NEWLINK GENETICS CORP
Form 10-K
March 05, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
ý Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the fiscal year ended December 31, 2017.
o 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
001-35342
NEWLINK GENETICS CORPORATION
(Exact name of Registrant as specified in Its Charter)

Delaware	42-1491350
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2503 South Loop Drive
Ames, Iowa 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:	Common Stock, par value $0.01
Name of each exchange on which registered:	The 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 o No ý
Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No ý
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 ý No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ý No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company o
(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý
The aggregate market value of the common stock held by non-affiliates of the registrant based on the closing sale price of the registrant’s common stock on June 30, 2017, as reported by the NASDAQ Global Market, was $159,637,289. Shares of the registrant’s common stock beneficially owned by each executive officer and director of

the registrant and by each person known by the registrant to beneficially own 10% or more of its outstanding common stock have been excluded, in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

As of March 2, 2018, there were 37,155,838 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders.

NewLink Genetics Corporation
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "p "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other sim expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements regarding the following: our plans to develop and commercialize our product candidates; our ongoing and planned preclinical studies and clinical trials; the timing of release of the results of interim analyses or other data from ongoing clinical studies; the timing for completion of enrollment and outcomes of our ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and other risks and uncertainties, including those listed under the caption "Risk Factors."

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our, or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements not specifically described above also may be found in these and other sections of this report.

We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so, even if new information becomes available, except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. You are also advised to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K.

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PART I

Item 1. BUSINESS

Overview

NewLink Genetics Corporation (the "Company", "NewLink", "we", "our" or "us") is a late clinical-stage immuno-oncology company focused on discovering and developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod, NLG802 (a prodrug of indoximod) and NLG919 (formerly navoximod or GDC-0919), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system’s tolerance to cancer.

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens, or TAAs. When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by IDO that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the break-down product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may also enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

We had a net loss of $72.0 million for the year ended December 31, 2017. We expect to continue to have losses for the foreseeable future as we advance our product candidates through late-stage clinical trials, pursue regulatory approval of our product candidates, and expand our commercialization activities in anticipation of one or more of our product candidates receiving marketing approval.

Founded in 1999 and headquartered in Ames, Iowa, and Austin, Texas, we have clinical, research and development staff dedicated to our pipeline of product candidates for patients with cancer and other diseases.

Our Strategy

Our strategy is to discover, develop and commercialize immunotherapeutic products for the treatment of patients with cancer where there are unmet needs with current therapies. The critical components of our business strategy in 2018 include:

- Initiating randomization portion of Indigo301, a pivotal Phase 3 trial for patients with advanced melanoma, in the second of third quarter of 2018
- Obtaining full Phase 2 results of indoximod plus checkpoint inhibitors in metastatic melanoma in the first half of 2018
- Initiating Indigo201, a randomized Phase 2 trial for patients with metastatic pancreatic cancer, in the first half of 2018
- Obtaining full Phase 2 results from the single-arm trial of indoximod plus gemcitabine nab-paclitaxel in metastatic pancreatic cancer in first half of 2018
- Presenting two abstracts at the AACR Annual Meeting 2018, including data from a Phase 1 study of indoximod for pediatric patients with malignant brain tumors and data providing additional characterization of the differentiated mechanism of action of indoximod
- Continuing to evaluate indoximod in additional oncology indications

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IDO Pathway Inhibitors

We have a clinical development program focused on the IDO Pathway. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include indoximod, NLG802 and NLG919. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod and NLG919 are two distinct small molecules that target the IDO pathway through different mechanisms of action and therefore could represent two different clinical and commercial opportunities. Indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the up regulation of mTOR, acts directly on T-cells, and modulates AhR-mediated effects. NLG919 and similar molecules of other companies seek to inhibit the IDO enzyme directly and thereby prevent the metabolism of tryptophan into kynurenine.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-PD-L1 or anti-CLTA4. Clinical data suggests an increase in activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with melanoma, pancreatic cancer, pediatric brain tumors, and acute myeloid leukemia. We believe there may be additional opportunities to apply indoximod to a broader set of cancer indications. Indoximod has been studied in more than 700 patients to date and has been generally well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents and a cancer vaccine.

A U.S. patent covering salt and prodrug formulations of indoximod was issued to us on August 15, 2017 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

In September 2017, we announced updated data from NLG2103 a Phase 2 clinical trial evaluating the addition of indoximod to the standard of care checkpoint inhibitors approved for patients with advanced melanoma (pembrolizumab, ipilimumab, or nivolumab). The interim data represent a cohort of 51 evaluable patients who received indoximod in combination with pembrolizumab. Evaluable patients were defined as those having at least one on-treatment imaging study. The primary outcome measure of the trial is objective response rate, or ORR, and secondary outcome measures include progression free survival, or

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PFS, disease control rate, or DCR, and evaluation of safety and tolerability. The ORR was 61% (31/51) with a complete response of 20% (10/51) and a DCR of 80% (41/51). The PFS, by RECIST criteria was 56% at one year with median PFS, or mPFS, of 12.9 months. We expect to present the full data set for all the patients in this study plus checkpoint blockade in metastatic melanoma in the first half of 2018.

A summary of the results for those 51 patients for both periods is set forth in the table below.

	Phase 2 Clinical Data n (%) (data as of August 2017)
ORR	31 (61)
CR (complete response)	10 (20)
PR (partial response)	21 (41)
SD (stable disease)	10 (20)
DCR	41 (80)
PD (progressive disease)	10 (20)
mPFS	12.9 months
PFS at 12 months	56%

Indigo301, our pivotal Phase 3 clinical trial, is an investigation of indoximod in combination with a checkpoint inhibitor compared to the checkpoint inhibitor alone for patients with advanced unresectable or metastatic melanoma. Indigo301 has a 1:1 randomized, double blind, placebo controlled design. Participating investigators will be allowed to choose either of the U.S. Food and Drug Administration, or FDA, approved PD-1 checkpoint inhibitors, KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab) and patients will then be randomized to receive indoximod or placebo in conjunction with the checkpoint inhibitor. The trial will have co-primary endpoints of progression free survival and overall survival. The planned enrollment is 624 patients. We intend to initiate the randomization portion of Indigo301 in the second or third quarter of 2018 and we expect to complete enrollment in 2019.

We plan to use our new salt formulation of indoximod in Indigo301. Clinical evaluation of the indoximod salt formulation is being addressed in ongoing trials. Initial data from these trials suggest that the tablets of indoximod salt, manufactured in accordance with the original specifications, achieved different exposure levels of indoximod in humans than we had anticipated. The exposure levels observed ranged from below to above the level typically observed with the standard clinical dose of indoximod freebase gel capsules. We have therefore made minor modifications, including a change to the specifications. We have accordingly extended the clinical evaluation to test the modified tablets in healthy volunteers. We expect the results of the evaluation of the new indoximod tablets within approximately 60 days of the filing of this Form 10-K, and those results will determine how quickly we can begin the pivotal portion of Indigo301. If results from these clinical trials raise meaningful concerns about the performance of the indoximod salt formulation, the time and expense required to initiate and complete our Indigo301 clinical trial would likely increase.

In addition, we have completed our own single-arm Phase 2 trial of indoximod plus chemotherapy in metastatic pancreatic cancer and expect to present the full data set in the first half of 2018. We also plan to initiate Indigo201, a randomized blinded Phase 2 trial of indoximod plus durvalumab plus chemotherapy in metastatic pancreatic cancer in collaboration with AstraZeneca.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above the levels currently achievable by direct oral administration. We filed an Investigational New Drug application, or IND, with the FDA in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

NLG919

NLG919, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, or the Genentech

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Agreement. The Genentech Agreement provided for the development and commercialization of NLG919. On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919 and such termination was effective December 6, 2017. As part of the partial termination, worldwide rights to NLG919 reverted back to the Company and Genentech granted us a license under certain of Genentech's intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities.

In addition, under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next generation IDO/tryptophan-2,3-dioxygenase, or TDO, inhibitors. The research program ended in November 2016, but our collaboration with Genentech continues with respect to next generation IDO/TDO inhibitors identified through the research program.

Additional Product Candidates

Additional clinical-stage product candidates in our pipeline include two product candidates that utilize our HyperAcute® Cellular Immunotherapy technology and two small molecules we acquired in 2017 from Daré Bioscience, Inc. (previously Cerulean Pharma Inc.). The HyperAcute Immunology candidates, tergenpumatucel-L and dorgenmeltucel-L, are in Phase 2 clinical trials for patients with advanced lung cancer and melanoma, respectively. We have substantially reduced our financial commitment for the HyperAcute Cellular Immunotherapy product candidates, and have no plans to conduct additional clinical trials. We also have two other small molecules, CRLX101 and CRLX301, being evaluated in early clinical development for patients with advanced solid malignancies. Additional clinical trials with the CRLX101 or CRLX301 product candidates are under consideration, pending the outcome of the current studies and the availability of resources.

Ebola Vaccine Candidate

In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck to develop and potentially commercialize our rVSVΔG-ZEBOV GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV GP vaccine product candidate was originally developed by the Public Health Agency of Canada, or PHAC, and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. rVSVΔG-ZEBOV GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV GP from the U.S. BioMedical Advanced Research & Development Authority, or BARDA, and the Defense Threat Reduction Agency, or DTRA, totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015, in 2017 funds of $2.1 million were de-obligated from the DTRA grant awards. We have received total awards of $118.8 million.

Cancer Market Overview

Cancer is the second-leading cause of death in the United States; the American Cancer Society estimated that more than 600,000 deaths will occur in 2018 and almost 1.7 million new cancer cases are expected to be diagnosed in 2018. Despite a number of advances in the diagnosis and treatment of cancer over the past decade, overall five-year survival rates from all cancer types is 69% for the period spanning 2007-2013 according to the National Cancer Institute. Cancer is characterized by abnormal cells that grow and proliferate, forming masses called tumors. Under certain circumstances, these proliferating cells can metastasize, or spread, throughout the body and produce deposits of tumor cells called metastases. As the tumors grow, they may cause tissue and organ failure and, ultimately, death. To be effective, cancer therapies must eliminate or control the growth of the cancer.

The specialized cells of the immune system recognize specific chemical structures called antigens. Generally, foreign antigens trigger an immune response that results in the removal of disease-causing agents from the body. Cancer cells, however, frequently display antigens that are also found on normal cells. The immune system may not be able to distinguish between tumors and normal cells and therefore may be unable to mount a strong anti-cancer response. Additionally, tumors often express abnormal proteins that could be recognized by the immune system. However,

tumors also have various immune-suppressive defense mechanisms that may prevent the immune system from fully activating and recognizing these abnormal antigens.

Current therapies, such as surgery, radiation, hormone treatments and chemotherapy, do not directly address this immune-evasive characteristic of cancer and may not have the desired therapeutic effect. Active immunotherapies stimulate the immune

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system, the body's natural mechanism for fighting disease, and may overcome some of the limitations of current standard-of-care cancer therapies.

Limitations of Current Cancer Therapies

We believe current cancer treatment alternatives suffer from a number of limitations that impair their effectiveness including:

- Toxicity. Chemotherapeutic agents are highly toxic to the human body and often cause a variety of side effects, which may include nausea and vomiting, bleeding, anemia and mucositis. Targeted therapeutics may have fewer systemic toxicities, but still tend to have off-target effects such as gastrointestinal inflammation, severe skin reactions and breathing difficulties. These effects limit a patient's ability to tolerate treatment thereby depriving the patient of the potential benefit of additional treatments or treatment combinations that might otherwise destroy or prevent the growth of cancer cells. Once educated as to the limited efficacy, limited increased survival and potentially significant toxicity of existing treatment alternatives, patients diagnosed with terminal cancer often choose to limit or forego therapy in order to avoid further compromising their quality of life. Patients with advanced stage cancer often cannot tolerate cancer therapy, and certain therapies have been shown to hasten death in some cases as the patient's health deteriorates.
- Development of resistance. While many current therapeutic approaches may be effective against a particular target, the overall impact of these therapies on treating cancer is limited because the abundance and diversity of tumor cells are believed to enable cancers to adapt and become resistant to these treatments over time resulting in reduced longer-term efficacy.
- Short-term approach. Incremental survival benefit is the primary objective of many currently marketed and development-stage cancer therapeutics. In general, many drugs show modest impact on overall survival or only affect progression-free survival. Other than surgical tumor removal, curative intent is often not a focus or realistic potential outcome of many current cancer therapies.
- Immune system suppression. Cancer is difficult to treat in part because cancer cells use sophisticated strategies to evade the immune system. Cancer treatment often involves the introduction of an agent, such as a chemical, an antibody or radiation, which causes cell apoptosis (programmed cell death) or inhibit the proliferation of all cells, including immune cells, thereby indirectly suppressing the immune system. A weakened immune system not only further inhibits the body's natural ability to fight cancer, but also causes patients to become more susceptible to infections and other diseases.

Grants and Contracts with the United States Government

Other than the upfront payments received in 2014 from Genentech and Merck, grants and contracts with the United States Government accounted for substantially all of our revenue in each of the last four fiscal years. In December 2014, BARDA awarded us a contract, as the prime contractor, in the amount of $30.0 million to support the manufacturing and development activities of our Ebola vaccine product candidate, including clinical development through a new 330-person Phase 1b clinical trial. In 2015, BARDA awarded us another $4.5 million under the base contract and exercised an $18.0 million option on our existing contract to support the scale-up of the manufacturing process related to our Ebola vaccine product candidate. In 2016, BARDA awarded us additional awards under the base contract of $24.5 million, for a total amount of $76.8 million received in awards. In October 2016, we announced that BARDA had issued us a new $24.8 million contract to support the advanced development of the investigational rVSVΔG-ZEBOV GP vaccine candidate, designated V920, designed to induce immunity against the Ebola Zaire virus. The new award includes an additional $51.0 million of contract options which may be exercised by BARDA. The new funding is in support of manufacturing facility readiness, manufacturing process qualification activities, and additional clinical trials to support regulatory approval of the V920 vaccine currently being led by our partner, Merck. We have also received funding from the United States Department of Defense to support the development of contract manufacturing for the vaccine product candidate for clinical trials. We were awarded funds of $6.4 million from DTRA under the initial base contract and additions to this contract during 2014. In September 2015, DTRA awarded us another $8.1 million base contract with future options totaling $5.2 million to support various development activities of our Ebola vaccine product candidate. In March 2016, DTRA awarded us another $2.9 million base contract with future options totaling $6.3 million. In 2017 funds of $2.1 million were deobligated from the DTRA

grant awards.

Manufacturing

We currently contract with manufacturing organizations to develop and manufacture the novel formulations for our

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indoximod and NLG802 product candidates. We believe that many suppliers would be available for the production of these product candidates, if required. We currently have no plans to build our own manufacturing facility to support these product candidates.

Should we need additional supply of the NLG919 product candidate, we would be responsible for the manufacturing and would seek to contract with manufacturing organizations to develop and manufacture NLG919. We currently have no plans to build our own manufacturing facility to support this product candidate.

Merck has assumed responsibility for manufacturing the Ebola vaccine product candidate in accordance with the Merck Agreement.

Sales and Marketing

We currently own exclusive worldwide commercial rights to all our product candidates other than the Ebola vaccine candidate. We plan to build a commercial infrastructure to support any of these products, should they receive FDA or other applicable regulatory authorization. In addition, we may pursue collaborations or co-promotion arrangements with pharmaceutical and biotechnology companies to complement these efforts or for particular indications or in specific territories. We intend that our commercial infrastructure will be a fully integrated and highly experienced team, consisting of sales, marketing, medical affairs, market access and other positions necessary for a successful product launch.

Competition

The biopharmaceutical industry is highly competitive. Given the significant unmet patient need for new therapies, oncology is an area of focus for many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and developing and acquiring technologies, obtaining patent protection, and securing sufficient capital resources for the often lengthy period between technological conception and commercial sales. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Immunotherapy Products for Cancer

The cancer immunotherapy landscape is broad but still in the early stages of development as compared to more established approaches like cytotoxic chemotherapy. Several immunotherapy products to treat cancer been approved in recent years. Multiple drugs classified as checkpoint inhibitors have been approved since 2011 targeting either CTLA-4, PD-1 or PDL-1 via antibody blockade. Additionally, there have been regulatory approvals for other immunotherapies in the classes of CAR-T and oncolytic virus. The indications for which these agents have been approved include some indications that we are pursuing or plan to pursue in our clinical development. Other indications in our clinical development plan, such as pancreatic cancer, malignant brain tumors and AML, do not

currently have any FDA approved immunotherapies for immune checkpoint inhibitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Competitors in

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our lead indoximod indication for patients with unresectable or metastatic melanoma include: Bristol Myers Squibb Company, Merck, Genentech Inc., and Incyte Corporation, each of which is conducting or is awaiting results from Phase 3 clinical trials in this indication. Many companies are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. We are also facing increasing competition in enrolling patients in our clinical trials. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

Strategic Collaborations

AstraZeneca Collaboration

On September 25, 2017, we entered into a clinical collaboration agreement with AstraZeneca to evaluate the combination of indoximod and durvalumab, AstraZeneca's anti-PD-L1 monoclonal antibody, along with standard of care chemotherapy for patients with metastatic pancreatic cancer. We and AstraZeneca have agreed to initiate a randomized, placebo-controlled, Phase 2 clinical trial with the primary objective to evaluate the efficacy and safety of the immuno-oncology-based indoximod/durvalumab combination compared to gemcitabine/ABRAXANE alone. Some patients will be enrolled into a smaller cohort evaluating the combination of durvalumab with gemcitabine/ABRAXANE. From the date of our agreement with AstraZeneca and for 90 days after the completion of such combination study, we may not conduct a clinical trial involving the combination of indoximod and any compound that targets PD-1 or PD-L1 (other than durvalumab) for the metastatic pancreatic cancer indication, and AstraZeneca may not conduct a clinical trial involving the combination of durvalumab and any IDO pathway inhibitor (other than indoximod) for the metastatic pancreatic cancer indication.

