in April 2020, and in May 2020, we recorded $1.0 million in additional fees related to a certain target reservation, which we received in June 2020. In November 2020, we recognized two research milestones, resulting in a $7.5 million additional payment, which we received in January 2021.

We recognized collaboration revenue from the Gilead Agreement of $12.1 million and $2.7 million during the years ended November 30, 2020 and 2019, respectively. As of November 30, 2020, there was $44.2 million of deferred revenue related to payments received by us under the Gilead Agreement.

Celgene Research and Collaboration Agreement

In September 2015, we entered into a strategic collaboration with Celgene Corporation (the Celgene Agreement and Celgene, respectively), with an initial research term of four years pursuant to which we received an upfront payment of $150.0 million. In addition, in September 2015, Celgene purchased 1,622,222 shares of our Series C redeemable convertible preferred stock at a price of $10.50 per share, resulting in net proceeds of $17.0 million. In January 2019, Celgene and Bristol-Myers Squibb Company (BMS) entered into a definitive merger agreement pursuant to which Celgene agreed to be acquired by BMS. Based on our request for notification of the future disposition of our agreement, in June 2019, Celgene notified us that it was terminating the Celgene Agreement. Upon termination of the Celgene Agreement in June 2019, any rights that Celgene had under the agreement reverted to us and no termination payments were due or payable.

We recognized no collaboration revenue from the Celgene Agreement during the year ended November 30, 2020. During the years ended November 30, 2019, we recognized $28.4 million in collaboration revenue under the Celgene Agreement. As of November 30, 2020, there was no deferred revenue related to payments received by us under the Celgene Agreement.

Formation of DeCART Therapeutics Inc.

In June 2020, we established DeCART Therapeutics Inc. (DeCART), a wholly owned subsidiary, with an investment of $3.0 million and granted DeCART a license to three of our compounds, including NX-0255, for drug-enhanced isolation of T cells nonexclusively with respect to one chimeric antigen receptor T cell (CAR-T) therapy target and exclusively with respect to three novel CAR-T therapy targets. DeCART expects to combine our protein modulation technologies with novel CAR-T therapies to address current immunotherapy limitations and improve outcomes for patients with cancer, and subsequently seek equity financing from third parties and become an independent operating entity. DeCART has granted to its external founders stock options to purchase shares of DeCART's common stock equal to 14% of the fully diluted capitalization of DeCART. Following either the third-party funding or the exercise of the stock option grants, DeCART will no longer be a wholly owned subsidiary.

Financial Overview

Since the commencement of our operations, we have devoted substantially all of our resources to conducting research and development activities, establishing and maintaining our intellectual property portfolio, establishing our corporate infrastructure, raising capital and providing general and administrative support for these operations. We have funded our operations to date primarily from proceeds received under collaboration and license agreements with Sanofi, Gilead, and Celgene and the issuance and sale of common and redeemable convertible preferred stock. We do not expect to generate product revenue unless and until we successfully develop and obtain approval for the commercialization of a product candidate, and we cannot assure you that we will ever generate significant revenue or profits.

Since inception, we have generally incurred significant losses and negative cash flows from operations. We incurred net losses of $43.2 million and $21.7 million during the years ended November 30, 2020 and 2019,

respectively. As of November 30, 2020, we had an accumulated deficit of $103.7 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations.

We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. We expect our expenses will increase substantially as we advance our product candidates through preclinical and into clinical development; enter advanced clinical development and scale up external manufacturing capabilities to supply clinical trials; apply our DELigase platform to advance additional product candidates and expand the capabilities of our platform; seek marketing approvals for any product candidates that successfully complete clinical trials; ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval; expand, maintain and protect our intellectual property portfolio; and hire additional clinical, regulatory, manufacturing, quality assurance and scientific personnel. Furthermore, we expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other administrative and professional services expenses.

Our net losses and cash flows may fluctuate significantly from period to period, depending on, among other things, variations in the level of expense related to the ongoing development of our product candidates, our DELigase platform or future development programs; the delay, addition or termination of clinical trials; and the execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under such arrangements.

As of November 30, 2020, we had $372.0 million in cash, cash equivalents and investments. In July 2020, we closed our IPO, and issued 12,550,000 shares of our common stock (including the exercise by the underwriters of their option to purchase an additional 1,550,000 shares of common stock in August 2020) at a price to the public of $19.00 per share for net proceeds of approximately $218.1 million, after deducting underwriting discounts and commissions of $16.7 million and expenses of $3.6 million. We expect that our existing cash, cash equivalents and investments are sufficient to fund our operations for at least the next 12 months. See the section titled "—Liquidity and Capital Resources" for more information. To finance our operations beyond that point, we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

We are subject to risks and uncertainties as a result of the current COVID-19 pandemic. The COVID-19 pandemic, which is impacting worldwide economic activity, 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 shutdowns that may be requested or mandated by governmental authorities. While the impact of the COVID-19 pandemic to our current operations has been minimal as we have only recently commenced clinical development of our first product candidate, the extent to which the COVID-19 pandemic will impact our business, financial condition, liquidity and results of operations in the future will depend on future developments that are highly uncertain and cannot be predicted at this time.

Components of Operating Results

Collaboration revenue

We have no products approved for commercial sale and to date have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future.

Our revenue to date has been generated from payments received pursuant to collaboration and license arrangements with strategic partners. Collaboration revenue consists of revenue received from upfront, milestone and contingent payments received from our collaborators. Prior to December 1, 2019, we recognized revenue from

upfront payments over the term of our estimated period of performance using either a straight-line or input/proportional performance approach, depending on the agreement, in accordance with Accounting Standards Codification (ASC) 605, *Revenue Recognition*. Revenue related to the upfront payment received pursuant to the Celgene Agreement was recognized using a straight-line basis. Effective December 1, 2019, we began recognizing revenue from upfront payments over the contract term using a cost-based input method under Topic 606, *Revenue from Contracts with Customers*. Revenue related to the upfront payments received pursuant to the Gilead Agreement was recognized using the input/proportional performance approach prior to December 1, 2019 and the cost-based input method beginning December 1, 2019. There would have been no difference between the revenue recognized under Topic 606 and the revenue recognized under ASC 605 for the Gilead Agreement. Revenue related to the upfront payment received pursuant to the Sanofi Agreement was recognized using the cost-based input method. The material right to the two additional targets under the Sanofi Agreement was accounted for using the practical alternative and the expected consideration to be received on the options was included for revenue allocation. We expect to continue recognizing revenue from upfront payments related to our collaboration agreements using the cost-based input method in the foreseeable future.

In addition to receiving upfront payments, we may also be entitled to milestones and other contingent payments upon achieving predefined objectives. If a milestone is considered probable of being reached, and if it is probable that a significant revenue reversal would not occur, the associated milestone amount would also be included in the transaction price.

We expect that any collaboration revenue we generate from our current collaboration and license agreements, and from any future collaboration partners, will fluctuate in the future as a result of the timing and amount of upfront, milestones and other collaboration agreement payments and other factors.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the discovery and development of our product candidates. We expense both internal and external research and development expenses to operations in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. We track the external research and development costs incurred for each of our product candidates.

Internal research and development costs include:

- payroll and personnel expenses, including benefits, stock-based compensation and travel expenses, for our research and development functions; and
- depreciation of research and development equipment, allocated overhead and facilities-related expenses.

External research and development expenses consist primarily of costs incurred for the development of our product candidates and may include:

- fees paid to third parties such as consultants, contractors and contract research organizations to conduct our discovery programs, preclinical studies and clinical trials;
- costs to acquire, develop and manufacture supplies for preclinical studies and clinical trials, including fees paid to third parties such as CMOs; and
- expenses related to laboratory supplies and services.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities to advance our product candidates into and through our preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our product candidate pipeline. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. To the extent that our product candidates advance and continue to advance into clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our

product candidates, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, manufacturing capability, competition with other products and commercial viability. As a result of these variables, we are unable to determine when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of payroll and personnel expenses, including benefits and stock-based compensation, facilities-related expenses and professional fees for legal, consulting, and audit and tax services. We expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to build our infrastructure, increase our headcount and operate as a public company. This may include expenses related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on a national securities exchange, additional insurance, investor relations activities and other administrative and professional services. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Interest and other income, net

Interest and other income, net primarily consists of interest earned on our cash, cash equivalents and investments. We expect interest income to vary each reporting period depending on our average bank deposit, money market fund, and investment balances during the period and market interest rates.

Provision (benefit) for income taxes

The provision for income taxes primarily consists of reserves for unrecognized tax benefits and minimum state taxes. The benefit for income taxes consists of a discrete tax benefit from an adjustment to the NOL deferred tax asset and valuation allowance. We have generated NOLs since inception and have established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding the realization of such assets.

Critical Accounting Policies and Estimates

Our accounting policies are more fully described in Note 2 of the consolidated financial statements to this Annual Report on Form 10-K. As disclosed in Note 2, the preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

Revenue Recognition

Prior to December 1, 2019, we recognized revenue in accordance with the Financial Accounting Standards Board's (FASB) Accounting Standards Codification (ASC) 605, *Revenue Recognition*. Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

We evaluate multiple element arrangements to determine if each deliverable represents a separate unit of accounting based on the following criteria:

- Delivered item or items have value to the customer on a standalone basis, and
- If the arrangement includes a general right of return relative to the delivered item or items, delivery or performance of the undelivered item or items is considered probable and substantially in our control.

The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price methodology in accordance with the selling price hierarchy, which includes vendor-specific objective evidence (VSOE) of selling price, if available, or third-party evidence of selling price if VSOE is not available, or the best estimate of selling price, if neither VSOE nor third-party evidence is available. The provisions of ASC 605 are then applied to each unit of accounting to determine the appropriate revenue recognition. In the event that a deliverable of a multiple element arrangement does not represent a separate unit of accounting, primarily because a deliverable does not provide value on a standalone basis, we recognize revenue from the combined unit of accounting using the input/proportional performance approach as research is delivered or on a straight-line basis over the estimated period of performance when there is no discernable pattern of performance.

We evaluate potential milestone payments associated with research and development arrangements in accordance with ASC 605-28, *Milestone Method.* Under the milestone method, we may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered a substantive milestone. We evaluate each contingent payment on an individual basis to determine whether they are considered substantive milestones, specifically reviewing factors such as the degree of certainty in achieving the milestone, the research and development risk and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. Revenues from milestones, if they are nonrefundable and deemed substantive, are recognized upon achievement of the milestones.

To the extent that non-substantive milestones are achieved, and we have remaining deliverables, milestone payments are deferred and recognized as revenue over the estimated remaining performance period using the appropriate measure of progress as determined for each agreement. We recognize revenue associated with the non-substantive milestones upon achievement of the milestone if we have no remaining deliverables. During the years ended November 30, 2019, no milestone payments were received, no milestone revenues were recognized and no milestones were considered substantive.

Effective December 1, 2019, we adopted Topic 606, *Revenue from Contracts with Customers* using the modified retrospective method, which was only applied to contracts that were not completed as of the adoption date. As of the adoption date, we had only one contract, a collaboration agreement with Gilead, not completed. Under Topic 606, we recognize revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform 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) we satisfy a performance obligation.

At contract inception, we assess the goods or services promised within each contract, whether each promised good or service is distinct, and determines those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

We enter into collaboration agreements under which we may obtain upfront payments, milestone payments, royalty payments and other fees. Promises under these arrangements may include research licenses, research services, including selection campaign research services for certain replacement targets, the obligation to share information during the research and the participation of alliance managers and in joint research committees, joint patent committees and joint steering committees. We assess these promises within the context of the agreements to determine the performance obligations.

Research and collaboration licenses: If a license is determined to be distinct from the other promises identified in the arrangement, we recognize revenue from upfront payments allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, upfront payments. We evaluate the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes research, development, or regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. We use the most likely amount method for research, development and regulatory milestone payments. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. If it is probable that a significant revenue reversal would not occur, the associated milestone amount is included in the transaction price.