Indigo201, the Phase 2 clinical trial, will be funded equally by both companies, with us serving as the study sponsor. Our share of the aggregate expense of the trial is not expected to have a material effect on our financial position. We expect to begin enrolling patients in the first half of 2018.

The market opportunity for the treatment of pancreatic cancer is substantial. Approximately 55,000 new cases of pancreatic cancer in the United States will be diagnosed in 2018 according to the American Cancer Society, and a little over 44,000 people will die of the disease this year. Pancreatic cancer is difficult to detect in its early stages and approximately 52% of all pancreatic cancers are metastatic, or advanced, in nature and are associated with a poor prognosis. The 5-year survival rate for pancreatic cancer overall is only 8%, and drops to a low of 3% for individuals whose pancreatic cancer has metastasized to distant regions of the body.

Genentech Agreement

In October 2014, we entered into the Genentech Agreement for the development and commercialization of NLG919, our clinical stage IDO pathway inhibitor, and a research collaboration for the discovery of next generation IDO/TDO inhibitors to be developed and commercialized under the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150.0 million in 2014 and funding for our participation in the research collaboration, which ended in November 2016.

On June 6, 2017, we received a formal notice of Genentech’s intent to terminate the Genentech Agreement with respect to NLG919. The agreement was terminated in part on December 6, 2017 and the rights to NLG919 reverted back to the Company. As part of the partial termination, Genentech granted to us an exclusive license under certain intellectual property of Genentech, to develop and commercialize NLG919, and we are obligated to pay to Genentech a royalty on future net sales of NLG919 in the low single digits.

Our collaboration with Genentech continues with respect to next generation IDO/TDO inhibitors identified through the research program.

Genentech retains the exclusive, sublicensable, royalty-bearing license that we granted to it, under certain of our patents and know-how, to develop and commercialize next generation IDO/TDO inhibitors, and we remain committed

to work exclusively with Genentech with respect to IDO/TDO compounds, other than indoximod and NLG919, for a specified number of years.

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Genentech would be responsible for and would fund development, manufacturing and commercialization of any next generation IDO/TDO compounds that it elects to pursue. We have retained the option under the Genentech Agreement to co-promote next generation IDO/TDO products with Genentech in the United States, subject to certain conditions, if and when such products are approved for sale. We would be eligible to receive milestone payments of up to $561.0 million upon achieving certain development, regulatory, and sales-based milestones with respect to any next generation IDO/TDO inhibitor products. We retain the right to exercise an option to co-promote any products for the U.S. market and we are also eligible to receive escalating royalty payments on potential commercial sales of products by Genentech.

We have retained all rights to indoximod, our proprietary IDO pathway inhibitor and reformulations or prodrugs related to indoximod, including the ability to develop, commercialize, license and divest indoximod in our discretion. Unless earlier terminated, the Genentech Agreement will continue in effect for as long as Genentech has payment obligations to us. Each party may terminate the Genentech Agreement for the other party's uncured material breach or the other party's bankruptcy or insolvency. Genentech may terminate the Genentech Agreement for convenience upon 180 days written notice.

Merck Agreement

In November 2014, we entered into the Merck Agreement to research, develop and potentially commercialize our Ebola vaccine product candidate and certain other aspects of our vaccine technology. The Ebola vaccine product candidate was originally developed by PHAC. Under the Merck Agreement, we received an upfront payment of $30.0 million in 2014 and a milestone payment of $20.0 million in 2015, and we have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. In July 2015, we announced that the international partnership studying the rVSVΔG-ZEBOV GP (Ebola) vaccine candidate in Guinea released interim data suggesting that it is effective in the prevention of Ebola in a large Phase 3 clinical trial. The rVSVΔG-ZEBOV GP product candidate will continue to be studied in clinical trials. In February 2017 the final report from the trial confirmed that rVSVΔG-ZEBOV GP offers substantial protection against Ebola virus disease, with no cases among vaccinated individuals without the infection from day 10 after vaccination in both randomized and non-randomized clusters.

Under the terms of the Merck Agreement, Merck is granted the exclusive rights to the Ebola vaccine product candidate. The Ebola vaccine product candidate is under a licensing arrangement with BioProtection Systems Corporation, or BPS, our wholly owned subsidiary and a licensee of PHAC. Under these license arrangements, PHAC retains non-commercial rights pertaining to the vaccine candidate. The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves BPS from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us.

Unless earlier terminated, the Merck Agreement will continue in effect for as long as Merck has royalty payment obligations to us. Merck may terminate the Merck Agreement for convenience upon a specified period of notice or for certain safety reasons with immediate effect. In the event of Merck's uncured material breach of its obligations under the Merck Agreement with respect to a particular product, we may terminate the Merck Agreement with respect to that product. We may also terminate the Merck Agreement with respect to certain products in the event Merck pursues an alternate product under certain circumstances. Each party may terminate the Merck Agreement for the other party's bankruptcy or insolvency.

Intellectual Property

We believe that patent protection and trade secret protection are important to our business and that our future success will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain and maintain patents and operate without infringing the proprietary rights of others both in the United States and abroad. We believe that obtaining identical patents and protection periods for a given technology throughout all markets of the world will be difficult because of differences in patent laws. In addition, the protection provided by non-U.S. patents,

if any, may be weaker than that provided by U.S. patents. We have established and continue to build proprietary positions for our IDO pathway inhibitor technology and our HyperAcute technology in the United States and abroad. As of December 31, 2017, our patent portfolio included nineteen patent families relating to our IDO pathway inhibitor technology and five patent families relating to our HyperAcute technology.

Our IDO pathway inhibitor technology patent portfolio contains several key U.S. patent families that protect indoximod, NLG802, and NLG919. A series of patents covering indoximod were exclusively licensed from Augusta University Research

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Institute, formerly known as Georgia Regents Research Institute, Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The first patent family contains six issued U.S. patents expiring in 2018, 2019 and 2021. This family contains patents having claims to pharmaceutical compositions of 1-methyl-tryptophan (US 8,198,265), methods of increasing T-cell activation (US 6,451,840) and methods of augmenting rejection of tumor cells (US 6,482,416) by administering an IDO inhibitor. The second patent family contains four issued U.S. patents directed to pharmaceutical compositions of indoximod (US 8,232,313, expires in 2024) and to methods of using indoximod to treat cancer (US 7,598,287, US 8,580,844 and 9,463,239 expires in 2027, 2025, and 2024, respectively). In addition, we have a granted US patent (US 9,732,035) and worldwide pending patent applications covering indoximod prodrugs and novel formulations of indoximod (PCT/US2016/035391). We do not currently have any granted non-U.S. patents covering indoximod prodrugs and novel formulations of indoximod, and we cannot assure that we will be able to secure any such patents.

We believe that significant barriers to entry in the IDO space are provided by three key patent families covering compositions of matter and methods of use of different classes of IDO inhibitor compounds, and are fully owned by us: 1) PCT/US2008/085167 with granted applications in Europe (EP2227233), China, Japan, Canada, and Hong Kong; 2) PCT/US2010/054289, with granted patents in the US (8,722,720), Europe (EP2493862) and Canada (CA2778115); and 3) PCT/US2012/033245, which covers the IDO inhibitor compound NLG919, currently in clinical development. The national counterparts of the third family provide protection at least until 2032, not counting any patent term adjustment in the United States. This patent has been granted in the United States, Europe, Australia, China, Israel, Japan, Mexico and New Zealand with multiple applications pending in other countries. Additional barriers to entry are provided through exclusive licenses with Lankenau Institute for Medical Research, or LIMR, and various NewLink-owned inventions, in which we are pursuing patent protection for specific combination therapies targeting the IDO pathway, as well as protection for novel families of inhibitor compounds and second generation products. Four patent families that cover different classes of IDO inhibitor compounds and methods of treatment of cancer have been licensed from LIMR and are represented by several international pending cases and the issued patents US 7,714,139, US 8,476,454, CA 2520586, US 7,705,022, US 8,008,281, JP 4921965, CN ZL200480014321.1, CA 2520172, US 8,383,613, US 8,389,568. An additional patent family co-owned by us and LIMR covers compositions and methods of use of another family of IDO inhibitor compounds (PCT/US2009/041609, with issued patents US 8,748,469, US9174942, Canada 2722159, China 102083429, and pending applications in Europe and Japan).

There is one principal family of patents and patent applications relating to our HyperAcute product candidates and HyperAcute technology. That patent family is exclusively licensed from Central Iowa Health System and includes two pending patent applications and 25 registered U.S. and foreign patents related to the HyperAcute technology. This patent family provides basic composition of matter patent protection and methods of manufacturing and use of such compositions extending until 2024 and has already resulted in granted patents in U.S. (US 7,763,461, US 8,551,474, US 8,535,658, US 9,474,801, US 9,474,771), Europe (EP 1549353 B1), Mexico (278681), Japan (4966496) and Canada (2501744), all covering pharmaceutical compositions for inhibiting pre-established tumor growth comprising attenuated allogeneic tumor cells modified with alpha-Gal. Similar composition claims as well as methods of use for treating pre-established tumors are currently being further pursued in the U.S. and China.

We exclusively license from Central Iowa Health System or own several other patents relating to alpha-Gal technology, which we believe provide additional barriers to entry in the space occupied by our HyperAcute technology. Additional coverage include five applications issued in the United States (US Patents No. 7,998,486, 8,357,777, 8,916,169, 9,090,643 and 9,512,158) and Europe (EP2089051) covering isolated tumor antigens comprising alpha-Gal residues. The issued United States and European patents expire between 2027 and 2029. Additional patent applications have been filed covering the use of carbohydrate-modified glycoproteins (PCT/US2014/025702) and correlates of efficacy to tumor vaccine (PCT/US2014/038231).

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also

oblige our employees, consultants, advisors and collaborators to assign or license to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products or new technologies that may be competitive with those being developed by us. Therefore, any of our product candidates may give rise to claims that it infringes the patents or proprietary rights of other parties now or in the future. Furthermore, to the extent that we, our consultants, or manufacturing and research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights to such intellectual property or in related or resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to

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be licensed from such other parties. A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that we are prevented from the development, manufacture or sale of products requiring such licenses. In addition, we could incur substantial costs in defending ourselves in legal proceedings instituted before patent and trademark offices in the United States, the European Union, or other ex-U.S. territories, or in a suit brought against us by a private party based on such patents or proprietary rights, or in a suit by us asserting our patent or proprietary rights against another party, even if the outcome is not adverse to us.

Licensing Agreements

IDO Pathway Inhibitor Technology

The following licensing agreement covers technologies and intellectual property rights related to our IDO pathway inhibitor technology and product candidates:

Augusta University Research Institute License Agreement

We are a party to a License Agreement dated September 13, 2005, or the AURI IDO Agreement, with Augusta University Research Institute, or AURI, which was formerly known as Georgia Regents Research Institute, the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The AURI IDO Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013, July 10, 2014, and March 15, 2016. The AURI IDO Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified AURI patent rights and related technology to make, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

Our license from AURI is subject to AURI's retained right to use, and to permit its academic research collaborators to use, such AURI patent rights and technology for research and educational purposes. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under such license, subject to the prior approval of AURI, not to be unreasonably withheld or delayed.

In consideration of such license grant, we are obligated to pay to AURI specified license fees (including issuing shares of our common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product (which, as a result of the March 15, 2016 amendment, includes certain prodrugs of indoximod), and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by AURI, we must pay to AURI a percentage of the consideration we receive from the sublicensee. We made a milestone payment of $1.0 million in connection with the March 15, 2016 amendment the AURI IDO Agreement.

If we fail to develop the licensed products in a non-cancer field, specifically infectious disease or diagnostics, AURI may convert our license in such field to a non-exclusive license.

Unless terminated earlier, the AURI IDO Agreement will remain in effect until the expiration of the last licensed AURI patents. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2027, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license.

AURI may terminate this agreement for our uncured material breach, bankruptcy or similar proceedings. We may terminate this agreement for AURI’s uncured material breach or upon written notice to AURI. For a period of one year following the termination of the agreement, we may sell our licensed products that are fully manufactured and part of our normal inventory at the date of termination. We have the right to assign the AURI Agreement to our affiliates or in connection with the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires the prior written consent of AURI.

The PTEN Drug Discovery Program

The following licensing agreement covers technologies and intellectual property rights for our PTEN drug discovery program:

Augusta University Research Institute License Agreement (PTEN)

We have a License Agreement with AURI dated March 15, 2016, or the AURI PTEN License Agreement, pursuant to which AURI granted us an exclusive, worldwide, sublicensable license, under specified AURI patents and related technology, to

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make, use, import, sell and offer for sale, in the cancer field, PTEN inhibitor products, or royalty-bearing products, that are covered by licensed patents or certain of our patents or that were researched or developed using licensed technology.

We notified AURI of our intent to terminate this license in February 2018 and the license will terminate in March 2018. Under the terms of the AURI PTEN License Agreement, we paid an upfront payment to AURI of $1.0 million in 2016 and were obligated to pay AURI potential milestone payments in an aggregate amount up to approximately $4.3 million and royalties at a single-digit or less percentage of net sales of royalty-bearing products. Our obligation to pay milestones and royalties will not terminate upon the termination of the AURI PTEN License Agreement and will continue on a country-by-country and product-by-product basis until the later of (a) expiration of the last valid claim of our patents covering such royalty-bearing product in such country and (b) 10 years after the first commercial sale of such product in such country. We do not anticipate incurring any future payment obligations because we are no longer pursuing the development of PTEN inhibitor products.

Concurrent with the termination notice for the AURI PTEN License Agreement, we also notified AURI that we would not renew the Research Services Agreement with AURI, or the AURI PTEN Research Services Agreement, which was signed concurrently with the AURI PTEN License Agreement and is set to expire in March 2018. Under this agreement, AURI performed certain research services directed to PTEN inhibitors as agreed by the parties during the term of the agreement in exchange for mutually agreed compensation. We own all data and results generated by AURI under the AURI PTEN Research Services Agreement, and AURI owns all other know-how and patents arising from its work under the AURI PTEN Research Services Agreement. Except for terms intended to survive past expiration, we have no further obligations to AURI under the AURI PTEN Research Services Agreement.

Vaccines for the Biodefense Field

The following licensing agreement to which BPS is a party covers technology and intellectual property rights applicable to BPS's development of vaccines for the biodefense field:

Public Health Agency of Canada License Agreement

BPS is a party to a license agreement with PHAC, dated May 4, 2010, which was amended and restated on December 5, 2017, or the PHAC License. Under the terms of the PHAC License, BPS has a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Zaire), a rVSV based on viral hemorrhagic fever, or VHF virus, and a worldwide, personal, non-transferable, non-exclusive, revocable, royalty-bearing license, under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Sudan), a VHF virus. The license granted to BPS is subject to Canada's retained rights to use the licensed patent rights and technology to improve the patent rights, carry out educational purposes, and for the development of the patent rights where BPS cannot obtain regulatory approval or meet demand. BPS may also grant sublicenses under the PHAC License, provided that each sublicense is consistent with the terms and conditions of the PHAC License and contain certain mandatory sublicensing provisions.

We granted a sublicense under the PHAC License to Merck in November 2014 when we entered into a license and collaboration agreement with Merck to develop and potentially commercialize our Ebola vaccine product candidate. The PHAC License provides express consent for Merck to sublicense or subcontract its sublicensed rights under certain circumstances.

In consideration of the license grants, under the terms of the PHAC License, BPS must pay to Canada annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$475,000, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, its affiliates or sublicensees in countries outside of Africa and GAVI eligible countries, which royalty rate varies depending on whether additional technology licenses are required to sell the licensed product, and whether the licensed product is covered by a valid claim of a patent licensed under the PHAC License. In addition to the milestones and royalties discussed above, BPS is required to pay to Canada a percentage in the low double digits of certain consideration BPS receives from Merck or any other sublicensee over specified thresholds. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products. If BPS breaches its obligations and

fails to cure the breach, PHAC may terminate the PHAC License.

In November 2014, we entered into a licenses and collaboration agreement with Merck to develop and potentially commercialize our Ebola vaccine product candidate. The Merck Agreement includes a sublicense of the patents subject to the PHAC License.

Unless terminated earlier, the PHAC License will remain in effect until the earlier of (i) July 28, 2033; or (ii) such time that BPS and its sublicensees cease all development and commercialization of the technologies that are licensed to the Company under the PHAC License. Canada may terminate this agreement for BPS's failure to use commercially reasonable efforts to

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commercialize, failure to pay, breach of confidentiality, cessation of business, criminal conviction or other breach of its obligations under the agreement. BPS may not assign the PHAC License to a third party without the prior written consent of Canada, not to be unreasonably withheld. This agreement will terminate automatically if BPS files for bankruptcy or similar proceedings or if BPS assigns the PHAC License under certain circumstances without prior written consent of Canada.

Government Regulation

We operate in a highly regulated industry that is subject to significant federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug, and Cosmetic Act, or FDC Act, and the Public Health Service Act, among others.

The FDC Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these laws and regulations, product development and product approval processes are very expensive and time consuming.

FDA Approval Process

In the United States, pharmaceutical products, including biologics, are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion 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, or NDAs, or biologic license applications, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or 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 or biologic 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 as well as animal trials to assess the characteristics and potential pharmacology and toxicity of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not objected to 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 in compliance with federal regulations, good clinical practices, or GCP, as well as 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 or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials to support NDAs or BLAs, which are applications 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 patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks.

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If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these trials are frequently referred to as Phase 1B clinical trials. Additionally, when product candidates can do damage to normal cells, it is not ethical to administer such drugs to healthy patients in a Phase 1 clinical trial. After completion of the required clinical testing, an NDA or, in the case of a biologic, a BLA, is prepared and submitted to the FDA. FDA approval of the marketing application is required before marketing of the product may begin in the U.S. The marketing application 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. Submission of an NDA or BLA also requires the payment of a substantial user fee, unless a waiver applies.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. 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 marketing applications. Most such applications for non-priority drug products are reviewed within 10 months of their acceptance for filing, and for priority designated applications, within six months of their acceptance for filing. The review process may be extended by the FDA for three additional months to consider new information submitted during the review or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a marketing application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. The FDA may also inspect one or more non-clinical study sites to assure compliance with GLP. Additionally, the FDA will inspect the proposed facility or the facilities at which the drug substance or drug product is manufactured, tested, packaged or labeled. The FDA will not approve the product unless it has compliance with GCP, GLP, and current good manufacturing practices, or cGMPs, and the marketing application (the NDA or, in the case of biologics, the BLA) contains data that provide substantial evidence that the drug is safe and effective in the indication or indications studied. Manufacturers of biologics also must comply with FDA's general biological product standards to demonstrate that the product is safe, pure and potent.

After the FDA evaluates the marketing application and the manufacturing facilities, it issues an Approval Letter, or a Complete Response letter. A Complete Response letter outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed in a resubmission of the marketing application, FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, 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. It is not unusual for the FDA to issue a Complete Response letter because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

An Approval Letter authorizes commercial marketing of the drug with specific prescribing information for specific indication or indications. As a condition of approval of the marketing application, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and Risk Evaluation and Mitigation Strategies, or REMS, which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for marketing of a drug or biologic through an NDA or BLA, respectively, applicants are required to list with the FDA each patent with claims that cover the applicant's product or FDA approved method of using this product. Upon approval of a product, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product,

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other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as “generic equivalents” to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. 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. 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 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.

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 applicant and patent holders once the ANDA has been accepted for filing by the FDA. The NDA applicant 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 notification 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 non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.

Ongoing Regulatory Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indication or indications and in accordance with the provisions of the approved labeling. 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, or in the case of biologics, a new BLA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs. We cannot be certain that the FDA or any other regulatory agency will grant approval for our product candidates for any other indications or any other product candidate for any indication on a timely basis, if at all.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced, routine or for-cause inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with

cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

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U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Federal and State Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to increase the transparency of and restrict certain marketing practices in the pharmaceutical and medical device industries in recent years. These laws include the Physician Payments Sunshine Act, anti-kickback statutes and false claims statutes.

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, are also applicable to our business. We could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include: the federal Anti-Kickback Statute, which prohibits soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters and was amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and the Physician Payments Sunshine Act, which requires certain pharmaceutical manufacturers to annually report information to CMS, as defined below, related to payments and other transfers of value to physicians, other healthcare providers and institutions, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members. There are also state law equivalents of each of the above federal laws, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Regulation Outside the United States

Drugs are also subject to extensive regulation outside of the United States. Whether or not we obtain approval in the United States, we will be subject to separate regulatory approval standards in foreign countries. In the E.U., for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in Europe). If this procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under two simplified application processes, the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After regulatory approval is received through any of the European registration procedures, pricing and reimbursement approvals are also required in most countries.

Price Controls

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. In many of the markets where we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to reimbursement programs with varying price control mechanisms. In the United States, the Medicare program is administered by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. Coverage and reimbursement for products and services under Medicare are determined pursuant to regulations promulgated by CMS and pursuant to CMS's subregulatory coverage and reimbursement determinations. It is difficult to predict how CMS may apply those regulations and subregulatory determinations to newly approved products, especially novel products, and those regulations and interpretive determinations are subject to change. Moreover, the methodology under which CMS makes coverage and reimbursement determinations is subject to change, particularly because of budgetary

pressures facing the Medicare program. Medicare regulations and interpretive determinations also may determine who may be reimbursed for certain services.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider a drug product to be cost effective compared to other available therapies,

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they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, risk sharing, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Such interest has resulted in several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. These controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals. As a result, the marketability of any product which receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement.

In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. In the years since its enactment, there have been, and continue to be, significant developments in, and continued legislative activity around, attempts to repeal or repeal and replace the ACA. Due to these efforts, there is significant uncertainty regarding future of the ACA, and its impact on a pharmaceutical company's business and operations. Even if favorable coverage and reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

Other Regulations

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

Legal Proceedings

In addition to the legal proceedings described in Note 14 to the consolidated financial statements included in Item 8 of this Form 10-K, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Employees

As of December 31, 2017 we had 76 employees. None of our employees are subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees are good.

Facilities

Our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. We have approximately 45,130 square feet, comprising executive office space and space dedicated to manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. The lease expires January 31, 2020, and we

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have the option to extend the lease for two additional five-year periods upon the same terms as the base lease. We lease an additional 11,800 square feet in Ames, Iowa under leases expiring on March 31, 2018.

We lease 2,686 square feet of additional executive and administrative space in Austin, Texas under a lease expiring in October 2019. We also entered into a lease for 3,255 square feet of additional clinical, regulatory and executives offices in Wayne, Pennsylvania beginning March 1, 2018 and expiring in January 2021.

Corporate Information

We were incorporated in the state of Delaware on June 4, 1999 under the name “NewLink Genetics Corporation.”

Available Information

We view our operations and measure our business as one reportable segment operating primarily in the United States. See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information. Additional information required by this item is incorporated herein by reference to Part II, Item 6 “Selected Financial Data.”

Our website address is www.newlinkgenetics.com; however, information found on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K. We make available free of charge on or through our website copies of our Annual Report, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

You can read our SEC filings over the Internet at the SEC’s web site at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not completed testing of any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to successfully commercialize indoximod, our business, financial condition and results of operations would be harmed.

The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. In addition, we have announced that we intend to begin Indigo301, a large-scale randomized pivotal Phase 3 clinical trial of indoximod in combination with PD-1 antibody for patients with advanced melanoma designed to support a new drug application. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

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If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We plan to use our new salt formulation of indoximod in Indigo301. Clinical evaluation of the indoximod salt formulation is being addressed in ongoing trials. Initial data from these trials suggest that the tablets of indoximod salt, manufactured in accordance with the original specifications, achieved different exposure levels of indoximod in humans than we had anticipated. The exposure levels observed ranged from below to above the level typically observed with the standard clinical dose of indoximod freebase gel capsules. We have therefore made minor modifications, including a change to the specifications. We have accordingly extended the clinical evaluation to test the modified tablets in healthy volunteers. We expect the results of the evaluation of the new indoximod tablets within approximately 60 days of the filing of this Form 10-K, and those results will determine how quickly we can begin the pivotal portion of Indigo301. If results from these clinical trials raise meaningful concerns about the performance of the indoximod salt formulation, the time and expense required to initiate and complete our Indigo301 clinical trial would likely increase.

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 must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing Investigational New Drug applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, or we may not be able to complete them at all.

We have not completed all of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;

- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;

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- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for our product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize our product candidates will be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation, or healthy volunteers willing to participate in certain trials. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- changes in the standard of care that make the trial as designed less attractive to clinicians and patients;
- availability of competing therapies and clinical trials, including announced Phase 3 clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- the results of clinical trials of other IDO pathway inhibitors;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

We have experienced difficulties enrolling patients in certain of our smaller clinical trials due to lack of referrals and may experience similar difficulties in the future. If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

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In addition, the inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events for reasons that may not be related to the product candidate we are testing or, in those trials where our product candidate is being tested in combination with one or more other therapies, for reasons that may be attributable to such other therapies, but which can nevertheless negatively affect clinical trial results.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA. The FDA is not bound by the recommendations of an Advisory Committee, but it typically follows such recommendations. In addition, should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability in future years.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, which may result in greater costs and a longer timeframe for regulatory approval than we estimate, yet we will receive limited revenues, if any, from any future sales of our Ebola vaccine product candidate.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, including obligations related to clinical trials, government contracting and licensing of the vaccine technology, which may cause us to incur costs or losses materially larger than we expect. However, because we have exclusively licensed the right to research, develop, manufacture and distribute our Ebola vaccine product candidate to Merck and we are only entitled to certain royalty and other payments under the Merck Agreement, we will receive limited revenues, if any, even if we or Merck are successful in developing and commercializing our Ebola vaccine product candidate.

The time and cost of product development and the timeframe for regulatory approval of any Ebola vaccine product candidate are uncertain and may be longer and more costly than we estimate. Our Ebola vaccine product candidate is a live virus based on vesicular stomatitis virus, or VSV. There are no commercial vaccines based upon this virus, and unforeseen problems related to the use of our live virus vaccine may prevent or materially increase costs and delays of further development or approval of our Ebola vaccine product candidate. There may be unknown safety risks associated with the vaccine, and regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by the vaccine.

Public perception of vaccine safety issues, including adoption of novel vaccines based upon VSV, may adversely influence willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe, and of patients to receive, novel vaccines. For example, our Ebola vaccine product candidate is currently being developed for prevention of, and may later be

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developed for treatment of patients infected with, Ebola, and public aversion to vaccines for Ebola or vaccines in general may adversely influence later-stage clinical trials of this product candidate or, if approved, its commercial success.

Even if approved, a number of factors may adversely affect commercial sales. Lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of our potential product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. If our Ebola vaccine product candidate eventually is approved and sold commercially, we will receive limited revenues under the Merck Agreement. Finally, in certain cases, our obligations to pay royalties to PHAC may exceed the royalties we receive from Merck.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice, or GCP, requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, requirements and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors indoximod, NLG802, NLG919, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

Some of our product candidates have been studied, or in the future may be studied, in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

We are currently supplying indoximod, our lead IDO pathway inhibitor product candidate, in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

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If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and can have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Even if ultimately approved, indoximod, NLG919, NLG802, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We or our collaborators may not be able to obtain the labeling claims necessary or desirable for the promotion of any potential future products. We or our collaborators may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us or our collaborators that may be expensive and/or time consuming to fulfill. In addition, if we or others identify adverse side effects after any of our potential products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our potential products, additional clinical trials, changes in labeling of our potential products and/or additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our potential products.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have limited experience in preparing applications for marketing approval, commercial-scale manufacturing, managing large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

We will need to increase our manufacturing capacity, which may include negotiating and entering into additional third-party agreements to meet our commercial manufacturing requirements.

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If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us could potentially be lower than if we market and sell these products ourselves.

We entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if our Ebola vaccine product candidate are approved by regulators for marketing and sale, Merck may be unsuccessful in its efforts to commercialize our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products, including to co-promote next generation IDO/TDO inhibitors in the United States, under the Genentech Agreement. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate numbers of physicians to educate them about the attributes of any future products;
- 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.

Because the establishment of sales, marketing and distribution capabilities depends on the progress toward commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to collaborate with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff. On July 28, 2017, we announced that Dr. Nicholas N. Vahanian would be on a temporary leave of absence and that during his absence, other members of the management team would assume his duties. Dr. Vahanian has since returned to work part-time. The long-term loss of services of key executives might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. Additionally, our only significant facility is located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and

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

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Risks Relating to Manufacturing Activities

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of such product candidates or market them. In addition, we currently rely on our partner Merck for the supply of our Ebola vaccine product candidate and other third party manufacturers for our supply of indoximod, NLG802, and NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of indoximod, NLG802, NLG919, our Ebola vaccine product candidate or other finished products.

Any prolonged delay or interruption in the operations of our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of product candidates could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to meet market demand for any products that are approved for sale on a timely basis.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third-party based on its own business priorities and at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates that may have been granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our product candidates, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs

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for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

Furthermore, we do not currently have experience with the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to negotiate and enter into relationships with third-party contract manufacturers.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products. All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our Company, our existing contract manufacturers and those we may engage in the future, and Merck in its capacity as our licensee, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for our Ebola vaccine product candidate, we are or will be subject to additional risks including the need to comply with export and import regulations.

If our current or future contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

Our costs for the manufacture and clinical development of our Ebola vaccine product candidate may exceed our current or any future funding for development efforts of our Ebola vaccine product candidate.

We have entered into certain manufacturing and clinical trial management agreements for our Ebola vaccine product candidate, and we expect to enter into additional agreements and incur additional costs related to our obligations under the Merck Agreement and our agreements with government agencies that are providing funding to us for the development of our Ebola vaccine product candidate. The total costs that we are likely to incur to fulfill our contractual obligations under agreements with third parties for the development of our Ebola vaccine product candidate may exceed our total amount of funding from all sources for such activities. In addition, we are likely to incur operating expenses related to our Ebola vaccine product candidate in addition to our direct contractual costs of administering clinical and other studies. Our failure to obtain sufficient grants or other funding for our Ebola vaccine development efforts will not relieve us of our obligations under our current or future contract manufacturing and other agreements for the Ebola vaccine product candidate.

Our facility is located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business insurance (real, personal and business income) of nearly $12.1 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not

have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

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Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including 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 also outsourced elements of our information technology infrastructure, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. 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, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Relating to Regulation of Our Industry

The industry within which we operate and our business are subject to extensive regulation, which is costly and time consuming and which may subject us to unanticipated delays.

The research, development, testing, manufacturing, labeling, packaging, marketing, distribution, promotion and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe and effective in the case of a small-molecule pharmaceutical product, or is safe, pure and potent in the case of a biologic, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations.

There can be no assurance that clinical trials for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate.

Even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties;
- injunctions;
- suspension of or withdrawal of regulatory approval;
- total or partial suspension of any ongoing clinical trials or of production;

- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or

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- seizure or detention of our products or import bans.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted BLA and NDA. A delay in obtaining, or failure to obtain, such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record-keeping and reporting of adverse experiences and other information. In addition, we would be required to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Noncompliance with these requirements could result in enforcement actions or penalties or could delay introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could also require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses including, but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistleblowing claim, even if without merit, could result in costly litigation or regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability of coverage and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payers may reimburse for our potential products, are uncertain.

In both the United States and foreign markets, sales of our proposed products will depend in part on the availability of coverage and reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations.

In addition, in both the United States and elsewhere, sales of prescription drugs are dependent in part on the availability of coverage and reimbursement to the consumer from third-party payers, such as government and private insurance plans. In the United States, there is no uniform policy for coverage and reimbursement among third party payers. In addition, the process for determining whether a third party payer will provide coverage for a pharmaceutical typically is separate from the process for setting the price of such product or for establishing the reimbursement rate

that the payer will pay for the product once coverage is approved. Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

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Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our customers and third-party payers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws may impact, among other things, our proposed sales, marketing and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- The federal False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the False Claims Act in the name of the government and share in the proceeds of the lawsuit.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.
- The federal Food, Drug and Cosmetic Act, or FDCA, prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health

Insurance Program to report annually to the Centers for Medicare and Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers;

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state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. It is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required 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 included a budget neutrality provision that required 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 and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business

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Healthcare legislative reform measures may have a material adverse effect on our business and results of operations. The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States, the pharmaceutical industry has been affected by the passage of the Patient Protection and Affordable Care Act, or the ACA, which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders 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. Concurrently, Congress has 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 of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump 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. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. Congress may consider other legislation to repeal and replace elements of the ACA.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative or administrative action, either in the United States or abroad.

Individual states have become increasingly aggressive in 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 to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by

third-party payers or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which pharmaceutical products and suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased

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reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last 10 years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including the European Union Directive 95/46/EC (the EU Data Protection Directive) and member state implementing legislation, may also apply to health-related and other personal information obtained outside of the United States The EU Data Protection Directive and the national implementing legislation of the individual European Union Member States impose strict obligations on the ability to process health-related and other personal information of EU data subjects, including in relation to collection, analysis and transfer. These include several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with EU data protection laws remains and data protection authorities

from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU.

In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation, which was officially adopted in April 2016 and will be applicable in

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May 2018, will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Financial Risks

Despite our profitable fiscal year ended December 31, 2014, we have a history of net losses. We incurred a net loss for the years ended December 31, 2016 and 2017 and expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014, primarily as a result of upfront payments under the Genentech Agreement and the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. Any future milestone payments under the Genentech Agreement would depend on Genentech's decision to pursue development of a new product candidate and achievement of specific milestones, and any royalties would depend on successful commercialization of licensed products. The potential milestone and royalty payments under the Genentech Agreement are highly uncertain and dependent on many factors outside of our control related to possible future clinical trials and commercialization. We do not expect any milestone or royalty payments under these or other agreements, if any, to be sufficient to make us profitable in future years. As a result of these and other factors, we incurred a net loss of $72.0 million for the year ended December 31, 2017 and we do not expect to be profitable for the foreseeable future. If we had not received the upfront payments under the Genentech Agreement and the Merck Agreement, we would have incurred a net loss for the year ended December 31, 2014. We anticipate that we will continue to incur operating losses over the next several years as we expand both our commercialization activities and our discovery and research activities.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability in future years is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We may require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);

- payments required with respect to development milestones we achieve under our in-licensing agreements;

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- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost of manufacturing our product candidates and any products we commercialize;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the potential requirement to repay our outstanding government provided loans;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing and receipt of revenues from existing or future products, if any; and
- payments received under any future strategic collaborations.