Sales-based milestones and royalties: For arrangements that include sales-based milestone or royalty payments based on the level of sales, and in which the license is deemed to be the predominant item to which the sales-based milestone or royalties relate to, we recognize revenue in the period in which the sales-based milestone is achieved and in the period in which the sales associated with the royalty occur. To date, we have not recognized any sales-based milestone or royalty revenue resulting from our collaboration arrangements.

Customer options: Customer options, such as options granted to allow a licensee to extend a license or research term, to select additional research targets or to choose to research, develop and commercialize licensed compounds are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the original contract, we allocate the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

Deferred revenue, which is a contract liability, represents amounts received by us for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the consolidated balance sheet date based on the estimated performance period of the underlying performance obligation. The noncurrent portion of deferred revenue represents amounts to be recognized after one year through the end of the performance period of the performance obligation.

All revenue was derived from customers located in the United States during the years ended November 30, 2020 and 2019.

Stock-Based Compensation

We account for stock-based compensation using a fair value-based method, which requires the recognition of compensation expense for costs related to all stock-based payments including stock options and purchase rights under the employee stock purchase plan. We estimate the fair value of stock-based payment awards on the date of grant using the Black-Scholes option pricing model. The model requires management to make a number of assumptions including expected volatility, expected term, risk-free interest rate and expected dividend yield. Prior to our IPO, the fair value of our common stock was determined by our board of directors with assistance from management and an independent third party valuation firm, using significant judgment and several factors including important developments in our operations, sales of preferred stock and the lack of liquidity of the common stock. Subsequent to the IPO, we determine the fair value using the market closing price of our common stock on the date of grant.

For stock-based payments with service conditions only, we use the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period. Subsequent to the adoption of ASU 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* as of December 1, 2019, stock-based compensation expense for non-employee stock-based awards is also measured based on the grant date fair value with the estimated fair value expensed over the period for which the non-employee is required to provide service in exchange for the award. For stock-based payments with performance conditions, we evaluate the probability of achieving performance conditions at each reporting date. We begin to recognize compensation cost using an accelerated attribution method when it is deemed probable that the performance condition will be met. We account for forfeitures as they occur.

Income taxes

We account for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when in management's estimate, it is more likely than not, that the deferred tax assets will not be recovered.

Financial statement effects of uncertain tax positions are recognized when it is more likely than not, based on the technical merits of the position, that it will be sustained upon examination. It is our policy to include penalties and interest expense related to income taxes as a component of the provision for income taxes.

Results of Operations

Comparison of the years ended November 30, 2020 and 2019

	Year ended November 30,		2020 vs 2019	
(in thousands)	**2020**	**2019**	**$**	**%**
Collaboration revenue[(1)]	$ 17,820	$ 31,115	$ (13,295)	-42.7%
Operating expenses:				
Research and development	66,494	45,025	21,469	47.7%
General and administrative	16,309	8,326	7,983	95.9%
Total operating expenses	82,803	53,351	29,452	55.2%
Loss from operations	(64,983)	(22,236)	(42,747)	192.2%
Interest income and other income	1,206	776	430	55.4%
Loss before income taxes	(63,777)	(21,460)	(42,317)	197.2%
(Benefit) provision for income taxes	(20,535)	239	(20,774)	-8692.1%
Net loss	$ (43,242)	$ (21,699)	$ (21,543)	99.3%

(1) Collaboration revenue for the years ended November 30, 2020 and 2019 includes related party revenue of $0 and $28.4 million, respectively.

Collaboration revenue

Our collaboration revenue for the years ended November 30, 2020 and 2019 is summarized as follows:

	Year ended November 30,		2020 vs 2019	
(in thousands)	2020	2019	$	%
Celgene	$ —	$ 28,420	$ (28,420)	-100.0%
Gilead	12,149	2,695	9,454	350.8%
Sanofi	5,671	—	5,671	100.0%
Total collaboration revenue	$ 17,820	$ 31,115	$ (13,295)	-42.7%

Our collaboration revenue decreased by $13.3 million for the year ended November 30, 2020 compared with the year ended November 30, 2019. The decrease in collaboration revenue was primarily attributable to the termination of the Celgene Agreement in June 2019, offset by an increase in revenue recognized related to the Gilead Agreement and the revenue related to the Sanofi Agreement.

Research and development expenses

Our research and development expenses for the years ended November 30, 2020 and 2019 are summarized as follows:

	Year ended November 30,		2020 vs 2019	
(in thousands)	2020	2019	$	%
Compensation and related personnel costs	$ 23,749	$ 16,662	$ 7,087	42.5%
Supplies and contract research	24,190	16,449	7,741	47.1%
Preclinical activities and contract manufacturing	8,773	3,532	5,241	148.4%
Facility and other costs	9,782	8,382	1,400	16.7%
Total research and development expenses	$ 66,494	$ 45,025	$ 21,469	47.7%

Our research and development expenses increased by $21.5 million, or 47.7%, during the year ended November 30, 2020, compared to the year ended November 30, 2019. The increase was primarily related to an increase of $7.7 million in supplies and contract research attributable to increases in our preclinical development activities and drug discovery research. There was also an increase of $7.1 million in compensation and related personnel costs attributable to an increase in headcount and higher non-cash stock-based compensation expense due to additional stock awards granted since November 30, 2019. Preclinical activities and contract manufacturing costs increased by $5.2 million, primarily due to preparation for upcoming clinical programs for our lead drug candidates.

General and administrative expenses

Our general and administrative expenses increased by $8.0 million, or 95.9%, during the year ended November 30, 2020, compared to the year ended November 30, 2019. The increase was primarily related to an increase of $4.0 million in compensation related expenses attributable to a higher headcount and non-cash stock-based compensation expense. We also had an increase of $1.8 million in legal and accounting expenses mainly related to external audit and legal fees and an increase of $1.9 million in consultant, insurance and other professional service expenses primarily related to becoming a public company.

Interest and other income, net

Interest and other income, net was $1.2 million and $0.8 million for the years ended November 30, 2020 and 2019, respectively. The increase was primarily related to interest received as part of the tax refund for a carryback claim that we filed in April 2020 in connection with the CARES Act. Other than the interest earned on tax refund, interest and other income, net in all periods is mainly related to interest earned on our deposits, money market funds and investments.

Provision (benefit) for income taxes

The provision for income taxes was a benefit of $20.5 million and an expense of $0.2 million during the years ended November 30, 2020 and 2019, respectively, and was related to a discrete tax benefit, which consists of carryback claims and the reversal of the uncertain tax liability related to research and development tax credits as a result of the CARES Act that was enacted on March 27, 2020 in response to the COVID-19 pandemic.

Liquidity and Capital Resources

Source of liquidity

On July 23, 2020, our registration statement on Form S-1 (File No. 333-239651) relating to our IPO of common stock became effective. The IPO closed on July 28, 2020 at which time we issued 11,000,000 shares of our common stock at a price to the public of $19.00 per share. In addition, the underwriters exercised their option to purchase an additional 1,550,000 shares of our common stock on July 31, 2020, and this transaction closed on August 4, 2020. Net proceeds from the IPO and the transaction with the underwriters were approximately $218.1 million, after deducting underwriting discounts and commissions of $16.7 million and expenses of $3.6 million.

To date, our operations have been funded through the issuance of common and redeemable convertible preferred stock and proceeds from collaboration agreements. We do not have any products approved for sale, and we have not generated any revenue from product sales. As of November 30, 2020, we had $372.0 million in cash, cash equivalents and investments.

In March 2020, we closed a sale of our Series D redeemable convertible preferred stock that resulted in net proceeds of $119.9 million.

In December 2019, we entered into the Sanofi Agreement, pursuant to which we received an upfront payment of $55.0 million in January 2020. Subsequently in January 2021, Sanofi paid us an additional $22.0 million to exercise its option to expand the number of targets beyond the initial targets included in the collaboration. In fiscal 2020, we received $3.5 million under the Gilead Agreement for milestones and additional fees. Subsequently in January 2021, we received an additional $7.5 million from Gilead for additional milestones.

Funding requirements

We expect that our existing cash, cash equivalents and investments are sufficient to continue operating activities for at least the next 12 months. We will need substantial additional funding to support our continuing operations and pursue our long-term business plan. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated pre-clinical studies and clinical trials.

Our future funding requirements will depend on many factors, including the following:

- the progress, costs and results of our planned Phase 1 clinical trials for our lead product candidates NX-2127 and NX-1607 and other drug candidates, and any future clinical development of such product candidates;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- the number and development requirements of other product candidates that we pursue;
- the scope of, and costs associated with, future advancements to our DELigase platform;
- the success of our collaborations with Sanofi, Gilead and any other collaborations we may establish;

- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our ability to establish additional collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates.

If adequate funds are not available at favorable terms, we may be required to reduce operating expenses, delay or reduce the scope of our product development and commercial expansion programs, obtain funds through arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise seek to develop or commercialize ourselves, or cease operations. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash flows

The following table summarizes our cash flows during the periods indicated:

	Year Ended November 30,	
(in thousands)	**2020**	**2019**
Cash (used in) provided by operating activities	$ (80)	$ 601
Cash (used in) provided by investing activities	(254,404)	8,498
Cash provided by financing activities	339,024	126
Net increase in cash, cash equivalents and restricted cash	$ 84,540	$ 9,225

Operating activities

Net cash used in operating activities was $0.1 million for the year ended November 30, 2020 and consisted of a decrease in net assets of $36.4 million and non-cash adjustments of $6.8 million, offset by our net loss of $43.2 million. The decrease in net assets consisted primarily of an increase in deferred revenue of $48.2 million related to proceeds received pursuant to the Sanofi Agreement and offset by revenue recognized pursuant to the Sanofi Agreement and the Gilead Agreement. The decrease in net assets was offset by an increase in contract assets of $7.5 related to unbilled revenue for Gilead milestones and an increase in income tax receivables of $3.9 million related to NOL carryback claims as a result of the CARES Act. Non-cash adjustments primarily consisted of stock-based compensation expenses of $4.3 million and depreciation and amortization expenses of $2.2 million.

Net cash provided by operating activities was $0.6 million for the year ended November 30, 2019 and consisted of a decrease in net assets of $19.5 million and non-cash adjustments of $2.8 million, offset by our net loss of $21.7 million. The decrease in net assets consisted primarily of an increase in deferred revenue of $16.9 million related to $48.0 million in proceeds received pursuant to the Gilead Agreement and offset by $31.1 million in revenue recognized pursuant to the Celgene Agreement and the Gilead Agreement and an increase in accrued and other liabilities of $2.4 million primarily related to an increase in accrued compensation from higher incentive compensation. Non-cash adjustments primarily consisted of depreciation and amortization expenses of $2.4 million

Investing activities

Net cash used in investing activities was $254.4 million for the year ended November 30, 2020 and consisted primarily of the purchase of investments of $275.2 million and purchases of property and equipment of $4.6 million, offset by the maturity of investments of $25.4 million.

Net cash provided by investing activities was $8.5 million for the year ended November 30, 2019 and consisted primarily of maturities of investments of $19.5 million, offset by the purchase of investments of $9.4 million.

Financing activities

Net cash provided by financing activities was $339.0 million for the year ended November 30, 2020 and consisted primarily of net proceeds from issuance of common stock related to our IPO in July 2020 and the sale of our Series D redeemable convertible preferred stock in March 2020.

Net cash provided by financing activities was $0.1 million for the year ended November 30, 2019 and consisted primarily of proceeds from the exercise of stock options of $0.1 million.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of November 30, 2020:

	Payments due by period				
(in thousands)	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations	$ 3,272	$ 6,803	$ 5,034	$ —	$ 15,109
Total contractual obligations	$ 3,272	$ 6,803	$ 5,034	$ —	$ 15,109

In addition, we enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice. These payments are not included in the table above.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements as defined in Item 303 of Regulation S-K.

Emerging Growth Company and Smaller Reporting Company Status

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act). We will remain an EGC until the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when a company has more than $700.0 million in market value of its stock held by non-affiliates as of the prior May 31, has been a public company for at least 12 months and has filed one annual report on Form 10-K.

Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, the information we provide may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an EGC we intend to rely on such exemptions, we are not required to, among other things: (i) provide an auditor's attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act; (ii) provide all of the compensation disclosure that may be required of non-EGCs under the Dodd-Frank Wall Street Reform and Consumer Protection Act; (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis); and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million as of the prior May 31 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 as of the prior May 31 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 of the prior May 31. If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company 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 EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Nurix Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nurix Therapeutics, Inc. and its subsidiary (the "Company") as of November 30, 2020 and 2019, and the related consolidated statements of operations, of comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of November 30, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 16, 2021

We have served as the Company's auditor since 2014.

NURIX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	November 30,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 119,356	$ 34,816
Short-term investments	161,792	2,904
Contract assets	7,500	—
Income tax receivable	3,846	—
Prepaid expenses and other current assets	5,940	1,634
Total current assets	298,434	39,354
Long-term investments	90,890	506
Property and equipment, net	6,672	3,871
Restricted cash	170	170
Other assets	177	147
Total assets	$ 396,343	$ 44,048
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,412	$ 1,598
Accrued and other current liabilities	8,328	4,927
Deferred revenue, current	32,799	9,612
Total current liabilities	44,539	16,137
Deferred revenue, net of current portion	60,685	35,693
Other long-term liabilities	850	1,737
Total liabilities	106,074	53,567
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, $0.001 par value— 0 and 48,441,667 shares authorized as of November 30, 2020 and November 30, 2019, respectively; 0 and 12,813,887 shares issued and outstanding (liquidation value—$0 and $48,383) as of November 30, 2020 and November 30, 2019, respectively	—	48,195
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value— 10,000,000 and 0 shares authorized as of November 30, 2020 and November 30, 2019, respectively; 0 shares issued and outstanding as of November 30, 2020 and November 30, 2019, respectively	—	—
Common stock, $0.001 par value— 500,000,000 and 65,000,000 shares authorized as of November 30, 2020 and November 30, 2019, respectively; 38,864,872 and 3,595,334 shares issued and outstanding as of November 30, 2020 and November 30, 2019, respectively	39	4
Additional paid-in-capital	393,841	2,740
Accumulated other comprehensive income (loss)	87	(2)
Accumulated deficit	(103,698)	(60,456)
Total stockholders' equity (deficit)	290,269	(57,714)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 396,343	$ 44,048

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

NURIX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended November 30,	
	2020	**2019**
Collaboration revenue[(1)]	$ 17,820	$ 31,115
Operating expenses:		
Research and development	66,494	45,025
General and administrative	16,309	8,326
Total operating expenses	82,803	53,351
Loss from operations	(64,983)	(22,236)
Interest and other income, net	1,206	776
Loss before income taxes	(63,777)	(21,460)
(Benefit) provision for income taxes	(20,535)	239
Net loss	$ (43,242)	$ (21,699)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.76)	$ (6.59)
Weighted-average number of shares outstanding, basic and diluted	15,673,424	3,292,514

(1) Collaboration revenue for the years ended November 30, 2020, and 2019 includes related party revenue of $0 and $28.4 million, respectively.

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

NURIX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended November 30,	
	2020	**2019**
Net loss	$ (43,242)	$ (21,699)
Other comprehensive income:		
Unrealized gain on available-for-sale investments	89	2
Total comprehensive loss	$ (43,153)	$ (21,697)

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

NURIX THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance as of November 30, 2018	12,813,887	$ 48,195	3,452,653	$ 4	$ 1,910	$ (4)	$ (38,757)	$ (36,847)
Exercise of stock options	—	—	158,474	—	104	—	—	104
Repurchase of unvested early exercised stock options	—	—	(15,793)	—	—	—	—	-
Vesting of early-exercised stock options	—	—	—	—	216	—	—	216
Stock-based compensation	—	—	—	—	510	—	—	510
Unrealized gain on available-for-sale investments	—	—	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	(21,699)	(21,699)
Balance as of November 30, 2019	12,813,887	48,195	3,595,334	4	2,740	(2)	(60,456)	(57,714)
Issuance of Series D redeemable convertible preferred stock at $12.75 per share, net of issuance costs of $336	9,431,364	119,914	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock	(22,245,251)	(168,109)	22,245,251	22	168,087	—	—	168,109
Issuance of common stock upon initial public offering, net offering costs of $20,304	—	—	12,550,000	13	218,134	—	—	218,147
Exercise of stock options	—	—	479,156	—	450	—	—	450
Repurchase of unvested early exercised stock options	—	—	(4,869)	—	—	—	—	—
Vesting of early-exercised stock options	—	—	—	—	129	—	—	129
Stock-based compensation	—	—	—	—	4,301	—	—	4,301
Unrealized gain on available-for-sale investments	—	—	—	—	—	89	—	89
Net loss	—	—	—	—	—	—	(43,242)	(43,242)
Balance as of November 30, 2020	—	$ —	38,864,872	$ 39	$ 393,841	$ 87	$ (103,698)	$ 290,269

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

NURIX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended November 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (43,242)	$ (21,699)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	2,180	2,354
Stock-based compensation	4,301	510
Net amortization (accretion) of premium (discount) on investments	273	(109)
Changes in operating assets and liabilities:		
Contract assets	(7,500)	—
Income tax receivable	(3,846)	—
Prepaid expenses and other assets	(3,941)	(15)
Accounts payable	1,234	302
Deferred revenue	48,179	16,885
Accrued and other liabilities	2,282	2,373
Net cash (used in) provided by operating activities	(80)	601
Cash flows from investing activities		
Purchases of investments	(275,224)	(9,351)
Maturities of investments	25,373	19,500
Purchases of property and equipment	(4,553)	(1,651)
Net cash (used in) provided by investing activities	(254,404)	8,498
Cash flows from financing activities		
Proceeds from issuance of common stock upon initial public offering, net of offering costs	218,147	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	119,914	—
Proceeds from exercise of stock options	970	142
Repurchase of unvested early exercised stock options	(7)	(16)
Net cash provided by financing activities	339,024	126
Net increase in cash, cash equivalents and restricted cash	84,540	9,225
Cash, cash equivalents and restricted cash at beginning of period	34,986	25,761
Cash, cash equivalents and restricted cash at end of period	$ 119,526	$ 34,986
Supplementary disclosures of cash flow information:		
Cash paid for income taxes	$ 1	$ 1
Supplemental disclosures of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable and accrued liabilities	$ 580	$ 152
Vesting of early exercised stock options	$ 129	$ 216
Conversion of redeemable convertible preferred stock into common stock upon closing of initial public offering	$ 168,109	$ —

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

NURIX THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Description of Business

Nurix Therapeutics, Inc. (the Company) previously known as Nurix, Inc., was incorporated in the state of Delaware on August 27, 2009 and is headquartered in San Francisco, California. The Company is a biopharmaceutical company focused on the discovery, development and commercialization of small molecule therapies designed to modulate cellular protein levels as a novel treatment approach for cancer and immune disorders. Leveraging the Company's expertise in E3 ligases together with its proprietary DNA-encoded libraries, the Company has built DELigase, an integrated discovery platform to identify and advance novel drug candidates targeting E3 ligases, a broad class of enzymes that can modulate proteins within the cell. The Company's drug discovery approach is to either harness or inhibit the natural function of E3 ligases within the ubiquitin-proteasome system to selectively decrease or increase cellular protein levels to treat disease.

The Company wholly owns a subsidiary, DeCART Therapeutics Inc. (DeCART), which was incorporated in the state of Delaware on June 22, 2020 and holds a license to three of the Company's compounds, including NX-0255, for drug-enhanced isolation of T cells nonexclusively with respect to one chimeric antigen receptor T cell (CAR-T) therapy target and exclusively with respect to three novel CAR-T therapy targets.

Initial Public Offering

On July 23, 2020, the Company's registration statement on Form S-1 (File No. 333-239651) relating to its initial public offering (IPO) of common stock became effective. The IPO closed on July 28, 2020 at which time the Company issued 11,000,000 shares of its common stock at a price to the public of $19.00 per share. In addition, the underwriters exercised their option to purchase an additional 1,550,000 shares of the Company's common stock on July 31, 2020, and this transaction closed on August 4, 2020. Immediately prior to the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 22,245,251 shares of common stock. Net proceeds from the IPO, including the exercise of the underwriters' option to purchase additional shares, were $218.1 million, after deducting underwriting discounts and commissions of $16.7 million and expenses of $3.6 million.

Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding. In connection with the closing of the IPO, the Company restated its Restated Certificate of Incorporation to change the authorized capital stock to 500,000,000 shares designated as common stock, and 10,000,000 shares designated as preferred stock, all with a par value of $0.001 per share.

Liquidity and Management Plans

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company's operations have historically been financed through the issuance of common and redeemable convertible preferred stock and proceeds received under the Company's collaboration and license agreements. Since inception, the Company has generally incurred significant losses and negative net cash flows from operations. During the year ended November 30, 2020, the Company incurred a net loss of $43.2 million and had negative net cash flows from operating activities of $0.1 million. The Company had an accumulated deficit of $103.7 million as of November 30, 2020 and will require substantial additional capital for research and development activities. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. As of November 30, 2020, the Company had cash and cash equivalents of $119.4 million and working capital of $253.9 million.

Management believes that its cash, cash equivalents and investments are sufficient to continue operating activities for at least 12 months following the issuance date of these consolidated financial statements. Future capital requirements will depend on many factors, including the timing and extent of spending on research and development and payments the Company may receive under its collaboration agreements with Sanofi S.A. (Sanofi) and Gilead Sciences, Inc. (Gilead) or future collaboration agreements, if any. There can be no assurance that, in the event the Company requires additional financing, such financing will be available at terms acceptable to the Company if at all. If additional capital is not available, failure to generate sufficient cash flows from operations, raise additional capital and reduce discretionary spending could have a material adverse effect on the Company's ability to achieve its intended business objectives.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Nurix Therapeutics, Inc. and its wholly owned subsidiary, DeCART. All intercompany balances and transactions have been eliminated in consolidation.

Reverse Stock Split

On July 17, 2020, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock and redeemable convertible preferred stock, each on a 1-for-3 basis (reverse stock split). The par value and authorized shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in the consolidated financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to the useful lives of long-lived assets, the measurement of stock-based compensation, accruals for research and development activities, income taxes and revenue recognition. The Company bases its estimates on historical experience and on other relevant assumptions that are reasonable under the circumstances. Actual results could materially differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and investments. The Company's investments consist of debt securities issued by highly rated corporate entities, the U.S. federal government or state and local governments. The Company's exposure to any individual corporate entity is limited by policy. Deposits may, at times, exceed federally insured limits, but minimal credit risk exists. The Company invests its cash equivalents in highly rated money market funds. The Company has not experienced any credit losses on its deposits of cash and cash equivalents.

Other Risks and Uncertainties

The Company is subject to a number of risks similar to other early-stage biopharmaceutical companies, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on its future financial position or results of operations: risks related to the successful discovery and development of its product candidates, ability to raise additional capital, development of new technological innovations by its competitors and delay or inability to obtain drug substance and finished drug product from the Company's third-party contract manufacturers necessary for the Company's product candidates, including due to the impact of the current coronavirus (COVID-19) pandemic, protection of intellectual property rights, litigation or claims against the Company based on intellectual property rights and regulatory clearance and market acceptance for any of the Company's products candidates for which the Company receives marketing approval.

Moreover, the current COVID-19 pandemic, which is impacting worldwide economic activity, poses the risk that the Company or its employees, contractors, suppliers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The extent to which the COVID-19 pandemic may directly or indirectly impact the Company's financial statements is highly uncertain and subject to change. Management considered the potential impact of the COVID-19 pandemic on its estimates and assumptions and there was not a material impact to the Company's consolidated financial statements as of and for the year ended November 30, 2020; however, actual results could differ from those estimates and there may be changes to management's estimates in future periods.