We anticipate that we will continue to generate significant losses in the future as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates. We believe that our existing cash and cash equivalents will allow us to fund our operating plan in the near and medium term. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. Pursuant to most of these license agreements, we are obligated to make aggregate payments ranging from approximately $200,000 to $4.3 million under our license agreements (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborators, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.

We have received significant financial assistance, primarily in the form of forgivable loans, from state and local governments. We have also received significant financial assistance, primarily in the form of grants and contracts, from federal agencies to support our infectious disease research. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

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Through our subsidiary, BioProtection Systems Corporation, or BPS, we have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

For the year ending December 31, 2017, we have a tax benefit due to our ability to carry net operating losses back to the year ended December 31, 2015 for U.S. federal income tax purposes. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates (including the recently enacted U.S. federal income tax law changes), our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

The recently enacted comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Risks Relating to Competition

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies

also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We may face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our

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competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or collaborate with third parties in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies have entered into the field of immuno-oncology and are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. We expect to face growing competition for enrollment of patients in our clinical trials, which could delay or adversely affect our ability to complete such trials. We may also be adversely effected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any

additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render indoximod, NLG802 and NLG919 product candidates, or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval but cannot compete effectively in the marketplace.

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Our future products, if any, may not be accepted in the marketplace and therefore, we may not be able to generate significant revenue, or any revenue.

Even if our potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our future products, if successfully developed, will compete with a number of traditional immuno-oncology products manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and reimbursement by government and private third-party payers.

Risks Relating to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, as well as our strategic collaborators and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Merck is responsible for clinical trials of our Ebola vaccine product candidate and Genentech is responsible for any clinical trials that it may conduct on next generation IDO/TDO inhibitor products, we are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and with GCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to commercialize the product candidate being tested in such trials, or may be delayed in doing so.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We are also dependent on Genentech and Merck for the development of the product candidates that are the subject of the Genentech Agreement and the Merck Agreement. If either company does not succeed in advancing any product candidate to final approval, or decides to discontinue its collaboration with us, such failure or decision, could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, or if we enter into collaborations that are ultimately unsuccessful, we may be unable to commercialize any potential product effectively or at all.

To successfully commercialize any potential product, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise, as we did in the case of the Genentech Agreement and the Merck Agreement. Such collaborations are complex, and any potential discussions may not result in a definitive agreement for many reasons. For example, 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 our clinical trials, the potential market for the subject product candidates, the costs and complexities of manufacturing and delivering the potential product to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for a potential product is necessary or beneficial and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the potential product

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in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, including the Genentech Agreement to develop and commercialize next generation IDO/TDO inhibitors and the Merck Agreement to develop and commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the subject potential product;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the potential product reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the potential product.

Under the Genentech Agreement, the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it is terminating the Genentech Agreement with respect to NLG919. Further, Genentech has the right to terminate the remainder of the Genentech Agreement for any reason, and Merck has the right to terminate the Merck Agreement for any reason, in each case, after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the development or commercialization efforts. The occurrence of any of these events could adversely affect the development or commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA in the future, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

We may explore strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in the process of seeking appropriate strategic collaborators, and such collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We are required under the AstraZeneca Agreement, Genentech Agreement and the Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the AstraZeneca Agreement, Genentech Agreement and the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;

- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;

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- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Relating to Protecting Our Intellectual Property

If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes, or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted thereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office, or USPTO. The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

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Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first-inventor-to-file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations. Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

In addition, if our competitors filed patent applications in the United States that claim technology also claimed by us, and such applications were filed before the Leahy-Smith Act took effect, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy; are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. An adverse outcome with respect to a third party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property becomes known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

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Risks Relating to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and commercial sale of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death. In addition, healthy volunteers in our indoximod clinical trial or our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidates and may initiate legal action against us.

We currently carry clinical trial liability insurance in the amount of $5.0 million in the aggregate for claims related to our product candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. There can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any future products by us or our collaborators.

On December 9, 2014, the United States Department of Health and Human Services declared our Ebola vaccine product candidate covered under the Public Readiness and Emergency Preparedness Act. This declaration provides immunity under U.S. law against legal claims related to the manufacturing, testing, development, distribution and administration of our vaccine candidate. It does not generally provide immunity for a claim brought in a court outside the United States.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We are involved in a securities class-action litigation and are at risk of additional similar litigation in the future that could divert management’s attention and adversely affect our business and could subject us to significant liabilities.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of securities. We are a party to the securities class action litigation described in Part I, Item 3 of this Annual Report on Form 10-K under the heading “Legal Proceedings.” The defense of this litigation may increase our expenses and divert our management’s attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in this litigation, or any amounts paid to settle this litigation could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this “Risk Factors” section of this Quarterly Report on Form 10-Q and the following:

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- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Genentech, Merck and AstraZeneca;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from political uncertainty, war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. We are currently party to the securities class action litigation described in Part II, Item 1 of this Annual Report on Form 10-K under the heading "Legal Proceedings." This litigation and others like it that could be brought against us in the future could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

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

As of December 31, 2017, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 52.4% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after December 31, 2017. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Global Market. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking only cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management,

including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;

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- the inability of stockholders to call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options or by future issuances of securities by us.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code.

Sections 382 and 383 of the Internal Revenue Code limit a corporation’s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. A Section 382 ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation’s business, results of operations, financial condition and cash flow.

Based on Section 382 ownership change analyses, we believe that, from our inception through December 31, 2016, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

U.S. GAAP and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We conduct our primary operations at leased facilities described below.

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Date
Ames, Iowa	Executive offices and research and development	56,930	March 2018 and January 2020
Austin, Texas	Executive and administrative offices	2,686	October 2019
Wayne, Pennsylvania	Clinical, regulatory, and executive offices	3,255	January 2021

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities, our warehousing facilities and our manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going activities.

Item 3. LEGAL PROCEEDINGS

In addition to the legal proceedings described in Note 14 to the consolidated financial statements included in Item 8 of this Form 10-K, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES

Our common stock is quoted on The NASDAQ Global Market under the symbol "NLNK." The following table sets forth the range of high and low sales prices for our common stock on The NASDAQ Global Market for the periods indicated.

	High	Low
Fiscal 2017		
First Quarter	$24.85	$10.18
Second Quarter	25.17	5.90
Third Quarter	19.30	6.25
Fourth Quarter	12.91	7.63
Fiscal 2016		
First Quarter	35.86	15.68
Second Quarter	20.21	9.23
Third Quarter	15.40	9.70
Fourth Quarter	16.59	9.88

As of March 2, 2018, we had 86 stockholders of record of our common stock. The actual number of stockholders may be 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 paid cash dividends. We do not expect to declare or pay any cash dividends on our common stock in the near future. We intend to retain all earnings, if any, to invest in our operations. The payment of future dividends is within the discretion of our board of directors and will depend upon our future earnings, if any, our capital requirements, financial condition and other relevant factors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference to Item 12 of Part III of this Annual Report on Form 10-K.

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Our Stock Performance

The following graph compares cumulative total return of our Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) The NASDAQ Biotechnology Index. The graph assumes (a) $100 was invested on November 11, 2011 in our Common Stock, the stocks comprising The NASDAQ Stock Market-United States and the stocks comprising The NASDAQ Biotechnology Index, and (b) the reinvestment of dividends. The comparisons shown in the graph are based on historical data and the stock price performance shown in the graph is not necessarily indicative of, or intended to forecast, future performance of our stock.

* $100 invested on November 11, 2011 in stock or index, including reinvestment of dividends.

Cumulative Total Return

	11/11/2011	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
NewLink Genetics Corporation	$100	$99	$177	$311	$561	$514	$145	$115
NASDAQ Composite	$100	$97	$113	$156	$177	$187	$201	$258
NASDAQ Biotechnology	$100	$110	$145	$240	$322	$358	$281	$340

Date*	Transaction Type	Closing Price**	Beginning No. Of Shares***	Dividend per Share	Dividend Paid	Shares Reinvested	Ending Shares	Cum. Total Return
11/11/2011	Begin	$7.08	14.124				14.124	$100.0
12/31/2011	Year End	$7.04	14.124				14.124	$99.4
12/31/2012	Year End	$12.50	14.124				14.124	$176.6
12/31/2013	Year End	$22.01	14.124				14.124	$310.9
12/31/2014	Year End	$39.75	14.124				14.124	$561.4
12/31/2015	Year End	$36.39	14.124				14.124	$514.0
12/31/2016	Year End	$10.28	14.124				14.124	$145.0
12/31/2017	Year End	$8.11	14.124				14.124	$115.0

* Specified ending dates are ex-dividends dates.

** All Closing Prices and Dividends are adjusted for stock splits and stock dividends.

*** ‘Begin Shares’ based on $100 investment.

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Recent Sales of Unregistered Securities

None

Repurchases of Equity Securities

During 2017, the Company repurchased 28,521 shares of its common stock at an average price of $10.11 per share.

During 2016, the Company repurchased 6,011 shares of its common stock at an average price of $13.77 per share.

Use of Proceeds

Not applicable.

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Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this annual report.

We derived the annual consolidated financial data from our audited consolidated financial statements. The statement of operations data for the years ended December 31, 2017, 2016, and 2015 and the balance sheet data as of December 31, 2017 and 2016 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We derived the summary consolidated statement of operations data for the years ended December 31, 2014 and 2013 and the balance sheet data as of December 31, 2015, 2014 and 2013 from our audited consolidated financial statements not included in this Annual Report on Form 10-K.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except per share data)				
Statement of operations data:					
Grant revenue	$28,321	$32,242	$32,358	$6,642	$1,093
Licensing and collaboration revenue	390	3,526	36,143	165,950	—
Total operating revenue	28,711	35,768	68,501	172,592	1,093
Operating expenses:					
Research and development	69,866	93,300	71,414	35,691	22,713
General and administrative	31,726	33,226	30,689	19,328	9,521
Total operating expenses	101,592	126,526	102,103	55,019	32,234
(Loss) income from operations	(72,881)	(90,758)	(33,602)	117,573	(31,141)
Other income and expense:					
Miscellaneous (expense) income	(126)	32	(14)	—	112
Interest income	616	237	78	86	12
Interest expense	(119)	(22)	(105)	(26)	(33)
Other income (expense), net	371	247	(41)	60	91
Net (loss) income before taxes	(72,510)	(90,511)	(33,643)	117,633	(31,050)
Income tax benefit (expense)	559	5,356	(6,738)	(21,616)	(130)
Net (loss) income	$(71,951)	$(85,155)	$(40,381)	$96,017	$(31,180)
Basic (loss) earnings per share	$(2.30)	$(2.94)	$(1.41)	$3.45	$(1.23)
Diluted (loss) earnings per share	$(2.30)	$(2.94)	$(1.41)	$3.09	$(1.23)
Basic average shares outstanding	31,304	28,979	28,587	27,839	25,275
Diluted average shares outstanding	31,304	28,979	28,587	31,025	25,275

	As of December 31,				
	2017	2016	2015	2014	2013
	(in thousands)				
Balance sheet data:					
Cash, cash equivalents, and certificates of deposit	$158,708	$131,490	$197,800	$202,797	$61,540
Working capital	153,435	130,007	193,302	198,601	60,094
Total assets	180,697	174,747	218,542	231,221	70,557
Royalty obligations, notes payable and obligations under capital leases	6,271	6,517	6,381	7,133	7,222
Accumulated deficit	(237,459)	(165,508)	(80,353)	(39,960)	(135,977)
Total stockholders' equity	151,557	129,466	195,744	196,936	58,327

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Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely.

Overview

We are a clinical-stage immuno-oncology company focused on discovering and developing novel immunotherapeutic products for the treatment of patients with cancer. We are committed to developing our small-molecule product candidates intended to treat a wide range of oncology indications. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod, NLG802 and NLG919 (formerly navoximod or GDC-0919), are IDO pathway inhibitors with mechanisms of action that seek to break the immune system's tolerance to cancer.

We had a net loss of $72.0 million for the year ended December 31, 2017. We expect to continue to have net losses over the next several years as we advance our product candidates through late-stage clinical trials, pursue regulatory approval of our product candidates, and expand our commercialization activities in anticipation of one or more of our product candidates receiving marketing approval.

Financial Overview

Revenues

We have never earned revenue from commercial sales of any of our product candidates. We generated revenues of $28.7 million for the year ended December 31, 2017. We had grant revenues of $28.3 million attributable to revenues earned for the performance of research and development under contracts and grants with the Department of Defense, or DOD, and BARDA. We also earned license and collaboration revenues of $390,000, which consisted of revenues recognized under the license and collaboration agreements with Merck and Genentech that we entered into during 2014.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, or licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments we may receive under potential strategic collaborations, and the amount and timing of payments we may receive upon the sale of any products, if approved, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales for several years, if ever. If we fail to complete the development of our product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

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Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries, bonuses, benefits and share-based compensation;
- the cost of acquiring and manufacturing clinical trial materials;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of research facilities and equipment;
- license fees for and milestone payments related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development expenses as incurred.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, duration and complexity of later stage clinical trials. We plan to continue to incur significant research and development expenses for the foreseeable future as we continue to seek regulatory approval and exclusivity for indoximod, further advance our earlier-stage research and development projects and strengthen our pipeline of immune stimulatory product candidates through our clinical and business development programs. For the years ended December 31, 2017, 2016 and 2015 we incurred $69.9 million, $93.3 million, and $71.4 million, respectively, in research and development expenses.

The following table summarizes our research and development expenses by category of costs for the periods indicated:

Research and Development Expenses by Category

(In thousands)

	Years Ended December 31,		
	2017	2016	2015
Compensation	$18,873	$21,905	$21,558
Equipment, supplies and occupancy	6,246	14,073	9,827
Outside clinical and other	44,747	57,322	40,029
Total research and development expenses	$69,866	$93,300	$71,414

At this time, we cannot accurately estimate or know the nature, specific timing or costs necessary to complete clinical development activities for our product candidates. We are subject to the numerous risks and uncertainties associated with developing biopharmaceutical products including the uncertain cost and outcome of ongoing and planned clinical trials, the possibility that the FDA or another regulatory authority may require us to conduct clinical or non-clinical testing in addition to trials that we have planned, rapid and significant technological changes, frequent new product and service introductions and enhancements, evolving industry standards in the life sciences industry and our future need for additional capital. In addition, we currently have limited clinical data concerning the safety and efficacy of our product candidates. A change in the outcome of any of these variables with respect to the development of any of our product candidates could result in a significant change in the costs and timing of our research and development expenses.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise associated with research and development expenses, intellectual property prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

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Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents and certificates of deposit. The primary objective of our investment policy is capital preservation. We expect our interest income to increase as we invest the net proceeds from our offerings pending their use in our operations.

Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with our notes payable and obligations under capital leases.

Restructuring Charges

In July 2017, we undertook an organizational realignment to refocus our clinical development efforts and align our resources to focus on our highest value opportunities. The restructuring activities included a reduction of our workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus.

In May 2016, we announced that our Phase 3 clinical trial IMPRESS, for algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, failed to achieve its primary endpoint. As a result, we adopted a restructuring plan designed to better align our workforce and operating costs to our revised pipeline development plans and operating needs. The restructuring plan included a reduction in our workforce; the exit of or reduction of certain leased facilities; and the renegotiation or termination of contracts with certain third parties. In connection with the restructuring plan, we also discontinued the development of our commercial manufacturing capabilities for algenpantucel-L, discontinued programs supporting the future commercialization of algenpantucel-L and recorded an impairment charge to fixed assets. We have retained some internal manufacturing ability to support the development of clinical supplies for our ongoing clinical trials of the other HyperAcute Cellular Immunotherapy product candidates. Refer to Note 13 for more information.

Income Tax Benefit and Expense

For the years ended December 31, 2017 and 2016, we had an income tax benefit of $559,000 and $5.4 million, respectively. Income tax expense was $6.7 million for the year ended December 31, 2015. Income tax differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the loss incurred for our foreign subsidiary and the ability to carry back current year losses to prior years. In addition, for the year ended December 31, 2017 the tax differs from the statutory U.S. federal tax rate due to our limited potential to carry back losses for 2017 to 2015.

The valuation allowance for deferred tax assets as of December 31, 2017 and 2016 was $50.2 million and $35.1 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2017 and 2016 was an increase of $15.1 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act repealed the corporate AMT for years beginning January 1, 2018, and provides that existing AMT credit carryovers are partially refundable beginning in 2018 as an offset to a taxable liability, with full refunds beginning in 2021. We have approximately $140,000 of AMT credit carryovers that are expected to be fully refunded by 2021. We released the valuation allowance previously recorded against this deferred tax asset and reclassified the amount as a noncurrent income tax receivable. The Tax Act had no other material impacts to the consolidated financial statements upon enactment. For all other net deferred tax assets as of December 31, 2017 and 2016, a full valuation allowance has been established due to the uncertainty of future recoverability.

As of December 31, 2017 and December 31, 2016, we had federal net operating loss carryforwards of $38.8 million and $1.4 million and federal research credit carryforwards of $26.2 million and $20.8 million, respectively. Sections 382 and 383 of the Internal Revenue Code limit a corporation’s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore

result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation’s business, results of operations, financial condition and cash flow.

Based on analysis, we believe that, from our inception through December 31, 2016, we experienced Section 382 ownership changes in September 2001 and March 2003 and one of our subsidiaries experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of us and one of our subsidiaries.

Even if another ownership change has not occurred, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or certain changes in the ownership of any of our 5% stockholders.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our audited consolidated financial statements in accordance with United States generally accepted accounting principles, or U.S. GAAP. Our preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. We have reviewed our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included later in this annual report, we believe the following accounting policies to be critical in the preparation of our financial statements.

Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period, which is based on an established protocol specific to each clinical trial. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

Share-Based Compensation

We are required to estimate the grant-date fair value of stock options, stock awards and restricted stock issued to employees and recognize this cost over the period these awards vest. We estimate the fair value of each stock option granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. Generally, we have issued stock options that vest over time. For these awards, we record compensation cost on a straight-line basis over the vesting period. Generally, we issue awards that vest either monthly or vest 25% on the first anniversary date of issuance with the remaining options

vesting ratably over the next 36 months, or as determined by the Board of Directors at the time of grant. We calculate the fair value of the award on the grant date, which is the date the award is authorized by the Board of Directors or Chief Executive Officer and the employee has an understanding of the terms of the award.

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The fair value of restricted stock units, or RSUs, are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of performance share units are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period.

We recorded noncash share-based compensation expense for employee and nonemployee stock options and restricted stock awards of $18.5 million, $16.7 million and $15.9 million during 2017, 2016 and 2015, respectively. As of December 31, 2017, the total compensation cost related to unvested option awards and restricted stock awards not yet recognized was $21.7 million and the weighted average period over which it is expected to be recognized was 2 years. We expect to continue to grant stock options and restricted stock awards in the future, which will increase our share-based compensation expense in future periods. If any of the assumptions used in the Black-Scholes model change significantly, share-based compensation expense for new awards or awards to nonemployees may differ materially in the future from that recorded in the current period for awards previously granted.

The following table summarizes our assumptions used in the Black-Scholes model for option grants during the last three years:

Black-Scholes Model Assumptions

	Years Ended December 31,		
	2017	2016	2015
Exercise price	$6.75-$23.09	$10.31-$34.73	$32.49-$56.87
Risk-free interest rate	1.91%-2.22%	1.19%-1.97%	1.51%-2.00%
Expected dividend yield	—	—	—
Expected volatility	68.9%-76.88%	67.1%-69.8%	62.5%-67.3%
Expected term (in years)	1.2-7.8	5.9-7.4	5.9-7.0

Exercise Price. We use the quoted market price as listed on the public exchange on the date of grant.

Expected Volatility. We use our historical stock price volatility. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

Expected Term (in Years). The expected term of a stock option is the period of time for which the option is expected to be outstanding. We use historical exercise and option expiration data to estimate the expected term for the Black-Scholes grant-date valuation.

Risk-Free Interest Rate. We use the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected Dividend Yield. The expected dividend yield for all of our stock option grants is 0%, as we have not declared a cash dividend since inception, and do not expect to do so in the foreseeable future.

Forfeitures. The share-based compensation expense recognized has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of our option plan, which we expect to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given share-based award over its vesting period will only be for those shares that actually vest.

Common Stock Fair Value. The fair value of the common stock is the quoted market price as listed on the NASDAQ Global Market.

Based on the per share closing price of our common stock on the NASDAQ Global Market of $8.11 per share on December 31, 2017, the intrinsic value of stock options outstanding at December 31, 2017, was $11.6 million, of which $11.6 million and $6,000 related to stock options that were vested and unvested, respectively, at that date.

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Revenue Recognition

We recognize revenue for the performance of services or the shipment of products when each of the following four criteria is met: (1) persuasive evidence of an arrangement exists; (2) products are delivered or as services are rendered; (3) the sales price is fixed or determinable; and (4) collectability is reasonably assured.

We follow ASC 605-25, Revenue Recognition - Multiple-Element Arrangements and ASC 808, Collaborative Arrangements , if applicable, to determine the recognition of revenue under our license and collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (1) licenses to our intellectual property, (2) materials and technology, (3) clinical supply, and/or (4) participation on joint research or joint steering committees. The payments we may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (1) the identification of deliverables, (2) whether such deliverables are separable from the other aspects of the contractual relationship, (3) the estimated selling price of each deliverable, and (4) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive non-refundable, up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. If management believes that the license to our intellectual property has stand-alone value, we generally recognize revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to our intellectual property does not have stand-alone value, we would recognize revenue attributed to the license on a straight-line basis over the contractual or estimated performance period. When the performance period is not specifically identifiable from the agreement, we would estimate the performance period based upon provisions contained within the agreement, such as the duration of the research or development term.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of collaborator's performance are recognized when earned.

See Note 6, License and Research Collaboration Agreements, to the accompanying audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further information.

Income Taxes

Income taxes are recorded for the amount of taxes payable for the current year and include deferred tax assets and liabilities for the effect of temporary differences between the financial and tax basis of recorded assets and liabilities using enacted tax rates. Deferred tax assets are reduce by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized. Income tax was a benefit of 0.8% of our loss before income taxes in 2017. A valuation allowance of $50.2 million as of December 31, 2017 offsets our net deferred tax assets.

The Company considers accounting for income taxes critical to our operations because management is required to make subjective judgments in developing our provision for income taxes, including the determination of deferred tax assets and liabilities, any valuation allowances that may be required against deferred tax assets, and reserves for uncertain tax positions.

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Results of Operations

Comparison of the Years Ended December 31, 2017 and 2016

Revenues. Revenues for the year ended December 31, 2017 were $28.7 million, as compared to $35.8 million in 2016, a decrease of $7.1 million. Grant revenue decreased by $4.0 million in 2017 due to a decrease in billings under the government grant contracts. Licensing and collaboration revenues decreased by $3.1 million due to lower revenues recognized under the Genentech and Merck Agreements in 2017.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2017 were $69.9 million, decreasing from $93.3 million for the same period in 2016. The $23.4 million decrease was due primarily to higher restructuring charges of $11.1 million incurred in 2016, including a non-cash charge of $4.0 million related to impaired assets, as compared to $600,000 of charges incurred in 2017. Remaining decreases included $6.2 million in clinical trial costs, $4.4 million in supplies, equipment and licensing, $3.6 million in personnel-related expense and $200,000 in manufacturing expense, offset by increases of $1.0 million in stock compensation expense and $600,000 in legal and consulting.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2017 were $31.7 million, decreasing from $33.2 million for the same period in 2016. The $1.5 million decrease was due to a reduction of $2.3 million in personnel-related spend, and decrease of $1.2 million in legal and consulting, offset by increases of $700,000 in stock compensation expense, $700,000 in supplies and equipment, and $600,000 in restructuring charges incurred in 2017.

Income Tax Benefit/Expense. Income tax for the year ended December 31, 2017 was a benefit of $559,000 compared to an income tax benefit of $5.4 million for the same period in 2016. The change is primarily due to the limited ability to carry 2017 losses back to 2015 compared to the larger benefit of $6.0 million generated by the ability to carry 2016 losses back to 2014. Our income tax benefit for the year ended December 31, 2017 was increased by the release of the valuation allowance previously recorded against the deferred income tax position for $140,000 due to AMT as a result of the Tax Act. Our 2016 income tax benefit was reduced by amounts recorded in 2016 for uncertain tax positions.

Net Loss. Net loss for the year ended December 31, 2017 was $72.0 million, a decrease from the net loss of $85.2 million for the same period in 2016 primarily due to the decrease in operating expenses offset by the decrease in revenues and the decrease in the income tax benefit. The diluted average shares outstanding for 2017 were 31.3 million, resulting in diluted loss per share of $2.30, as compared to 29.0 million diluted average shares outstanding and $2.94 a diluted loss per share for 2016.

Comparison of the Years Ended December 31, 2016 and 2015

Revenues. Revenues for the year ended December 31, 2016 were $35.8 million, as compared to $68.5 million in 2015, a decrease of $32.7 million. Licensing and collaboration revenues decreased by $32.6 million in 2016. In 2015, we received a Merck milestone payment of $20.0 million and revenues of $16.1 million were recognized in 2015 that were previously deferred as of December 31, 2014.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2016 were $93.3 million, increasing from $71.4 million for the same period in 2015. The $21.9 million increase was due primarily to $11.1 million of charges incurred as a result of the restructuring during the second quarter in 2016, including a non-cash charge of $4.0 million related to impaired assets, a $9.1 million increase in contract manufacturing and clinical trial costs, a $2.6 million increase in supplies and equipment, offset by a $900,000 decrease in stock compensation expense.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2016 were $33.2 million, increasing from $30.7 million for the same period in 2015. The $2.5 million increase was due to an increase of $2.9 million in personnel-related expenses due to changes in transiently increased staffing levels, share-based compensation expense and compensation increases, an increase of $500,000 due to charges incurred as a result of the restructuring, offset by a decrease of $930,000 in consulting, legal and licensing fees and supplies.

Income Tax Benefit/Expense. Income tax benefit for the year ended December 31, 2016 was $5.4 million, a change from income tax expense of $6.7 million for the same period in 2015. The change is primarily due to our ability to carry back the full taxable loss for 2016 to 2014 for a benefit of $6.0 million in the current year. Our income tax benefit for the year ended December 31, 2016 was reduced due to the net loss generated by our foreign subsidiary,

NewLink International, which is not deductible on the Company's consolidated federal income tax return, and amounts recorded in 2016 for uncertain tax positions.

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Net Loss Income. Net loss for the year ended December 31, 2016 was $85.2 million, an increase from net loss of $40.4 million for the same period in 2015, primarily due to the decrease in licensing and collaboration revenues and an increase in operating expenses, offset by an increase in grant revenue. The diluted average shares outstanding for 2016 were 29.0 million, resulting in diluted loss per share of $2.94, as compared to 28.6 million average shares outstanding and $1.41 diluted earnings per share for 2015.

Liquidity and Capital Resources

Before our initial public offering, or IPO, in 2011 we funded our operations principally through the private placement of equity securities, debt financing and interest income. We received aggregate proceeds, net of offering costs, of $76.3 million from the issuance of convertible preferred stock from inception through 2011. Since our IPO, in 2011, we have funded our operations principally through public offerings of common stock and payments under our collaboration agreements and government contracts. In our IPO, we received net proceeds, of $37.6 million. In February 2013 we received net proceeds of $49.0 million in an underwritten public offering. Between September 2013 and March 2015, we raised a total of $58.7 million in net proceeds under an ATM Offering with Cantor Fitzgerald & Co., or Cantor. We launched another ATM offering with Cantor in June 2017 under which we have sold 1,940,656 shares of the Company's common stock for aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor and other costs of $163,000 as of December 31, 2017.

On October 6, 2017, we successfully raised proceeds of $55.2 million, net of offering costs of $3.7 million, from the issuance of 5,750,000 shares of our common stock in an underwritten public offering.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Sources and Uses of Cash

(In thousands)

	Years Ended December 31,		
	2017	2016	2015
Net cash used in operating activities	$(48,281)	$(65,947)	$(24,087)
Net cash provided by (used in) investing activities	211	(66)	6,218
Net cash provided by financing activities	75,288	1,883	23,085
Net increase (decrease) in cash and cash equivalents	$27,218	$(64,130)	$5,216

For the year ended December 31, 2017, we used cash of $48.3 million in our operating activities. Net cash used in operating activities decreased $17.6 million during 2017 as compared to 2016, primarily due to the $10.9 million decrease in net loss, net of non-cash items, and the $6.7 million decrease in working capital.

For the year ended December 31, 2015, the sources and uses of cash was driven primarily by the increase in licensing and collaboration revenues, offset by increases in operating expenses and income tax expense.

For the years ended December 31, 2017, 2016 and 2015, our investing activities generated cash of $211,000, used cash of $66,000, and generated cash of $6.2 million, respectively. The cash provided by investing activities in the year ended December 31, 2017 was due to proceeds received from sales of property and equipment of $254,000, offset by $43,000 in purchase of property and equipment. The cash used by investing activities in the year ended December 31, 2016 was due to the maturity of our certificates of deposit for $2.2 million, offset by $2.3 million in purchases of property and equipment. The cash provided by investing activities in the year ended December 31, 2015 was due to the maturity of our certificates of deposit for $10.2 million, offset by $4.0 million in purchases of property and equipment.

For the years ended December 31, 2017, 2016 and 2015, our financing activities provided $75.3 million, $1.9 million, and $23.1 million, respectively. The cash provided by financing activities in the year ended December 31, 2017 was primarily due to the sale and issuance of common stock for net proceeds of $75.8 million, offset by the repurchase of common stock of $289,000 and payments on capital lease obligations and notes payable of $246,000. The cash provided by financing activities in the year ended December 31, 2016 was primarily due to the sale and issuance of common stock for net proceeds of $2.2 million, offset by the repurchase of common stock of $82,000 and payments on capital lease obligations and notes payable of $257,000. The cash provided by financing activities in the year ended December 31, 2015 was primarily due to the sale and issuance of common stock for net proceeds of $17.7 million accompanied by $6.1 million from excess tax benefit from employee stock plan awards, offset by the repurchase of

common stock of $561,000 and net payments on long-term obligations of $194,000.

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Obligations under our Royalty and Loan Agreements

March 2005 and March 2012 Iowa Economic Development Authority Loan

In March 2005, we entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there were no principal or interest payments due until the completion date for the project. The agreement provided us with financial assistance for research and product development activities at our Iowa State University Research Park facility. Additionally, under the agreement, we were obligated to pay a minimum of 0.25% royalties on all gross revenues of any products that we bring to market with a cumulative maximum royalty amount due of $3.2 million. Substantially all of our assets were pledged to secure this loan. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, or the IEDA Agreement, with the Iowa Economic Development Authority, or the IEDA, as successor in interest to the IDED.

March 2012 IEDA Royalty Obligation

Under the terms of the IEDA Agreement, the forgivable loan agreement between us and IEDA (as successor to IDED) was terminated and we were thereby released from the forgivable loan agreement's job creation, project expenditure, royalty and other requirements in exchange for agreeing to pay a royalty of 0.50% on all gross revenues of any products that we bring to market, with a cumulative maximum royalty obligation due of $6.8 million. Additionally, under the IEDA Agreement, the IEDA released its security interest in our assets. We are obligated to maintain our business substantially in the State of Iowa until the royalty obligation under the IEDA Agreement is satisfied.

2009 and 2012 Iowa State University Research Park Loans

In 2009, we executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of $800,000, which is due in monthly installments through March 2018. The note represents amounts owed by us to ISURP for certain improvements that were made to facilities we lease from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including our uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2009 note was $29,000 and $140,000 at December 31, 2017 and December 31, 2016, respectively.

In 2012, we executed a promissory note in favor of ISURP in an original principal amount of $456,000, which is due in monthly installments through September 2020. The note represents amounts owed by us to ISURP for certain additional improvements that were made to facilities we lease from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including our uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2012 note was $169,000 and $227,000 at December 31, 2017 and December 31, 2016, respectively.

March 2010 City of Ames Forgivable Loan

In March 2010, we entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provides us with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there were no principal or interest payments due until March 10, 2016.

The project calls for us to create or retain at least 150 full-time jobs located in Ames, Iowa by March 10, 2016. The agreement required us to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015, which requirement was met prior to the March 10, 2015 deadline. As of March 10, 2016, the Company had satisfactorily fulfilled all of the above terms of the loan agreement and the loan was forgiven. Accordingly, the entire outstanding loan amount of $397,000 was derecognized with a corresponding amount recorded in grant revenue for the year ended

December 31, 2016.

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Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biopharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2017:

Contractual Obligations Due

(In thousands)

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Short and long-term debt (including interest) (1)	$6,211	$95	$116	$6,000	$—
Operating lease obligations	12,660	1,157	1,104	1,008	9,391
Capital lease obligations	74	74	—	—	—
Total contractual cash obligations	$18,945	$1,326	$1,220	$7,008	$9,391

(1) Short and long-term debt includes an accrued royalty obligation of $6.0 million for which the timing of payment is uncertain. See section “March 2012 IEDA Royalty Obligation” above.

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Under the license agreements described below under the heading "Financial Obligations Related to Licensing and Development—In-Licensing Agreements" we are obligated to make potential milestone payments as listed in the following table. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined.

Licensor	Aggregate potential milestone payments
Augusta University Research Institute under AURI IDO Agreement	$2.8 million per licensed product
Augusta University Research Institute under the AURI PTEN Agreement	$4.3 million total
Public Health Agency of Canada	C$475,000

We incurred expense of approximately $1.4 million, $2.0 million, and $2.0 million, under all of the in-licensing agreements for the years ended December 31, 2017, 2016, and 2015, respectively.

Financial Obligations Related to Licensing and Development

In-Licensing Agreements

We are subject to a number of licensing agreements with respect to certain of the technologies that underlie our intellectual property. Unless otherwise noted, these agreements typically provide that we have exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to us meeting our financial and other contractual obligations under the agreements. Certain of the key licensing agreements with significant financial obligations include the following:

Augusta University Research Institute- IDO. We are a party to a License Agreement dated September 13, 2005, or the AURI IDO Agreement, with Augusta University Research Institute, or AURI, which was formerly known as Georgia Regents Research Institute, the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The AURI IDO Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013, July 10, 2014 and March 15, 2016. The AURI IDO Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified AURI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

In consideration of such license grant, we have paid AURI specified license fees (including issuing shares of our common stock) and have made certain investments toward the further development of licensed products within the specified time periods, and we are obligated to pay to AURI annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by AURI, we must pay to AURI a percentage of the consideration we receive from the sublicensee.