The Company relies on single source manufacturers and suppliers for the supply of its product candidates. Disruption from these manufacturers or suppliers would have a negative impact on the Company's business, financial position and results of operations.

Segments

The Company operates and manages its business as one reportable and operating segment. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews consolidated financial information on a company-wide basis for purposes of allocating resources and assessing financial performance.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents, which consist primarily of money market funds, are stated at fair value.

Cash, cash equivalents and restricted cash as reported within the consolidated statements of cash flows as of November 30, 2020 and 2019 consisted of the following (in thousands):

	November 30,	
	2020	2019
Cash and cash equivalents	$ 119,356	$ 34,816
Restricted cash	170	170
Cash, cash equivalents and restricted cash	$ 119,526	$ 34,986

Restricted Cash

The Company had $170,000 of restricted cash recorded as a non-current asset as of November 30, 2020 and 2019. Restricted cash consisted of $100,000 that serves as collateral for a business credit card account and $70,000 for a letter of credit required under a facility operating lease executed in 2014. These balances are included within the cash, cash equivalents and restricted cash balance in the accompanying consolidated statements of cash flows.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash equivalents, investments, accounts payable and accrued liabilities included in the Company's consolidated financial statements approximate their fair value due to short maturities or the nature of the financial instruments.

Investments

Investments consist of money market funds, U.S. Treasuries, corporate debt securities, U.S. government agency securities, corporate commercial paper and municipal securities. All of the Company's investments are classified as available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term investments or long-term investments. Management determines the appropriate classification of the investments at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. Investments with contractual maturities greater than 12 months are considered long-term investments.

Unrealized gains and losses on available-for-sale investments are reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit). Investments are regularly reviewed for other-than-temporary declines in fair value. The review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of investments in an unrealized loss position, the severity and duration of the unrealized losses, and whether it is more likely than not that the Company will be required to sell the investments before the recovery of their amortized cost basis. The cost of investments sold is based on the specific identification method.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Major improvements are capitalized, while maintenance and repairs are expensed when incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. The useful life of laboratory equipment, computer equipment, furniture and fixtures and software is generally three years. Tenant improvements are depreciated over the shorter of the lease term or the estimated useful life of the improvements. When assets are retired or disposed of, the cost together with related accumulated depreciation is removed from the Company's accounts and the resulting gain or loss is reflected in the Company's statements of operations.

Internal-Use Software Development Costs

The Company capitalizes qualifying costs incurred during the application development stage related to software developed for internal-use and amortize them over the estimated useful life of three years. Amortization of such costs begins when the project is substantially complete and ready for its intended use. Capitalized software development costs are classified as property and equipment, net on the balance sheet. The Company expenses costs incurred related to the planning and post-implementation phases of development as incurred.

Long-Lived Assets

Long-lived assets, such as property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. There were no such impairment losses during the years ended November 30, 2020 and 2019.

Deferred Offering Costs

The Company capitalizes within other assets certain legal, accounting and other third-party fees that are directly related to the Company's in-process equity financings, including the IPO, until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the carrying value of redeemable convertible preferred stock or, for issuances of common stock, in stockholder's equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, terminated or significantly delayed, the deferred offering costs are immediately written off to operating expenses. There were no deferred offering costs capitalized as of November 30, 2020 and 2019. Upon the closing of the IPO on July 28, 2020, the offering costs of $20.3 million were recorded in stockholder's equity (deficit) as a reduction of additional paid-in capital.

Revenue Recognition

Prior to December 1, 2019, the Company recognized revenue in accordance with the Financial Accounting Standards Board's (FASB) Accounting Standards Codification (ASC) 605, *Revenue Recognition*. Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

The Company evaluates multiple element arrangements to determine if each deliverable represents a separate unit of accounting based on the following criteria:

- Delivered item or items have value to the customer on a standalone basis, and
- If the arrangement includes a general right of return relative to the delivered item or items, delivery or performance of the undelivered item or items is considered probable and substantially in control of the Company.

The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price methodology in accordance with the selling price hierarchy, which includes vendor-specific objective evidence (VSOE) of selling price, if available, or third-party evidence of selling price if VSOE is not available, or the best estimate of selling price, if neither VSOE nor third-party evidence is available. The provisions of ASC 605 are then applied to each unit of accounting to determine the appropriate revenue recognition. In the event that a deliverable of a multiple element arrangement does not represent a separate unit of accounting, primarily because a deliverable does not provide value on a standalone basis, the Company recognizes revenue from the combined unit of accounting using the input/proportional performance approach as research is delivered or on a straight-line basis over the estimated period of performance when there is no discernable pattern of performance.

The Company evaluates potential milestone payments associated with research and development arrangements in accordance with ASC 605-28, *Milestone Method.* Under the milestone method, the Company may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered a substantive milestone. The Company evaluates each contingent payment on an individual basis to determine whether they are considered substantive milestones, specifically reviewing factors such as the degree of certainty in achieving the milestone, the research and development risk and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. Revenues from milestones, if they are nonrefundable and deemed substantive, are recognized upon achievement of the milestones.

To the extent that non-substantive milestones are achieved, and the Company has remaining deliverables, milestone payments are deferred and recognized as revenue over the estimated remaining performance period using the appropriate measure of progress as determined for each agreement. The Company recognizes revenue associated with the non-substantive milestones upon achievement of the milestone if the Company has no remaining deliverables. During the years ended November 30, 2019, no milestone payments were received, no milestone revenues were recognized and no milestones were considered substantive.

Effective December 1, 2019, the Company adopted Topic 606, *Revenue from Contracts with Customers* using the modified retrospective method, which was only applied to contracts that were not completed as of the adoption date. As of the adoption date, the Company had only one contract, a collaboration agreement with Gilead, not completed. Under Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within 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 Company satisfies a performance obligation.

At contract inception, the Company assesses the goods or services promised within each contract, whether each promised good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

The Company enters into collaboration agreements under which it may obtain upfront payments, milestone payments, royalty payments and other fees. Promises under these arrangements may include research licenses, research services, including selection campaign research services for certain replacement targets, the obligation to share information during the research and the participation of alliance managers and in joint research committees, joint patent committees and joint steering committees. The Company assesses these promises within the context of the agreements to determine the performance obligations.

Research and collaboration licenses: If a license is determined to be distinct from the other promises identified in the arrangement, the Company recognizes revenue from upfront payments allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, upfront payments. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes research, development, or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. The Company uses the most likely amount method for research, development and regulatory milestone payments. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. If it is probable that a significant revenue reversal would not occur, the associated milestone amount is included in the transaction price.

Sales-based milestones and royalties: For arrangements that include sales-based milestone or royalty payments based on the level of sales, and in which the license is deemed to be the predominant item to which the sales-based milestone or royalties relate to, the Company recognizes revenue in the period in which the sales-based milestone is achieved and in the period in which the sales associated with the royalty occur. To date, the Company has not recognized any sales-based milestone or royalty revenue resulting from its collaboration arrangements.

Customer options: Customer options, such as options granted to allow a licensee to extend a license or research term, to select additional research targets or to choose to research, develop and commercialize licensed compounds are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the original contract, the Company allocates the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

Deferred revenue, which is a contract liability, represents amounts received by the Company for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the consolidated balance sheet date based on the estimated performance period of the underlying performance obligation. The noncurrent portion of deferred revenue represents amounts to be recognized after one year through the end of the performance period of the performance obligation.

All revenue was derived from customers located in the United States during the years ended November 30, 2020 and 2019.

Research and Development Expenses

The Company expenses all research and development costs as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, preclinical studies, compound manufacturing costs, consulting costs and allocated overhead, including rent, equipment, depreciation and utilities.

The Company records accrued expenses for estimated costs of research and development activities conducted by third-party service providers, which include preclinical studies and clinical trials and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued expenses and other current liabilities on the consolidated balance sheet.

The Company estimates the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. The Company makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, the Company adjusts its accrued estimates. The Company's accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. The Company records advance payments to service providers as prepaid assets, which are expensed as the contracted services are performed.

Stock-Based Compensation

The Company accounts for stock-based compensation using a fair value-based method, which requires the recognition of compensation expense for costs related to all stock-based payments including stock options and purchase rights under the employee stock purchase plan. The Company estimates the fair value of stock-based payment awards on the date of grant using the Black-Scholes option pricing model. The model requires management to make a number of assumptions including expected volatility, expected term, risk-free interest rate and expected dividend yield. Prior to its IPO, the fair value of the Company's common stock was determined by the Company's board of directors with assistance from management and an independent third party valuation firm, using significant judgment and several factors including important developments in the Company's operations, sales of preferred stock and the lack of liquidity of the common stock. Subsequent to the IPO, the Company determines the fair value using the market closing price of the Company's common stock on the date of grant.

For stock-based payments with service conditions only, the Company uses the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period. Subsequent to the adoption of ASU 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* as of December 1, 2019, stock-based compensation expense for non-employee stock-based awards is also measured based on the grant date fair value with the estimated fair value expensed over the period for which the non-employee is required to provide service in exchange for the award. For stock-based payments with performance conditions, the Company evaluates the probability of achieving performance conditions at each reporting date. The Company begins to recognize compensation cost using an accelerated attribution method when it is deemed probable that the performance condition will be met. The Company accounts for forfeitures as they occur.

Income taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when in management's estimate, it is more likely than not, that the deferred tax assets will not be recovered.

Financial statement effects of uncertain tax positions are recognized when it is more likely than not, based on the technical merits of the position, that it will be sustained upon examination. It is the Company's policy to include penalties and interest expense related to income taxes as a component of the provision for income taxes.

Comprehensive loss

Comprehensive loss represents the net loss for the period and other comprehensive income. Other comprehensive income reflects certain gains and losses that are recorded as a component of stockholders' deficit and are not reflected in the statements of operations. The Company's other comprehensive income consists of changes in unrealized gains and losses on available-for-sale investments.

Net loss per share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, stock options, common stock subject to repurchase related to unvested restricted stock awards and early exercise of stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of redeemable convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods.

Recent Accounting Pronouncements

The Company is an "emerging growth company" (EGC), as defined in the JOBS Act. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of the public company effective dates.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* and has subsequently issued a number of amendments to Topic 606. As amended, Topic 606 provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. Topic 606 also requires entities to disclose both qualitative and quantitative information that enables users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers, including disclosure of significant judgments affecting the recognition of revenue. The Company adopted Topic 606 as of December 1, 2019 using the modified retrospective method, which was only applied to contracts that were not completed as of the adoption date. As of the adoption date, the Company had only one contract, the collaboration agreement with Gilead, not completed. The Company did not elect to use any of the practical expedients permitted related to adoption. The adoption of Topic 606 did not result in a cumulative adjustment to the accumulated deficit as it did not change the timing and pattern of revenue recognition for the collaboration agreement with Gilead. For the year ended November 30, 2020, there would have been no difference between the revenue recognized under Topic 606 and the revenue recognized under ASC 605 for the collaboration agreement with Gilead. The adoption of Topic 606 did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting* (ASU 2018-07), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. An entity should apply the requirements of Topic 718 to non-employee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). ASU 2018-07 is effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU 2018-07 as of December 1, 2019. The adoption did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), which for operating leases requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of lease payments, in its balance sheet. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, including a number of optional practical expedients that entities may elect to apply. ASU 2016-02 is effective for annual periods beginning after December 15, 2021 and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. ASU 2016-13 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt investments and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt investments rather than an other-than-temporary impairment that reduces the cost basis of the investment. ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those annual periods. Early adoption is permitted. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurements (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13), which modifies the disclosure requirements on fair value measurements by removing the requirement to disclose amounts of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation process for Level 3 fair value measurements, among other modifications to fair value measurement disclosure requirements. ASU 2018-13 is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted. The Company does not expect the adoption to have a material impact on its financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (ASU 2018-18). ASU 2018-18 clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. ASU 2018-18 is effective for annual periods beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2021. ASU 2018-18 requires retrospective adoption to the date the Company adopted Topic 606 by recognizing a cumulative-effect adjustment to the opening balance of retained earnings of the earliest annual period presented. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company does not expect the adoption to have a material impact on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes* (ASU 2019-12), which is intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application. ASU 2019-12 is effective for annual periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

3. Collaboration Agreements

Celgene (A Related Party)

In September 2015, the Company entered into a collaboration agreement with Celgene Corporation (the Celgene Agreement and Celgene, respectively), which was later acquired by Bristol-Myers Squibb Company (BMS) in November 2019, with an initial research term of four years for the discovery, development and commercialization of novel small molecule therapeutics in oncology, inflammation and immunology.