AURI - PTEN. We provided notice of termination of our License Agreement with AURI, dated March 15, 2016, or the AURI PTEN License Agreement, in February 2018. The termination will become effective in March 2018.

Under the terms of the AURI PTEN License Agreement, we paid an upfront payment to AURI of $1.0 million. Upon termination, we remain obligated to pay AURI potential milestone payments in an aggregate amount up to approximately $4.3 million and royalties at a single-digit or less percentage of net sales of royalty-bearing products. Our royalty obligations expire on a country-by-country and product-by-product basis upon the later of (1) expiration of the last valid claim of our patents covering such royalty-bearing product in such country and (2) 10 years after the first commercial sale of such product in such country. In addition, if we grant a license to certain of our patents that cover royalty-bearing products, we must pay to AURI a percentage of certain specified consideration that we receive from the licensee.

Concurrent with the termination notice for the AURI PTEN License Agreement, we also notified AURI that we would not renew the Research Services Agreement with AURI, or the AURI PTEN Research Services Agreement, which was signed concurrently with the AURI PTEN License Agreement and is set to expire in March 2018. Under this agreement, AURI performed certain research services directed to PTEN inhibitors as agreed by the parties during the

term of the agreement in exchange for

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mutually agreed compensation. We own all data and results generated by AURI under the AURI PTEN Research Services Agreement, and AURI owns all other know-how and patents arising from its work under the AURI PTEN Research Services Agreement. Except for terms intended to survive past expiration, we have no further obligations to AURI under the AURI PTEN Research Services Agreement.

The Genentech Agreement. In October 2014, we entered into the Genentech Agreement for the development and commercialization of NLG919, our clinical stage IDO pathway inhibitor, and a research collaboration for the discovery of next generation IDO/TDO inhibitors to be developed and commercialized under the Genentech Agreement. On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919. As part of the partial termination, worldwide rights to NLG919 reverted to us, and Genentech granted to us an exclusive, royalty-bearing license under certain Genentech intellectual property to develop and commercialize NLG919. If NLG919 is commercialized, we will be obligated to pay to Genentech royalties as a low single-digit percentage of net sales of NLG919.

Public Health Agency of Canada Agreement. BPS is a party to a license agreement with PHAC, dated May 4, 2010, which was amended and restated December 5, 2017, or the PHAC License. Under the terms of the PHAC License, BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Zaire), a rVSV based on viral hemorrhagic fever, or VHF virus, and a worldwide, personal, non-transferable, non-exclusive, revocable, royalty-bearing license, under specified patent rights and know-how, for the development and commercialization of products directed to the prevention, prophylaxis and treatment of Ebola (Sudan), a VHF virus.

In consideration of the license grants, BPS must pay to Canada, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$475,000, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, its affiliates or sublicensees in countries outside of Africa and GAVI eligible countries, which royalty rate varies depending on whether additional technology licenses are required to sell the licensed product, and whether the licensed product is covered by a valid claim of a patent licensed under the PHAC License. In addition to the milestones discussed above, BPS is required to pay to Canada a percentage in the low double digits of certain consideration BPS receives from Merck or any other sublicensee over specified thresholds. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products.

Collaborative Agreements with Medical Institutions

We have entered into numerous agreements with various medical institutions for the performance of clinical trials for various products in the past. They typically require the payment of fees by us for the performance of the clinical trials and the maintenance of confidentiality as to the associated technology. We may enter into additional agreements in the future.

Patents and Trademarks

As noted above, we presently have an extensive portfolio of patents and patent applications (and certain trademark registrations) with the United States Patent and Trademark Office. During the years ended December 31, 2017, 2016 and 2015, we incurred expenses related to the filing, maintenance, and initiation of our patent portfolio of $411,000, $196,000, and $489,000, respectively, for an increase of 110% for the 2017 period as compared to the same period in 2016, and a decrease of 60% for the 2016 period as compared to the same period in 2015. Increased costs in 2017 compared to 2016 were due to increased activity on new filings and pending cases. Decreased costs in 2016 compared to 2015 were due to decreased activity on pending cases.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-02, Leases, to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheet a right of use asset and related lease liability for all leases with terms greater than 12 months. The ASU also

requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. We do not currently have any material leases and therefore do not anticipate adoption to have a material impact on our consolidated financial statements and related disclosures.

On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective on January 1, 2018. We will adopt the standard on a modified retrospective basis at January 1, 2018, with an adjustment for the cumulative effect of all changes recognized in beginning retained earnings. The Company has completed its analysis of the adoption impact and will record an immaterial entry to beginning retained earnings.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2017 and December 31, 2016, we had cash and cash equivalents of deposit of $158.7 million and $131.5 million, respectively, consisting of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our certificates of deposit are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We expect to have the ability to hold our certificates of deposit until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial (or no) impact on our financial statements.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The report of KPMG LLP, our independent registered public accounting firm, the financial statements of us and our consolidated subsidiaries and the notes thereto are included beginning on page F-1.

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

We carried out an evaluation required by the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of December 31, 2017. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2017, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management’s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2017 based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. As a result of this assessment, management concluded that, as of December 31, 2017, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

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Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

The effectiveness of our internal control over financial reporting as of December 31, 2017, was audited by our independent registered public accounting firm, KPMG LLP, as stated in its report, which is included in this filing on page F-1.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls.

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all internal control issues and instances of fraud, if any, have been detected.

Item 9B. OTHER INFORMATION

None.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors and nominees is incorporated by reference to our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders, or the 2018 Proxy Statement.

Item 11. EXECUTIVE COMPENSATION

The information required by this item concerning the compensation of our directors and executive officers is incorporated by reference to the 2018 Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item concerning securities authorized under our equity compensation plans and security ownership of certain beneficial owners is incorporated by reference to the 2018 Proxy Statement.

Securities Authorized For Issuance Under Equity Compensation Plans

We maintain our 2009 Equity Incentive Plan, 2010 Non-Employee Directors' Stock Award Plan and 2010 Employee Stock Purchase Plan, each of which was approved by the Company's security holders, pursuant to which we may grant equity awards to eligible persons.

The following table gives information about equity awards under the foregoing plans as of December 31, 2017:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	
Equity compensation plans approved by security holders	7,370,442	$14.23	1,297,354	(1)(2)
Equity compensation plans not approved by security holders	—	$0.00	—	
Total	7,370,442	$14.21	1,297,354	

(1) The 2009 Equity Incentive Plan incorporates an evergreen formula pursuant to which, on each January 1st, the aggregate number of shares reserved for issuance under the plan will increase by a number equal to 4% of the outstanding shares on December 31st of the preceding calendar year, or such lesser amount (or no shares) as determined by our Board.

(2) Of these shares, as of December 31, 2017, 1,195,358 shares remained available under the 2009 Equity Incentive Plan, zero shares remained available under the 2010 Non-Employee Directors' Stock Award Plan and 101,996 shares remained available under the 2010 Employee Stock Purchase Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item concerning transactions with related persons is incorporated by reference to the 2018 Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item concerning fees and services of accountants and auditors is incorporated by reference to the 2018 Proxy Statement.

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Item 15(a)

(1) Financial Statements

(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto beginning on page F-1 of this report.

(3) Exhibits

The following exhibits are filed with this form 10-K or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

		Incorporated By Reference			
Exhibit Number	Description	Form	Filing Date	Number	Filed Herewith
2.1	Asset Purchase Agreement, dated March 19, 2017, between Bluelink Pharmaceuticals, Inc. and Cerulean Pharma, Inc.	8-K	3/20/2017	2.1	
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3	Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2	Reference is made to Exhibits 3.1, 3.2 and 3.3				
4.3	Amended and Restated Investor Rights Agreement by and between the Registrant and certain holders of the Registrant's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1	†Form of Indemnity Agreement by and between the Registrant and its directors and executive officers	S-1/A	11/8/2011	10.11	
10.2	†2000 Equity Incentive Plan	S-1	12/21/2010	10.2	
10.3.1	†Form of Stock Option Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.3	
10.3.2	†Form of Stock Option Grant Notice under 2000 Equity Incentive Plan	S-1	12/21/2010	10.4	
10.3.3	†Form of Stock Bonus Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.5	
10.4	†Amended and Restated 2009 Equity Incentive Plan	S-1	12/21/2010	10.6	
10.4.1	†Form of Stock Option Agreement under 2009 Equity Incentive Plan	S-1	12/21/2010	10.7	
10.4.2	†Form of Stock Option Grant Notice under 2009 Equity Incentive Plan	S-1	12/21/2010	10.8	
10.4.3	†Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.6	

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10.4.4	†	Form of Restricted Stock Unit Grant Notice [Four Year Annual Vesting] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.7
10.4.5	†	Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.8
10.5	†	2010 Employee Stock Purchase Plan	8-K	5/14/2013	10.2
10.6	†	2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	11/8/2016	10.2
10.6.1	†	Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.4
10.6.2	†	Form of Restricted Stock Unit Grant Notice under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.5
10.7	*	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46
10.7.1	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.47
10.7.2	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48
10.7.3	*	Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49
10.7.4	*	Amendment to License Agreement dated March 28, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3
10.7.5	*	Amendment to License Agreement dated July 10, 2014 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4
10.8	*	Patent License Agreement dated March 1, 2006 by and between the Registrant and Bresagen Xenograft Marketing Ltd.	S-1/A	11/8/2011	10.50
10.9	*	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and BioProtection Systems Corporation	S-1/A	11/8/2011	10.66
10.10	*	Letter of Intent for Cooperative Research and Development Agreement (CRADA #2166) dated May 7, 2007 by and between the Registrant and National Cancer Institute	S-1/A	11/8/2011	10.38
10.10.1		Amendment No. 1 to Letter of Intent for CRADA #2166 dated January 17, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.39
10.10.2		Amendment No. 2 to Letter of Intent for CRADA #2166 dated July 7, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.40
10.10.3		Amendment No. 3 to Letter of Intent for CRADA #2166 dated March 24, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.41
10.10.4		Amendment No. 4 to Letter of Intent for CRADA #2166 dated October 28, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.42
10.10.5		Amendment No. 5 to Letter of Intent for CRADA #2166 dated December 16, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.43
10.10.6		Amendment No. 6 to Letter of Intent for CRADA #2166 dated June 29, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.44
10.10.7		Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.45
10.10.8		Amendment No. 8 to Letter of Intent for CRADA #2166 dated June 2, 2011 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.79
10.11		Memorandum of Agreement dated December 6, 2005 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.48
10.12		Memorandum of Agreement dated April 13, 2006 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.49

10.13	Memorandum of Agreement dated February 20, 2008 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.50
10.14	Memorandum of Agreement dated May 1, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.51

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10.15	Memorandum of Agreement dated March 24, 2010 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.52
10.16	Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53
10.17	Lease dated August 10, 2005 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.82
10.18	Memorandum of Agreement dated September 29, 2011 by and between the Registrant and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.84
10.19	Memorandum of Agreement dated September 29, 2011 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.83
10.20	Memorandum of Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Iowa State University Research Park Corporation	8-K	11/18/2011	10.1
10.21	Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54
10.22	Iowa Values Fund Agreement dated March 18, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.56
10.23	Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58
10.24	Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.59
10.25	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57
10.26	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.60
10.27	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77
10.28	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78
10.29	Contract No. W911NF-08-C-0044 dated May 5, 2008 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.68
10.29.1	Amendment to Contract No. W911NF-08-C-0044 dated February 12, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.69
10.30 *	Contract No. HDTRA1-09-C-0014 dated September 25, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	11/8/2011	10.70
10.30.1	Amendment of Contract No. HDTRA1-09-C-0014 dated September 20, 2011 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	10/4/2011	10.80
10.31	Contract No. W911NF-09-C-0072 dated July 31, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.71
10.31.1	Amendment to Contract No. W911NF-09-C-0072 dated April 21, 2010 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.72
10.32	Grant Number 5U01AI066327-05 issued August 26, 2009 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.73
10.33	Grant Number 1R43AI084350-01A1 issued April 6, 2010 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.74
10.34		S-1/A	10/4/2011	10.81

	Grant Number 5R43AI084350-02 issued March 24, 2011 by and between BioProtection Systems Corporation and the National Institutes of Health			
10.35	NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2
10.36	NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3
10.37	Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4

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10.38		Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2012	8-K	3/28/2012	10.1	
10.39	*	Cooperative Research and Development Agreement between the Registrant and the National Cancer Institute, effective as of March 27, 2012	10-Q	5/10/2012	10.6	
10.40		Memorandum of Agreement dated May 7, 2012 by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/15/2013	10.1	
10.41		Memorandum of Agreement dated May 7, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.2	
10.42		Memorandum of Agreement dated November 6, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.3	
10.43		Memorandum of Agreement dated April 15, 2013 by and between the Registrant and Iowa State University Research Park Corporation	10-Q	5/8/2013	10.1	
10.44		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and the Registrant dated March 1, 2010	10-Q	8/8/2013	10.2	
10.45		Amendment of Contract No. HDTRA1-09-C-0014, by and between BioProtection Systems Corporation and the United States Department of Defense, dated as of September 18, 2013	10-Q	11/12/2013	10.1	
10.46		License Agreement Amendment, by and between NewLink Genetics Corporation and Georgia Health Sciences University Research Institute, dated as of July 13, 2013	10-Q	11/12/2013	10.2	
10.47		Memorandum of Agreement, dated January 4, 2014, by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/12/2014	10.93	
10.48	*	License and Collaboration Agreement dated November 21, 2014 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.	10-K	3/16/2015	10.105	
10.48.1	*	Amendment to License and Collaboration Agreement dated December 5, 2017 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.				X
10.49		Memorandum of Agreement dated October 25, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005	10-K	3/16/2015	10.106	
10.49.1		Memorandum of Agreement dated July 9, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005	10-K	2/29/2016	10.62.1	
10.50		Memorandum of Agreement dated December 29, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	3/16/2015	10.107	
10.50.1		Memorandum of Agreement dated February 12, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	3/16/2015	10.108	
10.50.2		Memorandum of Agreement dated September 21, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	2/29/2016	10.63.2	
10.51	†	2015 Bonus Awards	8-K	1/7/2016	10.1	
10.52	†	2016 Salaries, Bonus Targets and Equity Awards	8-K	1/7/2016	10.2	
10.53	*	Sixth Amendment, effective March 15, 2016, to the License Agreement between Augusta University Research, Inc., the Georgia Health Sciences University Research Institute, Inc., and Medical College of Georgia Institute	10-Q/A	11/3/2016	10.8	

		and the Registrant, dated September 13, 2005.			
10.54	*	License Agreement, effective March 15, 2016, by and between Augusta University Research Institute, Inc. and the Registrant	10-Q/A	11/3/2016	10.9
10.55	*	Research Services Agreement, dated March 18, 2016, between the Registrant and Augusta University Research Institute, Inc.	10-Q/A	11/3/2016	10.10
10.56		Controlled Equity Offering Sales Agreement, dated November 29, 2016, between the Registrant and Cantor Fitzgerald & Co.	8-K	11/29/2016	10.1
10.57	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Charles J. Link	8-K	1/7/2016	10.3
10.58	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Dr. Nicholas N. Vahanian	8-K	1/7/2016	10.4

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10.59	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Carl Langren	8-K	1/7/2016	10.5
10.60	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Brian Wiley	8-K	1/7/2016	10.6
10.61	*	Amended and Restated License Agreement by and between BioProtection Systems Corporation and Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, acting through the Public Health Agency of Canada, dated December 5, 2017.			X
21.1		Subsidiary Information			X
23.1		Consent of KPMG LLP, independent registered public accounting firm			X
24.1		Power of Attorney (included on signature page hereto)			X
31.1		Rule 13a-14(a)/15d-14(a) Certification			X
31.2		Rule 13a-14(a)/15d-14(a) Certification			X
32.1	#	Section 1350 Certification			X
101.INS		XBRL Instance Document (filed electronically herewith)			X
101.SCH		XBRL Taxonomy Extension Schema Document (filed electronically herewith)			X
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document (filed electronically herewith)			X
101.LAB		XBRL Taxonomy Extension Label Linkbase Document (filed electronically herewith)			X
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document (filed electronically herewith)			X
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document (filed electronically herewith)			X

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† Indicates management contract or compensatory plan.

* Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 19434, as amended.

The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

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Item 16. FORM 10-K SUMMARY

None.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link, Jr.	By: /s/ John B. Henneman, III
Charles J. Link, Jr.	John B. Henneman, III
Chief Executive Officer	Chief Financial Officer and Secretary
(Principal Executive Officer)	(Principal Financial Officer)
Date: March 5, 2018	Date: March 5, 2018

By: /s/ Carl W. Langren
Carl W. Langren
Vice President Finance
(Principal Accounting Officer)
Date: March 5, 2018

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Charles J. Link, Jr. and John B. Henneman, III, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Charles J. Link, Jr.	Chief Executive Officer, Chairman of Board of Directors and Director (Principal Executive Officer)	March 5, 2018
Charles J. Link, Jr.		
/s/ John B. Henneman, III	Chief Financial Officer and Secretary (Principal Financial Officer)	March 5, 2018
John B. Henneman, III		
/s/ Carl W. Langren	Vice President Finance (Principal Accounting Officer)	March 5, 2018
Carl W. Langren		
/s/ Thomas A. Raffin	Director	March 5, 2018
Thomas A. Raffin		
/s/ Ernest J. Talarico, III	Director	March 5, 2018
Ernest J. Talarico, III		
/s/ Lota Zoth	Director	March 5, 2018
Lota Zoth		
	Director	March 5, 2018

/s/ Paul R. Edick Paul Edick	Director	March 5, 2018
/s/ Paolo Pucci Paolo Pucci	Director	March 5, 2018
/s/ Nicholas N. Vahanian Nicholas N. Vahanian	Director	March 5, 2018

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

NewLink Genetics Corporation:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of NewLink Genetics Corporation and subsidiaries (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, equity, and cash flows for each of the years in the three-year period ended December 31, 2017, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have

a material effect on the financial statements.

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Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

/s/ KPMG LLP

We have served as the Company's auditor since 2002.

Des Moines, Iowa

March 5, 2018

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NewLink Genetics Corporation
and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 158,708	$ 131,490
Prepaid expenses and other current assets	6,226	5,921
Current income tax receivable	356	5,975
Other receivables	10,176	24,526
Total current assets	175,466	167,912
Non-current assets:		
Property and equipment, net	5,091	6,835
Income tax receivable	140	—
Total non-current assets	5,231	6,835
Total assets	$ 180,697	$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,256	$ 22,883
Accrued expenses	12,467	14,309
Current portion of unearned revenue	56	391
Current portion of deferred rent	92	90
Current portion of notes payable and obligations under capital leases	160	232
Total current liabilities	22,031	37,905
Long term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	111	285
Deferred rent	998	1,091
Total long-term liabilities	7,109	7,376
Total liabilities	29,140	45,281
Stockholders' Equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at December 31, 2017 and 2016; issued and outstanding shares — 0 at December 31, 2017 and 2016	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at December 31, 2017 and 2016; issued 37,168,122 and 29,193,718 at December 31, 2017 and 2016 and outstanding 37,109,556 and 29,163,673 at December 31, 2017 and December 31, 2016	372	292
Additional paid-in capital	389,786	295,535
Treasury stock, at cost: 58,566 and 30,045 shares at December 31, 2017 and 2016	(1,142)	(853)
Accumulated deficit	(237,459)	(165,508)
Total stockholders' equity	151,557	129,466
Total liabilities and stockholders' equity	$ 180,697	$ 174,747

See accompanying notes to consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,		
	2017	2016	2015
Grant revenue	$28,321	$32,242	$32,358
Licensing and collaboration revenue	390	3,526	36,143
Total operating revenues	28,711	35,768	68,501
Operating expenses:			
Research and development	69,866	93,300	71,414
General and administrative	31,726	33,226	30,689
Total operating expenses	101,592	126,526	102,103
Loss from operations	(72,881)	(90,758)	(33,602)
Other income and expense:			
Miscellaneous (expense) income	(126)	32	(14)
Interest income	616	237	78
Interest expense	(119)	(22)	(105)
Other income (expense), net	371	247	(41)
Loss before taxes	(72,510)	(90,511)	(33,643)
Income tax benefit (expense)	559	5,356	(6,738)
Net loss	$(71,951)	$(85,155)	$(40,381)
Basic and diluted loss per share	$(2.30)	$(2.94)	$(1.41)
Basic and diluted average shares outstanding	31,304,309	28,979,327	28,586,585

See accompanying notes to consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Equity
(In thousands, except share and per share data)

	Common Stock					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	27,980,849	$ 280	$ 236,838	$ (222)	$ (39,960)	$ 196,936
Share-based compensation	—	—	15,940	—	—	15,940
Exercise of stock options and vesting of restricted stock awards	477,284	5	3,350	—	—	3,355
Sales of shares under stock purchase plan	40,248	—	851	—	—	851
Issuance of common stock under the ATM Offering (net of offering costs of $54 thousand)	329,402	3	13,531	—	—	13,534
Shares withheld for statutory tax withholding	(14,183)	—	—	(561)	—	(561)
Shares issued from treasury	542	—	—	12	(12)	—
Tax benefit from employee stock plan awards	—	—	6,100	—	—	6,100
Net loss	—	—	—	—	(40,381)	(40,381)
Balance at December 31, 2015	28,814,142	$ 288	$ 276,610	$ (771)	$ (80,353)	$ 195,774
Share-based compensation	—	—	16,707	—	—	16,707
Exercise of stock options and vesting of restricted stock awards	296,933	4	1,675	—	—	1,679
Sales of shares under stock purchase plan	58.609	—	543	—	—	543
Shares withheld for statutory tax withholding	(6,011)	—	—	(82)	—	(82)
Net loss	—	—	—	—	(85,155)	(85,155)
Balance at December 31, 2016	29,163,673	$ 292	$ 295,535	$ (853)	$ (165,508)	$ 129,466
Share-based compensation	—	—	18,508	—	—	18,508
Exercise of stock options and vesting of restricted stock awards	212,961	2	960	—	—	962
Sales of shares under stock purchase plan	70,787	1	444	—	—	445
Issuance of common stock under the ATM Offering (net of offering costs of $561 thousand)	1,940,656	19	19,314	—	—	19,333
Issuance of common stock under public offering (net of offering costs of $3.7 million)	5,750,000	58	55,025	—	—	55,083
Shares withheld for statutory tax withholding	(28,521)	—	—	(289)	—	(289)
Net loss	—	—	—	—	(71,951)	(71,951)
Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557

See accompanying notes to consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2017	2016	2015
Cash Flows From Operating Activities			
Net loss	(71,951)	(85,155)	(40,381)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	18,508	16,707	15,940
Depreciation and amortization	1,407	2,084	1,592
Forgiveness of debt	—	(397)	—
Impairment of fixed assets	—	3,958	—
Loss on sale of fixed assets	126	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(305)	(965)	3,379
State research and development credit receivable	—	—	13
Other receivables	14,350	(19,139)	(1,672)
Accounts payable and accrued expenses	(15,469)	24,770	245
Income taxes (receivable) payable	5,479	(6,834)	9,622
Unearned revenue	(335)	(68)	(12,752)
Deferred rent	(91)	(908)	(73)
Net cash used in operating activities	(48,281)	(65,947)	(24,087)
Cash Flows From Investing Activities			
Maturity of certificates of deposit	—	2,180	10,213
Purchase of equipment	(43)	(2,246)	(3,995)
Proceeds on sale of fixed assets	254	—	—
Net cash provided by (used in) investing activities	211	(66)	6,218
Cash Flows From Financing Activities			
Issuance of common stock, net of offering costs	74,416	—	13,534
Issuance of common stock under share-based compensation plans	1,407	2,222	4,206
Excess tax benefits from share-based compensation awards	—	—	6,100
Repurchase of common stock	(289)	(82)	(561)
Payments under capital lease obligations and principal payments on notes payable	(246)	(257)	(194)
Net cash provided by financing activities	75,288	1,883	23,085
Net increase (decrease) in cash and cash equivalents	27,218	(64,130)	5,216
Cash and cash equivalents at beginning of year	131,490	195,620	190,404
Cash and cash equivalents at end of year	$158,708	$131,490	$195,620
Supplemental disclosure of cash flows information:			
Cash paid for interest	$15	$22	$105
Cash paid for taxes	643	1,022	4,814
Proceeds from income tax refunds	6,651	197	13,796
Noncash financing and investing activities:			
Purchased leasehold improvements and equipment in accounts payable and accrued expenses	—	—	398
Assets acquired under capital lease	$—	$231	$—

See accompanying notes to consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

1. Description of Business Activities

NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation on June 4, 1999 and initiated operations in April of 2000.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development.

The Company has incurred significant losses in all years since being incorporated, except for the year ended December 31, 2014, and has never generated revenue from commercial sales of its drugs.

The accompanying financial statements as of and for the year ended December 31, 2017 have been prepared assuming the Company will continue as a going concern. The Company raised net proceeds of $37.6 million from its IPO, completed a follow-on offering of its common stock raising net proceeds of $49.0 million, and raised an additional $58.7 million in net proceeds from an at the market offering prior to March 31, 2015.

On November 29, 2016, the Company entered into a sales agreement with Cantor Fitzgerald & Co., under which the Company may sell up to $40.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the ATM Offering). As of December 31, 2017, the Company has raised net proceeds of $19.3 million from the ATM Offering. On October 6, 2017, the Company raised proceeds of $55.2 million, net of offering costs of $3.7 million, from the issuance of 5,750,000 shares of common stock in a public offering.

In connection with two license and collaboration agreements the Company entered into during 2014, the Company received a nonrefundable upfront cash payment of $150.0 million from Genentech Inc., a member of the Roche Group, or Genentech, in 2014, and a nonrefundable upfront cash payment of $30.0 million from Merck, Sharpe and Dohme Corp., or Merck, in 2014, as well as an additional milestone payment of $20.0 million from Merck in February 2015.

The Company's cash and cash equivalents after these agreements and offerings are expected to be adequate to satisfy the Company's liquidity requirements through 2019. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include pursuing alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company's ability to continue as a going concern.

2. Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the financial statements of NewLink and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

For the purposes of the consolidated statements of cash flows, the Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents of $158.7 million and $131.5 million at December 31, 2017 and 2016, respectively, consist of checking accounts, money

market accounts and treasury bills.

Leasehold Improvements and Equipment, and Deferred Rent

Leasehold improvements and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost. Equipment under capital leases is stated at the present value of future minimum lease payments. Depreciation on all leasehold improvements and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years and contract manufacturing organization equipment has a useful life of five years.

Deferred rent reflects improvement allowances from the Company's lessors deferred to be recognized as part of lease expense over the remaining term of the lease, which is recognized on a straight-line basis. Total deferred rents were $1.1 million and $1.2 million as of December 31, 2017 and 2016, respectively.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future net undiscounted cash flows expected to be generated by the asset group, primarily relating to proceeds for selling the assets. If such assets are considered to be impaired, the impairment to be recognized is measured at the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Revenue Recognition

The Company recognizes revenue for the performance of services or the shipment of products when each of the following four criteria is met: (1) persuasive evidence of an arrangement exists; (2) products are delivered or as services are rendered; (3) the sales price is fixed or determinable; and (4) collectability is reasonably assured.

The Company receives payments from government entities under its grants and contracts with the National Institute of Health, the Department of Defense, and the United States Department of Health and Human Services. These agreements provide the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues are recognized in the period during which the related costs are incurred, provided that the conditions under which the costs submitted or to be submitted for reimbursement have been met and the Company has only perfunctory obligations outstanding.

During the years ended December 31, 2017, 2016, and 2015, the Company has earned $28.3 million, $32.2 million, and $32.4 million in grant revenue, respectively. The Company had $9.3 million and $23.9 million of receivables from the government contracts recorded in other receivables and $465,000 and $4.3 million of unbilled expenses relating to the government contracts recorded in prepaid expenses and other assets on the balance sheet as of December 31, 2017 and 2016, respectively. The Company had $1.8 million and $2.9 million of accrued expenses for subcontractor fees and $4.9 million and $19.3 million of subcontractor fees in accounts payable for amounts incurred under the government contracts as of December 31, 2017 and 2016, respectively.

The Company follows ASC 605-25, Revenue Recognition - Multiple-Element Arrangements and ASC 808, Collaborative Arrangements , if applicable, to determine the recognition of revenue under our license and collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (1) licenses to our intellectual property, (2) materials and technology, (3) clinical supply, and/or (4) participation on joint research or joint steering committees. The payments the Company may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (1) the identification of deliverables,

(2) whether such deliverables are separable from the other aspects of the contractual relationship, (3) the estimated selling price of each deliverable, and (4) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit

utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Company typically receives non-refundable, up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. If management believes that the license to our intellectual property has stand-alone value, the Company generally recognizes revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to our intellectual property does not have stand-alone value, the Company would recognize revenue attributed to the license on a straight-line basis over the contractual or estimated performance period. When the performance period is not specifically identifiable from the agreement, the Company would estimate the performance period based upon provisions contained within the agreement, such as the duration of the research or development term.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, the Company recognizes a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of collaborator's performance are recognized when earned.

Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

The Company estimates its accrued expenses through a process of reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed and estimating the level of service performed and the associated cost incurred for the service that may not be invoiced from the provider. The estimates of accrued expenses as of each balance sheet date are based on facts and circumstances known at that time. Such estimates are periodically confirmed with the service providers to verify accuracy.

The Company bases its expenses related to clinical trials on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on behalf of the Company. Invoicing from third-party contractors for services performed can lag several months. The Company accrues the costs of services rendered in connection with third-party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs as contracted. Differences between actual clinical trial costs and estimated clinical trial costs are adjusted for in the period in which they become known through operations.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee-related expenses, which include salaries, bonuses, benefits and share-based compensation; manufacturing-related costs; clinical trial expenses which include expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials; facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of research facilities and equipment; license fees for and milestone payments related to in-licensed products and technology; and costs associated with non-clinical activities and regulatory approvals.

Patents

The Company generally applies for patent protection on processes and products. Patent application costs are expensed as incurred as a component of general and administrative expense, as recoverability of such expenditures is uncertain.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operating

results in the period that includes the enactment date. Management assesses the realizability of deferred tax assets and records a valuation allowance if it is more likely than not that all or a portion of the deferred tax assets will not be realized.

The Company accounts for the effect of any uncertain tax positions based on a more likely than not threshold to the recognition of the tax positions being sustained based on the technical merits of the position under scrutiny by the applicable taxing authority. If a tax position or positions are deemed to result in uncertainties of those positions, the unrecognized tax position is estimated based on a cumulative probability assessment that aggregates the estimated tax liability for all uncertain tax positions. Interest and penalties assessed, if any, are recorded in its consolidated statement of operations in interest expense and other expenses. As of December 31, 2017 and 2016, the Company had a recognized uncertain tax position of $653,000.

Share-Based Compensation

The Company is required to estimate the grant-date fair value of share-based payment transactions with employees which include stock options, restricted stock units (RSUs) and performance shares (PSUs) and recognizes the compensation cost over the requisite service period based on the estimated fair values as well as expected forfeiture rates. The Company estimates the fair value of each award granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. The Company calculates the fair value of the award on the grant date, which is the date the award is authorized by the Board of Directors or Chief Executive Officer and the employee has an understanding of the terms of the award. Generally, the Company has issued employee awards that vest either monthly or 25% vest on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 months. The Company records compensation cost on a straight-line basis over the vesting period. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period.

The Company has issued awards to nonemployee consultants and advisers. All grants to nonemployees are valued using the same fair value method that we use for grants to employees. The compensation cost on these awards is measured each period until vesting, and is recognized through the earlier of the vesting of the award or completion of services by the nonemployee.

Following is a description of the inputs for the Black-Scholes model:

Exercise Price

The Company uses the quoted market price as listed on the public exchange on the date of grant. If Incentive Stock Options are granted to a 10% stockholder in the Company, the exercise price shall not be less than 110% of the common stock’s fair market value on the date of grant.

Expected Term (in Years)

The expected term of a stock option is the period of time for which the option is expected to be outstanding. The Company uses historical exercise and option expiration data to estimate the expected term for the Black-Scholes grant-date valuation.

Risk-Free Interest Rate

The Company uses the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected Dividend Yield

The expected dividend yield for all of the Company's stock option grants is 0%, as the Company has not declared a cash dividend since inception and has no plans to declare a dividend.

Expected Volatility

The Company uses its historical stock price volatility. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

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Forfeitures

The share-based compensation expense has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of the Company's option plan, which the Company expects to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock-based award over its vesting period will only be for those shares that actually vest.

Segments

The Company operates in one segment. The Company conducts research and development activities based from facilities located in Ames, Iowa and has corporate headquarters in Ames, Iowa and Austin, Texas. The Company conducts preclinical and clinical research in the biopharmaceutical industry. The chief operating decision maker uses cash flow as the primary measure to manage the business and management does not segment its business for internal reporting or decision-making.

Financial Instruments and Concentrations of Credit Risk

The fair values of cash and cash equivalents, receivables and accounts payable, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. The fair value of notes payable and capital lease obligations was $271,000 and $517,000 as of December 31, 2017 and 2016, respectively, and was determined using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high quality securities such as money market funds.

Earnings per share (EPS)

The Company computes basic EPS attributable to the Company's common stockholders by dividing net income (loss) attributable to the Company by our weighted-average common shares outstanding during the period. Diluted EPS reflects the potential dilution beyond shares for basic EPS that could occur if securities or other contracts to issue common stock were exercised, converted into common stock, or resulted in the issuance of common stock that would have shared in our earnings. The Company computes basic and diluted EPS using net income (loss) attributable to the Company's common stockholders, and its actual weighted-average shares.

Concentration of Revenue

Genentech, a member of the Roche Group, and Merck Sharpe and Dohme Corp., or Merck, accounted for 1.2% and 0.2%, respectively, of the $28.7 million of revenue for the year ended December 31, 2017, with the remainder obtained from government grants. Genentech and Merck accounted for 7.6% and 2.3%, respectively, of the $35.8 million of revenue earned for the year ended December 31, 2016, with the remainder obtained from government grants. Genentech and Merck accounted for 21.5% and 31.3%, respectively, of the $68.5 million of revenue earned for the year ended December 31, 2015, with the remainder obtained from government grants.