Under the terms of the Celgene Agreement, the Company received an upfront payment of $150.0 million in September 2015. In addition, in September 2015, Celgene purchased 1,622,222 shares of Series C redeemable convertible preferred stock at a price of $10.50 per share, resulting in net proceeds of $17.0 million. As of November 30, 2019, BMS held approximately 10% of total shares outstanding on an as-converted basis.

In January 2019, Celgene and BMS entered into a definitive merger agreement pursuant to which Celgene agreed to be acquired by BMS. Based on the Company's request for notification of the future disposition of the agreement, in June 2019, Celgene notified the Company that it was terminating the Celgene Agreement. Upon termination of the Celgene Agreement in June 2019, any rights that Celgene had under the agreement reverted to the Company and no termination payments were due or payable. The Company determined it had no remaining deliverables to be performed under the Celgene Agreement and as a result recognized all remaining deferred revenue in June 2019.

Collaboration revenue related to the Celgene Agreement was $0 and $28.4 million for the years ended November 30, 2020 and 2019, respectively. As of November 30, 2020 and 2019, deferred revenue of $0 was recorded on the consolidated balance sheet.

Gilead

In June 2019, the Company entered into a global strategic collaboration agreement with Gilead, which was amended in August 2019 (the Gilead Agreement), to discover, develop and commercialize a pipeline of targeted protein degradation drugs for patients with cancer and other challenging diseases using the Company's DELigase platform to identify novel agents that utilize E3 ligases to induce degradation of five specified drug targets.

Under the Gilead Agreement, Gilead has the option to license drug candidates directed to up to five targets resulting from the collaboration and is responsible for the clinical development and commercialization of product candidates resulting from the collaboration. The Company retains the option to co-develop and co-promote, under a profit share structure, up to two product candidates in the United States, provided that the Company may only exercise such option once per licensed product and Gilead retains the right to veto the Company's option selection for any one product candidate of its choice. The collaboration excludes the Company's current internal protein degradation programs for which the Company retains all rights, and also excludes the Company's future internal programs, provided that the Company has distinguished future programs as excluded from the scope of the collaboration.

Over time, Gilead may elect to replace the initial drug targets with other drug targets. For drug targets that are subject to the collaboration, the Company is obligated to use commercially reasonable efforts to undertake a research program in accordance with a research plan agreed to by the parties and established on a target-by-target basis. The Company has primary responsibility under the agreement for performing preclinical research activities (including target validation, drug discovery, identification or synthesis) pursuant to a research plan. Each party will bear its own costs in the conduct of research activities. Gilead will be responsible for any development, commercialization and manufacturing activities, unless the Company exercises its co-development and co-promotion option. For those programs that the Company exercises its option to co-develop and co-promote, the Company and Gilead will split U.S. development costs as well as U.S. profits and losses evenly, and the Company will be eligible to receive royalties on net ex-U.S. sales and reduced milestone payments.

Upon signing the Gilead Agreement, Gilead paid the Company an upfront payment of $45.0 million plus $3.0 million in additional fees. As of November 30, 2020, the Company is eligible to receive up to approximately $2.3 billion in total additional payments, including up to $697.5 million upon the achievement of specified development milestones, up to $1.5 billion upon the achievement of specified sales milestones, subject to reduction for any product for which the Company exercises its option to co-develop and co-promote, and up to $139.8 million in certain additional fees related to target licensing, reservation and selection and research term extensions. In addition, the Company is eligible to receive tiered royalties from mid-single digit to low tens percentages on annual net sales from any commercial products directed to the optioned collaboration targets, subject to certain reductions and excluding sales in the United States of any products for which the Company exercises its option to co-develop and co-promote, for which the Company and Gilead share profits and losses evenly. In June 2019, the Company received the $45.0 million upfront payment and $3.0 million in additional fees. In February 2020, the Company achieved a research milestone, resulting in a $2.5 million additional payment, which was received by the Company in April 2020. In May 2020, the Company recorded $1.0 million in additional fees related to certain target reservation, which was received in June 2020. In November 2020, the Company recognized two research milestones, resulting in a $7.5 million additional payment, which was received in January 2021.

Subject to earlier expiration in certain circumstances, the Gilead Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the later of (1) the expiration of the last to expire patent with a valid claim covering the applicable licensed product in the applicable country, (2) the expiration of any regulatory exclusivity for the applicable licensed product in the applicable country or (3) ten years after the first commercial sale of the applicable licensed product in the applicable country covered by the Gilead Agreement, provided that the term for any profit-shared licensed product in the United States will expire upon the expiration or termination of the applicable profit-share term as set forth in an applicable profit-share agreement to be negotiated upon the Company's exercise of its option to co-develop and co-promote such licensed product. If Gilead does not exercise an option to license a drug candidate, then the Gilead Agreement will terminate at the end of the last to expire option period.

The Company identified the following promises in the Gilead Agreement: (1) the research licenses, (2) the research services, including selection campaign research services for certain replacement targets and (3) the obligation to share information during the research and to participate in the joint research committee and joint steering committee. The Company determined that the research licenses are not capable of being distinct due to the specialized nature of the research services to be provided by the Company, and, accordingly, this promise was combined with the research services and participation in the joint research committee as one single performance obligation. The Company concluded that, at the inception of the Gilead Agreement, Gilead's options to obtain an exclusive development, manufacturing and commercialization license for each collaboration target, to extend the five-year research term and to perform selection campaign research services for certain replacement targets do not represent material rights and are not considered performance obligations because they do not contain a significant and incremental discount. The Company concluded that Gilead's target reservation right is not a performance obligation as it does not require any specific action from the Company and it is rather an exclusivity right and an attribute of other performance obligations in the Gilead Agreement, such as the research licenses.

In order to determine the transaction price, the Company evaluated all the payments to be received during the duration of the contract. Certain milestones and additional fees were considered variable consideration, which were not included in the transaction price based on the most likely amount method as of November 30, 2020. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company determined that the transaction price at the inception of the Gilead Agreement consists of the upfront payment of $45.0 million and $3.0 million in additional fees. Upon the achievement of research milestones in February and November 2020, and additional fees related to a target reservation in May 2020, $11.0 million in variable consideration was added to the transaction price, and a cumulative effect was recorded as revenue in the period the transaction price increased. The transaction price is recognized as collaboration revenue using the cost-based input method over the estimated contract term of five years. The contract term was determined to be the five-year initial research term which represents the estimated timing of completion of the identified deliverables. Additionally, the Company considered the impact of Gilead terminating the agreement prior to the completion of the research services during the initial five-year research term and determined that there were significant economic costs to Gilead for doing so, and as such, did not adjust the contract term.

Using the cost-based input method, which the Company determined most faithfully depicts the transfer of its performance obligation to Gilead, the Company recognizes revenue based on actual costs incurred as a percentage of total estimated costs as the Company completes its performance obligation. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. These actual costs consist primarily of internal FTE efforts and third-party contract costs related to the Gilead Agreement.

For the year ended November 30, 2020, the Company recognized collaboration revenue related to the Gilead Agreement of $12.1 million, of which $9.4 million was included in deferred revenue as of November 30, 2019, and $0.9 million was related to performance obligation satisfied in previous periods. For the year ended November 30, 2019, the Company recognized revenue related to the Gilead Agreement of $2.7 million. As of November 30, 2020, $44.2 million was recorded as deferred revenue, of which $14.5 million was current, on the consolidated balance sheet related to the Gilead Agreement.

As of November 30, 2020, the Company recognized contract assets of $7.5 million on the consolidated balance sheet related to the Gilead Agreement. The contract assets represent unbilled revenue related to the research milestones achieved in November 2020. The Company invoiced Gilead in December 2020 and Gilead paid the amount in January 2021.

Sanofi

In December 2019, the Company entered into a strategic collaboration with Sanofi, which became effective in January 2020 and was subsequently expanded and amended in January 2021 (the Sanofi Agreement), to discover, develop and commercialize a pipeline of targeted protein degradation drugs for patients with challenging diseases in multiple therapeutic areas using the Company's DELigase platform to identify small molecules designed to induce degradation of three specified initial drug targets, with an option by Sanofi to expand to a total of five targets. Over time and subject to certain limitations, Sanofi may elect to replace the drug targets with other reserved targets.

Under the Sanofi Agreement, Sanofi has exclusive rights and is responsible for the clinical development, commercialization and manufacture of product candidates resulting from the collaboration while the Company retains the option to co-develop, co-promote and co-commercialize up to two targets, one of which must be selected from a list of targets designated at the execution of the Sanofi Agreement and one of which must be selected from targets identified by Sanofi in the future. The Company's right to exercise its option to co-develop, co-promote and co-commercialize a given target is dependent on its ability to demonstrate, within a given timeframe, that it has sufficient cash resources and personnel to commercialize the product. The collaboration excludes the Company's current internal protein degradation programs for which it retains all rights, and also excludes future internal programs, provided that the Company distinguished future programs as excluded from the scope of the collaboration.

For drug targets that are subject to the collaboration, the Company has primary responsibility for conducting preclinical research activities (including target validation, drug discovery, identification or synthesis) in accordance with the applicable research plan agreed to by the parties and established on a target-by-target basis. The Company is obligated to use commercially reasonable efforts to identify relevant target binders and chimeric targeting molecules in order to identify development candidates. Subject to certain exceptions, each party will bear its own costs in the conduct of such research. Sanofi will be responsible for any development and commercialization activities unless the Company exercises its co-development and co-promotion option. For those programs that the Company exercises its option to co-develop, co-promote and co-commercialize, the Company will be responsible for a portion of the U.S. development costs, and the parties will split U.S. profits and losses evenly and the Company will be eligible to receive royalties on ex-U.S. net sales and reduced milestone payments on such optioned products.

Upon signing the Sanofi Agreement, Sanofi paid the Company an upfront payment of $55.0 million, which was received in January 2020. Subsequently in January 2021, Sanofi paid the Company an additional $22.0 million to exercise its option to expand the number of targets beyond the initial targets included in the collaboration. The Company is eligible to receive additional payments if Sanofi exercises an option to extend the license term with respect to a particular target. As of November 30, 2020, the Company is eligible to receive up to approximately $2.5 billion in total payments, including payments of up to $500.0 million upon the achievement of specified development milestones, up to $625.0 million upon the achievement of specified regulatory milestones and up to $1.3 billion upon the achievement of certain sales milestones, as well as up to $163.1 million in certain additional fees related to target licensing and reservation. In addition, the Company is eligible to receive tiered royalties ranging from mid-single digit to low teen percentages on annual net sales of any commercial products that may result from the collaboration, subject to certain reductions and excluding sales in the United States of any products for which the Company exercises its option to co-develop and co-promote, for which the parties share profits and losses evenly.

The Company identified the following promises in the Sanofi Agreement: (1) the research licenses, (2) the research services, (3) the obligation to share information during the research term and (4) the participation of alliance managers in the joint research committee and joint patent committee. The Company determined that the research licenses are not capable of being distinct due to the specialized nature of the research services to be provided by the Company, and, accordingly, this promise was combined with the research services as one single performance obligation. The Company also determined that Sanofi's exclusive right to add up to two additional targets constitutes a material right as it represents a significant and incremental discount that Sanofi would not have received without entering into the Sanofi Agreement. The option to extend the license term does not represent a material right because it does not contain a significant and incremental discount.

In order to determine the transaction price, the Company evaluated all the payments to be received during the duration of the contract. Milestone and additional fees were considered variable consideration, which were not included in the transaction price based on the most likely amount method as of November 30, 2020. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. At the inception of the Sanofi Agreement, the Company determined that the transaction price consists of the upfront payment of $55.0 million. To account for the material right related to the two additional targets, instead of determining the standalone selling price for the option directly, the Company applied the practical alternative to allocating the transaction price by determining the consideration that it expects to receive in exchange for the research activities that it expects to provide on the two additional targets for a total of five targets. The practical alternative can be applied as the research activities for the two additional targets are similar to the research activities for the initial three targets. Consequently, for the purpose of applying the practical alternative to estimating the standalone selling price of the material right, an expected consideration of $77.0 million was used for revenue recognition allocation, which represents the $55.0 million paid upfront for the three initial drug targets, and the $22.0 million for the additional consideration related to two additional targets which was included as part of applying the practical alternative, which was subsequently exercised by Sanofi. Revenue is recognized over the research term of four years, the contractual initial research period, using the cost-based input method, which the Company determined most faithfully depicts the transfer of its performance obligations to Sanofi, based on actual costs incurred as a percentage of total estimated costs as the Company completes its performance obligations. The cumulative effect of revisions to estimated costs to complete the Company's performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. These actual costs consist primarily of internal FTE efforts and third-party contract costs related to the Sanofi Agreement.

For the year ended November 30, 2020, the Company recognized collaboration revenue related to the Sanofi Agreement of $5.7 million . As of November 30, 2020, $49.3 million was recorded as deferred revenue, of which $18.3 million was current, on the consolidated balance sheet related to the Sanofi Agreement.

4. Consolidated Balance Sheet Components

Property and Equipment, Net

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

	November 30,	
	2020	2019
Laboratory equipment	$ 14,120	$ 10,821
Leasehold improvements	2,664	2,483
Computer equipment	745	654
Furniture and fixtures	506	478
Software	1,316	282
Software in progress	504	156
Total property and equipment, gross	19,855	14,874
Less: Accumulated depreciation and amortization	(13,183)	(11,003)
Total property and equipment, net	$ 6,672	$ 3,871

Depreciation and amortization expense was $2.2 million and $2.4 million for the years ended November 30, 2020 and 2019, respectively. All long-lived assets are maintained in the United States.

Accrued and Other Current Liabilities

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

	November 30,	
	2020	2019
Accrued compensation	5,725	$ 3,751
Accrued contract research and lab supplies	1,238	322
Accrued professional services	591	512
Accrued taxes	74	33
Other	700	309
Total	$ 8,328	$ 4,927

5. Fair Value Measurements

In accordance with the authoritative guidance on fair value measurements and disclosures under U.S. GAAP, the Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1—Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly, including inputs in markets that are not considered to be active; and

Level 3—Inputs that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability.

The following tables presents the Company's financial assets, which consist of cash equivalents and investments classified as available-for-sale investments, that are measured at fair value on a recurring basis as of November 30, 2020 and 2019 (in thousands):

November 30, 2020	Level	Amortized cost	Unrealized gain	Unrealized loss	Estimated fair value
Money market funds	Level 1	$ 114,357	$ —	$ —	$ 114,357
U.S. treasury securities	Level 1	48,002	22	(1)	48,023
Corporate debt securities	Level 2	23,287	11	(6)	23,292
U.S. government agency securities	Level 2	9,011	15	—	9,026
Corporate commercial paper	Level 2	80,411	—	—	80,411
Municipal securities	Level 2	6,032	9	(2)	6,039
Long-term investments:					
Corporate debt securities	Level 2	11,207	11	(10)	11,208
U.S. government agency securities	Level 2	70,373	25	(7)	70,391
Municipal securities	Level 2	9,269	22	—	9,291
Total		$ 371,949	$ 115	$ (26)	$ 372,038
Included in Cash and cash equivalents		$ 119,356	$ —	$ —	$ 119,356
Included in Short-term investments		$ 161,744	$ 57	$ (9)	$ 161,792
Included in Long-term investments		$ 90,849	$ 58	$ (17)	$ 90,890

November 30, 2019	Level	Amortized cost	Unrealized gain	Unrealized loss	Estimated fair value
Money market funds	Level 1	$ 23,834	$ —	$ —	$ 23,834
U.S. treasury securities	Level 1	10,982	—	—	10,982
Corporate debt securities	Level 2	1,503	—	(1)	1,502
U.S. government agency securities	Level 2	1,402	—	—	1,402
Long-term investments:					
Corporate debt securities	Level 2	507	—	(1)	506
Total		$ 38,228	$ —	$ (2)	$ 38,226
Included in Cash and cash equivalents		$ 34,816	$ —	$ —	$ 34,816
Included in Short-term investments		$ 2,905	$ —	$ (1)	$ 2,904
Included in Long-term investments		$ 507	$ —	$ (1)	$ 506

The Company classifies its money market funds and U.S. treasury securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The Company classifies its investments in corporate debt securities, U.S. government agency securities, corporate commercial paper, and municipal securities as Level 2 assets within the fair value hierarchy. The fair values of these investments are estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. There were no transfers of financial instruments between valuation levels during the years ended November 30, 2020 and 2019.

As of November 30, 2020 and 2019, none of the Company's available-for-sale investments that were in an unrealized loss position had been in an unrealized loss position for more than 12 months. During the years ended November 30, 2020 and 2019, the Company did not recognize any other-than-temporary impairment losses.

The Company's short-term investments have maturities of less than one year from the respective consolidated balance sheet dates. The Company's long-term investments have maturities of between one and two years from the respective consolidated balance sheet dates.

6. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may be involved in legal proceedings in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. Legal fees and other costs associated with such actions are expensed as incurred. As of November 30, 2020, the Company had no outstanding, pending or threatened litigation.

Indemnifications

In the ordinary course of business, the Company often includes standard indemnification provisions in its arrangements with its partners, suppliers and vendors, among others. Pursuant to these provisions, the Company may be obligated to indemnify such parties for losses or claims suffered or incurred in connection with its service, breach of representations or covenants, intellectual property infringement or other claims made against such parties. These provisions may limit the time within which an indemnification claim can be made. It is not possible to determine the maximum potential amount under these indemnification obligations due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement. The Company has not incurred any material costs as a result of such indemnifications and has not accrued any liabilities related to such obligations in these consolidated financial statements as management believes such liability is immaterial.

In addition, the Company has entered into indemnification agreements with directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company's consolidated financial statements. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not specified in the agreements. However, the Company currently has directors' and officers' insurance that reduces its exposure and may enable the Company to recover a portion of any future amounts paid.

Operating Leases

The Company leases office and laboratory facilities in San Francisco, California under a lease agreement. The original lease term was scheduled to end 60 months following the Company's full occupancy of the leased premises, which occurred in April 2015. In October 2015, the Company entered into a second lease agreement for additional space in the same building as its existing office and laboratory facilities. In November 2017, the Company entered into an amendment to its original lease agreement that combined the Company's two leases into a single lease agreement and extended the term of the lease agreement through April 30, 2025. The Company is required to pay base rent plus the tenant's proportionate share of operating expenses as defined in the lease agreement. Under the terms of the lease agreement, the Company paid the landlord security deposits totaling $91,000 and issued a letter of credit to the landlord in the amount of $70,000, which is collateralized by a restricted deposit of $70,000. In June 2020, the Company entered into a new lease agreement for additional space in the same building as the Company's existing office for a 14-month term ending on July 31, 2021.

In December 2015, the Company entered into its first sublease agreement under which a portion of the Company's leased space is subleased to another tenant. The term of the sublease, which was originally scheduled to end on December 31, 2017, was extended through December 31, 2018 as the result of an amendment executed in November 2017. The sublessee defaulted on this sublease agreement in August 2018, upon which a new creditor negotiated a second amendment to sublease dated October 2018 and the sublease agreement became a month to month agreement that ended in February 2019. The Company entered into its second sublease agreement with a different tenant in November 2018, which was subsequently amended in March 2019 to increase the size of the space. The term of the second sublease ended in August 2019.

Rent expense and sublease income was as follows (in thousands):

	Year Ended November 30,	
	2020	2019
Rent expense under operating leases	$ 3,023	$ 2,927
Sublease income	—	(311)
Net rent expense	$ 3,023	$ 2,616

Future minimum lease payments under the Company's lease agreement as of November 30, 2020 were as follows (in thousands):

Year ending November 30,	Operating Leases
2021	$ 3,272
2022	3,365
2023	3,438
2024	3,541
2025	1,493
Total minimum lease payments	$ 15,109

7. Common Stock

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue up to 500,000,000 and 65,000,000 shares of $0.001 par value common stock as of November 30, 2020 and 2019, respectively. Holders of common stock are entitled to dividends when and if declared by the Company's board of directors, subject to the prior rights of the preferred stockholders. The holder of each share of common stock is entitled to one vote. As of November 30, 2020, no dividends have been declared.

Common stock reserved for future issuance, on an as-if converted basis, as of November 30, 2020 and 2019, consists of the following and has been adjusted for the 1-for-3 reverse stock split:

	November 30,	
	2020	2019
Conversion of redeemable convertible preferred stock	—	12,813,887
Issuance of options under stock option plan	4,387,862	1,913,792
Shares available for future stock option grants	3,035,684	412,204
Shares available for issuance under employee stock purchase plan	730,000	—
Total common stock reserved for future issuance	8,153,546	15,139,883

8. Redeemable Convertible Preferred Stock

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue zero and 48,441,667 shares of redeemable convertible preferred stock as of November 30, 2020 and 2019, respectively, with a par value of $0.001 per share. Designated and outstanding redeemable convertible preferred stock and its principal terms were as follows at November 30, 2019 (in thousands, except share amounts):

	Shares authorized	Shares issued and outstanding	Liquidation value	Net carrying value
Series A-1	1,800,000	600,000	$ 900	$ 892
Series A-2	6,625,000	2,208,332	5,300	5,209
Series B	35,150,000	8,383,333	25,150	25,100
Series C	4,866,667	1,622,222	17,033	16,994
Total	48,441,667	12,813,887	$ 48,383	$ 48,195

In March 2020, the Company issued 9,431,364 shares of Series D redeemable convertible preferred stock at an issuance price of $12.75 per share, resulting in net proceeds of $119.9 million. The Series D redeemable convertible preferred stock had a liquidation price per share equal to the original issue price per share.

Immediately prior to the closing of the IPO in July 2020, all shares of redeemable convertible preferred stock then outstanding, including 9,431,364 shares of Series D redeemable convertible preferred stock, converted into 22,245,251 shares of common stock. There were no shares of redeemable convertible preferred stock outstanding as of November 30, 2020.

The redeemable convertible preferred stock was recorded in mezzanine equity because while it was not mandatorily redeemable, it would have become redeemable at the option of the preferred stockholders upon the occurrence of a deemed liquidation event that was considered not solely within the Company's control.

9. Stock-Based Compensation

2020 Equity Incentive Plan

In July 2020, the Company's board of directors approved, and the Company adopted the 2020 Equity Incentive Plan (the 2020 Plan). The 2020 Plan became effective on July 22, 2020. The 2020 Plan provides for the granting of stock options, stock appreciation rights (SARs), restricted stock awards (RSAs), restricted stock units (RSUs), performance awards and stock bonus awards to employees, directors, consultants, independent contractors and advisors of the Company. Under the 2020 Plan, the Company generally grants stock-based awards with service-based vesting conditions only. Options granted typically vest over a four-year period but may be granted with different vesting terms. In the case of an incentive stock option granted to an employee who at the time of grant owns stock representing more than 10% of the total combined voting power of all classes of stock, the exercise price shall be no less than 110% of the fair value per share on the date of grant, and the award shall expire five years from the date of grant. In the case of all other stock options, the per share exercise price shall be no less than 100% of the fair value per share on the date of grant.

Following the effectiveness of the 2020 Plan, the Company ceased making grants under the 2012 Equity Incentive Plan (the 2012 Plan). However, the 2012 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2012 Plan that cease to be subject to such awards by forfeiture or otherwise after the termination of the 2012 Plan will be available for issuance under the 2020 Plan.

As of November 30, 2020, there were 3,035,684 shares of common stock reserved for future issuance pursuant to the 2020 Plan. In December 2020, an additional 1,554,594 shares of common stock were reserved for issuance pursuant to the 2020 Plan.

2012 Equity Incentive Plan

In April 2012, the Company's board of directors approved, and the Company adopted the 2012 Plan. The 2012 Plan provides for the granting of stock options, SARs, RSAs, and RSUs to employees, directors, consultants and advisors of the Company. Options granted under the 2012 Plan generally vest over four years. Options granted under the 2012 Plan may, but need not, be exercisable immediately, with any shares issued on exercise being subject to the Company's right of repurchase.

As of November 30, 2020, there were no shares of common stock reserved for issuance pursuant to the 2012 Plan.

Activity under the 2020 Plan and 2012 Plan is set forth below and has been adjusted for the 1-for-3 reverse stock split (in thousands, except per share data):

	Number of options outstanding	Weighted-average exercise price	Weighted-average contractual life (in years)	Aggregate intrinsic value [1]
Balances as of November 30, 2019	1,913,792	$ 1.46	0.38	$ 762
Options granted	3,059,392	14.49		
Options exercised	(479,151)	2.04		
Options forfeited	(106,171)	3.79		
Balances as of November 30, 2020	4,387,862	$ 10.43	9.02	$ 141,249
Options vested and expected to vest as of November 30, 2020[2]	4,529,374	$ 10.22	9.00	$ 146,733
Options exercisable as of November 30, 2020	3,025,413	$ 5.45	8.69	$ 112,466

(1) The aggregate intrinsic values were calculated as the pre-tax difference between the exercise price of stock options and the quoted market price of the Company's common stock on November 30, 2020 for all in-the-money stock options. The total intrinsic value of stock options exercised during the years ended November 30, 2020 and 2019, was $3.4 million and $0.1 million, respectively.

(2) Certain stock options granted by the Company prior to the date of IPO are exercisable at the date of grant, with unvested shares subject to repurchase by the Company in the event of voluntary or involuntary termination of employment of the stockholder. Such exercises are recorded as a liability in the consolidated balance sheet and reclassified into equity as the options vest. As of November 30, 2020, a total of 141,512 shares of common stock were subject to repurchase by the Company at the lower of (i) the fair market value of such shares on the date of repurchase, or (ii) the original exercise price of such shares. The corresponding exercise value of $0.5 million as of November 30, 2020 is recorded in share-based compensation liability.

2020 Employee Stock Purchase Plan

In July 2020, the Company's board of directors adopted the 2020 Employee Stock Purchase Plan (the 2020 ESPP) that became effective upon the date of the IPO in order to enable eligible employees to purchase shares of common stock with accumulated payroll deductions. The 2020 ESPP is intended to qualify under Section 423 of the Internal Revenue Code, as amended. Under the 2020 ESPP, eligible employees are offered the option to purchase shares of common stock at a discount over a series of offering periods. Each offering period may consist of one or more purchase periods. The purchase price for shares of common stock purchased under the 2020 ESPP will be 85% of the lesser of the fair market value of the Company's common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of each purchase period in the applicable offering period.

As of November 30, 2020, there were 730,000 shares of common stock reserved for issuance pursuant to the 2020 ESPP. The first offering period commenced as of July 23, 2020, the date on which the Company's registration statement on Form S-1 relating to its IPO of common stock became effective and ended on February 15, 2021. The first purchase period was the same as the first offering period and the first purchase date was the last trading day of the purchase period, which was February 12, 2021.

In December 2020, an additional 388,648 shares of common stock were reserved for issuance pursuant to the 2020 ESPP.

Stock-Based Compensation

During the years ended November 30, 2020 and 2019, the weighted-average grant date fair value of options granted was $9.50 and $1.41 per share, respectively. The total fair value of employee options vested during the years ended November 30, 2020 and 2019 was $3.1 million and $0.5 million, respectively.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The fair value of the employee stock options granted during the following years was estimated using the following assumptions:

	November 30,	
	2020	2019
Expected term	5.41 - 6.98 years	5.92 - 6.08 years
Expected volatility	73% - 79%	111 - 116%
Risk-free interest rate	0.34% - 1.79%	1.42 - 2.55%
Dividend yield	0%	0%

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The expected term assumption was determined based on the expected term as disclosed for comparable publicly traded biopharmaceutical companies since the Company does not have sufficient experience to estimate the expected term based on historical exercises. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company does not have sufficient trading history for its common stock. The risk-free rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The expected dividend yield is 0.0% as the Company has not paid and does not anticipate paying dividends on its common stock.

The following table sets forth stock-based compensation expense related to stock options and ESPP that is included in the Company's consolidated statements of operations (in thousands):

	Year Ended November 30,	
	2020	2019
Research and development	$ 1,726	$ 307
General and administrative	2,575	203
Total stock-based compensation	$ 4,301	$ 510

As of November 30, 2020, the total compensation cost related to stock-based awards not yet recognized was $26.8 million, which is expected to be amortized on a straight-line basis over the weighted-average remaining vesting period of approximately 3.5 years.

10. Defined Contribution Plan

The Company sponsors a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan), which provides for the Company to make discretionary matching or discretionary annual contributions to the 401(k) Plan, for its employees. Substantially all of the Company's employees are eligible to participate. Employees may contribute a percentage of their annual compensation to the plan, subject to statutory limitations. The Company made contributions to the 401(k) Plan during the years ended November 30, 2020 and 2019. The Company recorded contribution expense of $0.4 million and $0.3 million during the years ended November 30, 2020 and 2019, respectively.

11. Income Taxes

The Company recorded a current income tax benefit of $20.5 million for the year ended November 30, 2020, primarily due to carryback of net operating losses to prior years and changes in reserves for unrecognized tax benefits. The Company recorded a current income tax expense of $0.2 million for the year ended November 30, 2019, primarily due to reserves for unrecognized tax benefits, minimum state taxes and a true-up from the prior year. The Company had generated net operating losses (NOLs) since inception and has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

Loss before provision for income taxes includes the following component (in thousands):

	November 30,	
	2020	2019
Domestic	$ (63,777)	$ (21,460)
	$ (63,777)	$ (21,460)

The provision for income taxes consists of the following: (in thousands):

	November 30,	
	2020	2019
Current:		
Federal	$ (20,577)	$ 238
State	42	1
Total (benefit) provision for income taxes	$ (20,535)	$ 239

The effective tax rate differs from the federal statutory rate as follows:

	November 30,	
	2020	2019
Federal statutory income tax rate	21.0%	21.0%
State income tax rate	6.2	10.2
Research and development tax credits	4.0	6.6
Unrecognized income tax benefits	0.6	(1.0)
Federal rate impact due to CARES Act	13.1	—
Change in valuation allowance	(10.3)	(37.0)
Other	(2.4)	(0.9)
Total	32.2%	(1.1)%

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the deferred tax assets for federal and state income taxes are as follows (in thousands):

	Year ended November 30,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 25,145	$ 31,533
Research and development tax credits	9,330	6,941
Deferred revenue	10,536	—
Stock based compensation	773	37
Accruals and other	1,624	1,260
Gross deferred tax assets	47,408	39,771
Valuation allowance	(47,408)	(39,763)
Total deferred tax assets	—	8
Deferred tax liabilities:		
Property and equipment	—	(8)
Total deferred tax liabilities	—	(8)
Net deferred tax assets	$ —	$ —

Realization of the deferred tax assets is dependent upon future taxable income, the amount, if any, and timing of which are uncertain. The Company has established a valuation allowance to offset deferred tax assets as of November 30, 2020 and 2019 due to the uncertainty of realizing future tax benefits from its NOL carryforwards and other deferred tax assets. The valuation allowance increased by $7.6 million during the year ended November 30, 2020. The increase in the valuation allowance in 2020 is primarily related to an increase on the deferred tax asset for deferred revenue. The valuation allowance increased by $8.5 million during the year ended November 30, 2019. The increase in the valuation allowance for 2019 is primarily due to an increase in NOL carryforwards.

As of November 30, 2020, the Company had NOL carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of $55.7 million and $153.3 million, respectively. Federal NOL carryforwards generated for tax years beginning before December 31, 2017 can be carried forward twenty years and begin expiring in 2029. Federal NOL carryforwards of $52.0 million for tax years beginning after December 31, 2017 can be carried forward indefinitely.

State NOL carryforwards begin expiring in 2029. As of November 30, 2020, the Company had federal and state research credit carryforwards of $7.7 million and $7.0 million, respectively. If not utilized, the federal credit carryforwards will begin expiring in 2032 and the state credits carry forward indefinitely.

Internal Revenue Code Section 382 places a limitation on the utilization of NOL and tax credit carryforwards in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. The Company has identified two ownership changes that have triggered a limitation on pre-change NOLs under Section 382. A majority of the Company’s pre-change NOLs remain available within the carryforward period provided by the Internal Revenue Code, subject to availability of taxable income. As a result of the ownership changes, the Company has determined that approximately $0.4 million of NOLs will expire unutilized, and as such, these NOLs are not reflected in the Company’s deferred tax asset balance.

Unrecognized Tax Benefits

The Company has recorded a liability related to uncertain tax positions in the financial statements. The Company believes that it is reasonably possible that unrecognized income tax benefits will decrease by $1.5 million within the next twelve months as a result of audit settlements with the Internal Revenue Service (IRS). It is the Company's policy to include penalties and interest expense related to income taxes as a component for the provision for income taxes. The Company has unrecognized tax benefits of $5.4 million as of November 30, 2020, all of which are offset by a full valuation allowance. There are no tax benefits included in the balance of unrecognized tax benefits that, if recognized, would affect the effective tax rate. There are no interest and penalties accrued as of November 30, 2020. A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the years ended November 30, 2020 and 2019 is as follows (in thousands):

	Years ended November 30,	
	2020	2019
Balance at beginning of period	$ 2,920	$ 2,157
Additions based on tax positions related to prior period	2,295	137
Additions based on tax positions related to current period	1,326	626
Settlements	(1,180)	—
Balance at end of period	$ 5,361	$ 2,920

The Company files income tax returns in the United States and in various states. The Internal Revenue Service (the IRS) commenced an examination of the Company's U.S. income tax return for the year ended December 31, 2016 in the first quarter of 2018 that is anticipated to be completed in 2021. In September 2020, the Company and the IRS reached a settlement on a R&D credit issue. The Company removed the associated unrecognized tax benefit reserve and decreased its R&D credit carryforward by $1.0 million. The Company also increased its uncertain tax benefit reserve related to its 2018 and 2019 R&D credits. Additionally, the California Franchise Tax Board (the FTB) initiated an examination of the Company's California tax return for the years ended December 31, 2015 and 2016. As of the filing date, the FTB has not yet issued any assessments. All of the Company's tax years will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss or credits.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits net operating loss (NOL) carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in taxable years 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. Any tax benefit as a result of the CARES Act is primarily due to the carryback of NOLs to prior taxable years and increased interest expense deductions. In April 2020, the Company filed a refund claim of $15.7 million to carryback its NOLs generated in the fiscal year ended November 30, 2018, and in November 2020, the Company filed an additional refund claim to carryback its NOLs generated in the fiscal year ended November 30, 2019 to recover an additional $3.9 million of income tax. Additionally, as a result of the CARES Act, NOL carryback claims displaced certain research and development credits that were originally used to offset previous tax expense. As a result, the Company recorded an income tax benefit of $20.6 million, which consist of the carryback claims and the reversal of the uncertain tax liabilities. The Company received the cash for the first refund claim of $16.3 million including an interest income of $0.6 million, leaving the remaining income tax receivable of $3.9 million for the anticipated tax refund claims on the consolidated balance sheet as of November 30, 2020.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (TCJA) was enacted into law and the effect of the tax law change was reflected in the period of enactment. Most significantly for the Company, the TCJA reduced the income tax rate to 21% effective January 1, 2018. The Company included the impact of the reduced tax rate in its fiscal year ended November 30, 2018. The Company's 2018 and 2019 net operating losses were carried back to pre-2017 years when the tax rate was 35%. The Company recorded an income tax benefit for the use of the net operating losses at the higher rate.

12. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders, which excludes shares which are legally outstanding but subject to repurchase by the Company (in thousands, except share and per share data):

	Year Ended November 30,	
	2020	2019
Numerator:		
Net loss	$ (43,242)	$ (21,699)
Denominator:		
Weighted-average number of shares outstanding, basic and diluted	15,673,424	3,292,514
Net loss per share attributable to common stockholders, basic and diluted	$ (2.76)	$ (6.59)

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share of common stock for the periods presented because their effect would have been anti-dilutive:

	November 30,	
	2020	2019
Redeemable convertible preferred stock on an as-converted basis	—	12,813,887
Options to purchase common stock	4,387,862	1,913,792
Options early exercised subject to vesting	141,512	139,393
Shares expected to be purchased under employee stock purchase plan	60,512	—
Total	4,589,886	14,867,072

13. Related Party Transactions

As of November 30, 2020 and 2019, post-acquisition of Celgene, BMS owned 1,622,222 shares of the Company's common stock and 1,622,222 shares of the Company's Series C redeemable convertible preferred stock, respectively. For the years ended November 30, 2020 and 2019, the Company recorded collaboration revenue under the Celgene Agreement of $0 and $28.4 million, respectively. As of November 30, 2020 and 2019, deferred revenue related to the Celgene Agreement was $0. In June 2019, the Celgene Agreement was terminated in its entirety with no further payments from Celgene and no remaining deliverables from the Company. See Note 3, "Collaboration agreements—Celgene (a related party)" for a discussion of the Celgene Agreement.

14. Subsequent Events

In December 2020, the Company submitted an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for NX-2127, an orally available BTK degrader for the treatment of relapsed or refractory B-cell malignancies. On January 15, 2021, the Company received a study-may-proceed letter from the FDA to conduct a Phase 1 clinical trial to assess the safety and efficacy of NX-2127. The Phase 1 clinical program is intended to support the clinical development of NX-2127 in multiple indications, including non-Hodgkin lymphoma and chronic lymphocytic leukemia.

In January 2021, the Company entered into the first amendment to a global strategic collaboration with Genzyme Corporation, a subsidiary of Sanofi S.A. (the Sanofi Agreement), to expand the number of drug targets under the Sanofi Agreement. See Note 3, "Collaboration agreements—Sanofi)" for a discussion of the Sanofi Agreement.

15. Quarterly Financial Information (unaudited)

The following table provides selected unaudited quarterly financial data for the years ended November 30, 2020 and 2019 (in thousands, except share and per share data):

	Three Months Ended			
	February 29, 2020	May 31, 2020	August 31, 2020[(1)]	November 30, 2020
Collaboration revenue	$ 2,864	$ 4,182	$ 4,085	$ 6,689
Net loss	$ (12,391)	$ 7,580	$ (18,517)	$ (19,914)
Weighted-average number of shares outstanding, basic and diluted	3,539,390	3,731,838	16,937,934	38,702,486
Net loss per share attributable to common stockholders, basic and diluted	$ (3.50)	$ 2.03	$ (1.09)	$ (0.51)

	Three Months Ended			
	February 28, 2019	May 31, 2019	August 31, 2019	November 30, 2019
Collaboration revenue	$ 9,234	$ 9,439	$ 10,580	$ 1,862
Net loss	$ (2,685)	$ (3,068)	$ (2,427)	$ (13,519)
Weighted-average number of shares outstanding, basic and diluted	3,195,047	3,433,080	3,667,335	3,812,210
Net loss per share attributable to common stockholders, basic and diluted	$ (0.84)	$ (0.89)	$ (0.66)	$ (3.55)

(1) ***Q3 2020 Revision of Net Loss per Share***

During the fourth quarter of 2020, the Company identified an error in the computation and disclosure of the basic and diluted weighted-average number of shares outstanding and the basic and diluted net loss per share for the three and nine months ended August 31, 2020 included in the Quarterly Report on Form 10-Q for the period ended August 31, 2020. The error primarily resulted from the inclusion of the absolute number of shares converted from redeemable convertible preferred stock into common stock rather than the weighted-average number of shares converted from redeemable convertible preferred stock into common stock as a result of the closing of the IPO. The Company evaluated the materiality of the error in accordance with SEC Staff Accounting Bulletin No. 99, *Materiality* and ASC 250, *Accounting for Changes and Error Corrections*, and concluded the error was not material to the previously issued condensed consolidated financial statements. However, the Company has revised its previously reported basic and diluted weighted-average number of shares outstanding and basic and diluted net loss per share, which decreased the weighted-average number of shares outstanding from 31,383,936 to 16,937,934 and increased the basic and diluted net loss per share from $0.59 to $1.09 for the three months ended August 31, 2020. It also decreased the weighted-average number of shares outstanding from 27,688,972 to 8,052,905 and increased the basic and diluted net loss per share from $0.84 to $2.90 for the nine months ended August 31, 2020. The error will be corrected in the Company's future filings that contain such financial information.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal accounting and financial officer, respectively, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of November 30, 2020.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our President and Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures, our President and Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of November 30, 2020 due to the material weakness in our internal control over financial reporting described below. In light of this fact, our management has performed additional analyses, reconciliations, and other post-closing procedures and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the consolidated financial statements for the periods covered by and included in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm as permitted during the transition period for newly public companies under the rules of the SEC.

Material Weakness in Internal Control over Financial Reporting

As disclosed in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, we identified a material weakness in our internal control over financial reporting. Specifically, we did not design and maintain formally documented controls and accounting policies and procedures, including information technology general controls, segregation of duties over the review and approval of account reconciliations and manual journal entries, and the period-end financial reporting process. This material weakness resulted in the revision to the basic and diluted weighted-average number of shares outstanding and basic and diluted net loss per share calculations for the three- and nine-month periods ended August 31, 2020. Additionally, this material weakness could result in a misstatement of substantially all of our account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Remediation Plan

To address our material weakness, we are in the process of implementing new financial systems and controls. We intend to continue to take steps to remediate the material weakness through formalizing documentation of policies and procedures and further evolving our accounting processes.

While we believe that these efforts will improve our internal control over financial reporting, the design and implementation of our remediation is ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weakness in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

Changes in Internal Control Over Financial Reporting

As described under the Remediation Plan above, we continued formalizing documentation of policies and procedures and implementing new controls during the quarter ended November 30, 2020. Such remediation actions were changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended November 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness Over Financial Reporting

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 there can be no assurance that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be set forth in our definitive proxy statement for our 2021 Annual Meeting of Stockholders (Proxy Statement) to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics is available on our website at www.nurixtx.com. Amendments to, and waivers from, the code of business conduct and ethics that apply to any director, executive officer or persons performing similar functions will be disclosed at the website address provided above and, to the extent required by applicable regulations, on a Current Report on Form 8-K filed with the SEC.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

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

The information required by this item will be set forth in the Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

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

The information required by this item will be set forth in the Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements filed as part of this Annual Report on Form 10-K are listed in the "Index to Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) Exhibits

The following is a list of exhibits filed with this Annual Report on Form 10-K incorporated herein by reference (numbered in accordance with Item 601 of Regulation S-K):

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation	10-Q	001-39398	3.1	October 14, 2020	
3.2	Restated Bylaws	10-Q	001-39398	3.2	October 14, 2020	
4.1	Form of Common Stock Certificate	S-1	333-239651	4.1	July 2, 2020	
4.2	Amended and Restated Investor Rights Agreement, dated March 9, 2020, by and among the Registrant and certain of its stockholders	S-1	333-239651	4.2	July 2, 2020	
4.3	Description of Registrant's Securities					X
10.1	Form of Indemnity Agreement	S-1	333-239651	10.1	July 2, 2020	
10.2*	2012 Equity Incentive Plan, as amended, and forms of award agreements	S-1	333-239651	10.2	July 2, 2020	
10.3*	2020 Equity Incentive Plan and forms of award agreements	S-1/A	333-239651	10.3	July 20, 2020	
10.4*	2020 Employee Stock Purchase Plan and forms of award agreements	S-1/A	333-239651	10.4	July 20, 2020	
10.5*	Employment Agreement, dated July 15, 2020, by and between the Registrant and Arthur T. Sands	S-1/A	333-239651	10.5	July 20, 2020	
10.6*	Employment Agreement, dated July 15, 2020, by and between the Registrant and Gwenn Hansen	S-1/A	333-239651	10.7	July 20, 2020	
10.7*	Employment Agreement, dated July 15, 2020, by and between the Registrant and Christine Ring					X
10.8	Lease Agreement, dated as of March 24, 2014, between ARE-San Francisco No. 26, LLC and the Registrant	S-1	333-239651	10.8	July 2, 2020	
10.9†	Collaboration, Option and License Agreement, dated June 10, 2019, by and between the Registrant and Gilead Sciences, Inc., as amended	S-1	333-239651	10.9	July 2, 2020	
10.10†	Collaboration and License Agreement, dated December 19, 2019, by and between the Registrant and Genzyme Corporation	S-1	333-239651	10.10	July 2, 2020	
10.11†	First Amendment to Collaboration and License Agreement, dated January 6, 2021, by and between the Registrant and Genzyme Corporation					X
10.12*	Letter Agreement, dated June 15, 2020, by and between the Registrant and Arthur T. Sands	S-1	333-239651	10.11	July 2, 2020	

10.13*	Severance and Change in Control Plan and form of Participation Agreement thereunder	S-1/A	333-239651	10.12	July 20, 2020	
21.1	Subsidiaries of the Registrant					X
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (reference is made to the signature page hereto)					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1‡	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

* *Indicates a management or compensatory plan or arrangement in which directors or executive officers are eligible to participate.*

† *Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.*

‡ *The certifications furnished in Exhibits 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and are not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act of the Exchange Act.*

Item 16. Form 10-K Summary

None.

SIGNATURES

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

NURIX THERAPEUTICS, INC.

Date: February 16, 2021

By: /s/ ARTHUR T. SANDS

Arthur T. Sands, M.D., Ph.D.

President, Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Arthur T. Sands and Hans van Houte, and each of them, as his or her true and lawful attorneys-in-fact, proxies, and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, proxies, and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies, and agents, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ ARTHUR T. SANDS **Arthur T. Sands, M.D., Ph.D.**	President, Chief Executive Officer and Director (*Principal Executive Officer*)	February 16, 2021
/s/ HANS VAN HOUTE **Hans van Houte**	Chief Financial Officer (*Principal Financial and Accounting Officer*)	February 16, 2021
/s/ DAVID L. LACEY **David L. Lacey, M.D.**	Director	February 16, 2021
/s/ LEON CHEN **Leon Chen, Ph.D.**	Director	February 16, 2021
/s/ JULIA P. GREGORY **Julia P. Gregory**	Director	February 16, 2021
/s/ LORI A. KUNKEL **Lori A. Kunkel, M.D.**	Director	February 16, 2021
/s/ JEFFREY K. TONG **Jeffrey K. Tong, Ph.D.**	Director	February 16, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Arthur T. Sands, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nurix 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 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)) 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. 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

    c. 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 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.

By: /s/ ARTHUR T. SANDS
Arthur T. Sands, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 16, 2021

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Hans van Houte, certify that:

1. I have reviewed this Annual Report on Form 10-K of Nurix 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 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)) 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. 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

    c. 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 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.

By: /s/ HANS VAN HOUTE
Hans van Houte
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 16, 2021

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

Each of the undersigned officers of Nurix Therapeutics, Inc. (the Company) certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Annual Report on Form 10-K of the Company for the period ended November 30, 2020 (the Annual Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

2. The information contained in this Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ ARTHUR T. SANDS
Arthur T. Sands, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ HANS VAN HOUTE
Hans van Houte
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 16, 2021

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished to the Securities and Exchange Commission as an exhibit to the Form 10-K and shall not be considered filed as part of the Form 10-K.