Recent Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. The Company will adopt the standard on a modified retrospective basis at January 1, 2018, with an adjustment for the cumulative effect of all changes recognized in beginning retained earnings. The Company has completed its analysis of the adoption impact and will record an immaterial entry to beginning retained earnings.

In February 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-02, Leases, to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheet a right of use asset and related lease liability for all leases with terms greater than twelve months. The ASU also requires disclosures about the amount,

timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company does not currently have any material leases and therefore does not anticipate adoption to have a material impact on its consolidated financial statements and related disclosures.

3. Leases

(a) Capital Leases

The following is an analysis of the leased property under capital leases by major class (in thousands):

	Asset Balances at December 31,	
Class of property	2017	2016
Lab equipment	$720	$720
Leasehold improvements	27	27
Computer equipment	54	54
Total property under capital leases	801	801
Less accumulated depreciation and amortization	(652)	(586)
Capital leased assets, net	$149	$215

The depreciation and amortization reflected above has been recorded in both research and development and general administrative expense in the consolidated statements of operations.

The following is a schedule of the future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of December 31, 2017 (in thousands):

Year Ending December 31:	
2018	$74
Less amount representing interest	(1)
Present value of net minimum lease payments	$73

(b) Operating Leases

The Company has certain facility leases with terms ranging between one and five years. Lease expense is recognized on a straight-line basis. Rental expense for operating leases during the years ended December 31, 2017, 2016 and 2015, was $1.2 million, $1.7 million, and $1.7 million, respectively, including those with terms less than one year, and has been included in both research and development and general and administration in the consolidated statements of operations.

Future minimum lease payments under the noncancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2017 are as follows (in thousands):

Year Ending December 31:	
2018	$1,157
2019	1,104
2020	1,008
Thereafter	9,391
Total	$12,660

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4. Leasehold improvements and equipment

Leasehold improvements and equipment at December 31, 2017 and 2016 consisted of the following:

	Year Ended December 31,	
	2017	2016
Leasehold improvements	$5,310	$5,310
Computer and office equipment	2,326	2,219
Lab and leased equipment	3,979	4,056
Contract manufacturing organization equipment	114	486
Assets not placed in service	—	490
Total leasehold improvements and equipment	11,729	12,561
Less accumulated depreciation and amortization	(6,638)	(5,726)
Total leasehold improvements and equipment, net	$5,091	$6,835

5. Long-Term Debt and Conversion to Royalty Obligation

March 2005 Iowa Department of Economic Development Loan

In March 2005, the Company entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there were no principal or interest payments due until the completion date for the project. The balance outstanding under the loan agreement was $6.0 million as of December 31, 2011. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, or the IEDA Agreement, with the Iowa Economic Development Authority (the IEDA), as successor in interest to the IDED.

March 2012 IEDA Royalty Obligation

Under the terms of the IEDA Agreement the Company agreed to pay a 0.5% royalty on future product sales up to a cap of $6.8 million in exchange for IDED’s release of the Company's job creation and project expenditure obligations and their release of the security interest in substantially all of the Company's assets. As no payments are expected in the next 12 months, the entire accrued royalty obligation of $6.0 million is considered long-term as of December 31, 2017.

2009 and 2012 Iowa State University Research Park Notes

In 2009, the Company executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of $800,000, which is due in monthly installments through March, 2018. The note represents amounts owed by the Company to ISURP for certain improvements that were made to facilities the Company leases from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including the Company’s uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2009 note was $29,000 and $140,000 at December 31, 2017 and December 31, 2016, respectively.

In 2012, the Company executed a promissory note in favor of ISURP in an original principal amount of $456,000, which is due in monthly installments through September 2020. The note represents amounts owed by the Company to ISURP for certain additional improvements that were made to facilities the Company leases from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under

this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including the Company's uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. The balance outstanding under the 2012 note was $169,000 and $227,000 at December 31, 2017 and December 31, 2016, respectively.

March 2010 City of Ames Forgivable Loan

In March 2010, the Company entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provided the Company with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there were no principal or interest payments due until March 10, 2016.

The project called for the Company to create or retain at least 150 full-time positions located in Ames, Iowa by March 10, 2016. The agreement required the Company to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015, which requirement the Company met by the March 10, 2015 deadline. As of March 10, 2016, the Company had satisfactorily fulfilled all of the above terms of the loan agreement and the loan was forgiven. Accordingly, the entire amount of $397,000 was derecognized with a corresponding amount recorded in grant revenue for the year ended December 31, 2016.

6. License and Research Collaboration Agreements

Genentech, a Member of the Roche Group

In October 2014, the Company entered into a worldwide exclusive collaboration and license agreements with Genentech for the development and commercialization of NLG919, one of NewLink's clinical stage IDO pathway inhibitors and for a research collaboration for the discovery of next generation IDO/TDO compounds to be developed and commercialized under this agreement. Under the terms of the agreement, the Company received a nonrefundable upfront cash payment of $150.0 million from Genentech in 2014. On June 6, 2017, we received a formal notice of Genentech’s intent to terminate the Genentech Agreement with respect to NLG919. As part of the partial termination, worldwide rights to NLG919 reverted to us, and Genentech granted to us an exclusive, royalty-bearing license under certain Genentech intellectual property to develop and commercialize NLG919. If NLG919 is commercialized, we will be obligated to pay to Genentech royalties as a low single-digit percentage of net sales of NLG919.

The Genentech Agreement continues with regards to any next generation products as defined under the Genentech Agreement and the Company is eligible to receive milestone payments of up to $561.0 million upon achieving certain development, regulatory, and sales-based milestones with respect to next generation IDO/TDO products. The Company retains the right to exercise an option to co-promote any next generation IDO/TDO products with Genentech for the U.S. market and is also eligible to receive escalating royalty payments on potential commercial sales of next generation IDO/TDO products by Genentech.

The Company was obligated to deliver multiple non-contingent deliverables related to the NLG919 upfront cash payment. These deliverables include the NLG919 development and commercialization license, research license, program materials and technology, clinical supply of NLG919 product, manufacturing technology, participation in a joint research committee, or JRC, and providing an alliance manager. The Company's obligations under the JRC ended November 2016. The NLG919 development and commercialization license and research license are separate deliverables, but without the ability to develop NLG919, the ability to perform research on the compound would not benefit Genentech. Therefore, the Company believes that the value of the development and commercialization license cannot be separated from the research license value and the two are valued together. The other deliverables qualify as separate units of accounting.

The respective standalone value from each of these deliverables has been determined by applying the best estimated selling price method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of service. The estimated selling price determination required the use of significant estimates. To determine the stand-alone value of the license, we considered the negotiation discussions that led to the final terms of the agreement. The Company utilized historical cost plus an estimated gross margin to estimate the selling price for program materials and technology, manufacturing

technology, clinical supply, participation in a JRC, and participation of an alliance manager. The program materials and technology, clinical supply of NLG919, participation in a JRC and participation of an alliance manager were delivered throughout the duration of the agreement. The license and manufacturing technology was delivered shortly after the effective date of the agreement.

The Company recognized revenue under this agreement of $335,000 for the year ended December 31, 2017. This amount includes the recognition of $335,000 for providing an alliance manager to the collaboration. Revenues of $56,000 remain deferred as of December 31, 2017 for the deliverable of providing an alliance manager through the first part of 2018. All other deliverables identified within the collaboration and license agreement have been completed in their entirety.

The Company recognized revenue under this agreement of $2.7 million for the year ended December 31, 2016. This amount includes the recognition of $180,000 for participation in the JRC and $670,000 for providing an alliance manager to the

collaboration. Additionally, $1.9 million was recognized for amounts received as reimbursement for the Company's employees working on the project. Revenues of $391,000 remain deferred as of December 31, 2016 for deliverables identified within the collaboration and license agreement that have not yet been completed in their entirety.

The Company recognized revenue under this agreement of $14.7 million for the year ended December 31, 2015. This amounts includes the recognition of $9.4 million for program materials and technology transfer, $2.5 million for the clinical supply of NLG919 product, $151,000 for participation in the JRC, and $502,000 for providing an alliance manager to the collaboration. Additionally, $2.1 million was recognized for amounts received as reimbursement for the Company's employees working on the project. Revenues of $1.2 million remain deferred as of December 31, 2015 for deliverables identified within the collaboration and license agreement that have not yet been completed in their entirety.

The Company is eligible to receive from Genentech tiered royalty payments based on product sales, with royalty rates varying based on the territory of the sales, the product, the licenses incorporated in the development, and the opt-in by the Company during development. Royalties will be accounted for as contingent revenue and will be recognized as earned in accordance with contract terms, when Genentech results are reported, the amount can be reasonably estimated, and collectability is reasonably assured.

Merck Sharpe & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement with Merck to develop, manufacture and commercialize rVSVΔG-ZEBOV GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada, or PHAC. Under the terms of the agreement, the Company granted Merck an exclusive, royalty-bearing license to the rVSVΔG-ZEBOV GP and related technology. NewLink received a $30.0 million non-refundable, upfront payment in December 2014, and was also eligible for a one-time $20.0 million non-refundable milestone payment upon the initiation of the pivotal clinical trial using the current rVSVΔG-ZEBOV GP vaccine product as one arm of the trial. In February 2015, this milestone was achieved and the Company received the milestone payment. On December 5, 2017, the Merck Agreement was amended in connection with our entry into an Amended and Restated PHAC license on December 5, 2017

NewLink can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single-digit to double-digits on the rVSVΔG-ZEBOV GP license agreement product sales on increasing levels of annual net sales worldwide. Merck will lead the development of rVSVΔG-ZEBOV GP in order to create a marketable product safe for human use.

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. The Company recognized revenue under this agreement of $815,300 for the year ended December 31, 2016. This amount includes the recognition of $53,800 relating to the remaining deliverables and $761,500 for the reimbursement of costs associated with the Ebola clinical trials not reimbursed under the Company's government contracts. No revenue remains deferred as of December 31, 2016.

The Company recognized revenue under this agreement of $21.4 million for the year ended December 31, 2015. This amount includes the recognition of the $20.0 million milestone payment from Merck after notification from Merck that the milestone event specified in the license and collaboration agreement between the two companies relating to the further development of the rVSV-EBOV vaccine product candidate had been achieved. The milestone pertains to the initiation of a key clinical trial for the vaccine. The Company recognized $170,000 in revenue relating to the other deliverables and $1.2 million for the reimbursement of costs associated with Ebola clinical trials not reimbursed under the Company's government contracts. Revenue of $53,800 was deferred as of December 31, 2015.

The Company is eligible to receive from Merck tiered royalty payments based on product sales, with royalty rates varying based on Merck sales of the current rVSVΔG-ZEBOV GP vaccine product and Merck sales of other products included within the Company’s patent rights. Royalties will be recognized as earned in accordance with contract terms, when Merck results are reported, the amount can be reasonably estimated, and collectability is reasonably assured.

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7. Stockholders' Equity

Common Stock

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the Company stockholders. Subject to preferences applicable to outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Company's Board of Directors.

In the event of liquidation, dissolution, or winding up of the Company, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities subject to prior distribution rights of the preferred stock.

Preferred Stock

As of December 31, 2017 and 2016, the Company had no outstanding preferred stock. The Company's Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the voting power and such designations, preferences, and rights of such series, subject to approval of outstanding preferred series shareholders.

8. Common Stock Equity Incentive Plans

In April 2000, the stockholders approved NewLink’s 2000 Equity Incentive Plan. as amended, or the 2000 Plan, and in July 2009, the stockholders approved NewLink’s 2009 Equity Incentive Plan, as amended, or the 2009 Plan. Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan were effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, NewLink may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the NewLink Board of Directors, advisors, and consultants to NewLink. As of December 31, 2017 there were 10,238,220 shares of common stock authorized for the 2009 Plan and 1,195,358 shares remained available for issuance. As of December 31, 2016 there were 9,071,674 shares of common stock authorized for issuance pursuant to the 2009 Plan and 1,044,717 shares remained available for issuance.

The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,286
January 1, 2013	838,375
January 1, 2014	1,066,340
January 1, 2015	1,119,255
January 1, 2016	1,152,565
January 1, 2017	1,166,546

Subsequent to year end, on January 1, 2018, an additional 1,484,382 shares of common stock were added to the shares reserved for future issuance under the 2009 plan. The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company’s stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2012 through 2017 were made pursuant to an “evergreen provision,” in accordance with which, on January 1 of each year, from 2012 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the

preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

Under the terms of the Company's 2010 Non-Employee Directors' Stock Option Plan, as amended, or the Directors' Plan, which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the reserve. As of December 31, 2017, zero shares remained available for issuance under the Directors' Plan.

Under the terms of the Company's 2010 Employee Stock Purchase Plan, as amended, or the 2010 Purchase Plan, which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the reserve. As of December 31, 2017, 101,996 shares remained available for issuance under the plan. During the years ended December 31, 2017 and 2016, 70,787 and 58,609 shares of common stock, respectively, were purchased under the terms of the 2010 Purchase Plan.

Share-based Compensation

Share-based employee compensation expense for the years ended December 31, 2017, 2016 and 2015, was $18.5 million, $16.7 million, and $15.9 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations. As of December 31, 2017, the total compensation cost related to unvested option awards not yet recognized was $18.0 million and the weighted average period over which it is expected to be recognized was 2 years. The total income tax benefit recognized in the consolidated statements of operations for stock-based compensation arrangements was $16.6 million, $13.7 million and $7.8 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Stock Options

The Company's Board of Directors determines the vesting period for each stock option award. Generally, stock options awarded to date under the 2009 Plan vest monthly or vest 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 months, though some options have effective vesting periods that begin prior to the date of grant. In such cases, compensation expense was recognized for the vested portion of the award upon grant. The stock options may include provisions for early exercise of options. If any shares acquired are unvested, they are subject to repurchase at the Company's discretion until they become vested.

The following table summarizes the stock option activity for the year ended December 31, 2017:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	6,278,542	$ 14.93	
Options granted	1,526,787	11.61	
Options exercised	(120,716)	7.96	
Options forfeited	(324,947)	19.88	
Options expired	(157,445)	33.27	
Outstanding at end of period	7,202,221	13.72	5.3
Options exercisable at end of period	5,489,349	$ 12.51	4.3

Based on the December 31, 2017 price of $8.11 per share, the intrinsic value of stock options outstanding at December 31, 2017, was $11.6 million, of which $11.6 million and $6,000 related to stock options that were vested and unvested, respectively, at that date.

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The following table summarizes options that were granted during the years ended December 31, 2017, 2016 and 2015, and the range of assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Years Ended December 31,		
	2017	2016	2015
Number of options granted	1,526,787	1,346,758	1,019,445
Risk-free interest rate	1.91%-2.22%	1.19%-1.97%	1.51%-2.00%
Expected dividend yield	—	—	—
Expected volatility	68.9%-76.88%	67.1%-69.8%	62.5%-67.3%
Expected term (in years)	1.2-7.8	5.9-7.4	5.9-7.0
Weighted average grant-date fair value per share	$7.72	$11.91	$26.36

The following table summarizes the intrinsic value of options exercised and the fair value of awards vested during the years ended December 31, 2017, 2016 and 2015:

	Years Ended December 31,		
	2017	2016	2015
Intrinsic value of options exercised	$1.0 million	$1.1 million	$16.7 million
Fair value of awards vested	$15.0 million	$15.1 million	$9.6 million

The fair value of options vested for the year ended December 31, 2015, includes the accelerated vesting as a result of an employee's departure from the Company of $2.8 million.

Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for so long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are equity classified within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's Common Stock on The NASDAQ Global Market on the date of grant.

During the year ended December 31, 2017 and 2016, there were 0 and 193,834 shares of restricted stock granted, respectively. Compensation expense is determined for the issuance of restricted stock by amortizing using either a straight-line basis or the accelerated attribution method over the requisite service period, or the vesting period, the aggregate fair value of the restricted stock awarded based on the closing price of the Company's common stock on the date of grant.

A summary of the Company's unvested restricted stock at December 31, 2017 and changes during the year ended December 31, 2017 is as follows:

	Restricted Stock	Weighted Average Grant Date Fair Value
Unvested at beginning of period	288,964	$ 34.94
Granted	—	—
Vested	(92,245)	33.70
Forfeited/cancelled	(28,498)	33.72
Unvested at end of period	168,221	$ 35.82

As of December 31, 2017, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $3.7 million and is expected to be recognized over a weighted-average period of 1.6 years. The fair value of restricted stock awards vested during the year ended December 31, 2017 was $932,000.

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The Company does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. The Company expects shares issued to be issued from treasury shares or new shares.

9. Income Taxes

U.S. Tax Reform

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code that affect fiscal 2017. The Tax Act also makes a number of changes to U.S. federal income tax laws that will affect 2018 and later years, including, but not limited to, a reduction of the U.S. federal corporate income tax rate from 35% to 21%, the repeal of the corporate alternative minimum tax ("AMT"), the limitation on net operating loss deductions to 80 percent of taxable income for losses beginning after December 31, 2017 and the repeal of the current two-year carryback provision for net operating losses arising after 2017.

In connection with its analysis of the impact of the Tax Act, the Company has recorded a net tax benefit of $140,000 in 2017 which is for the release of the valuation allowance that had previously been recorded to offset the AMT deferred income tax benefit and classified this amount as a noncurrent income tax receivable. The Tax Act provides that AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021. The Tax Act had no other material impacts to the consolidated financial statements upon enactment.

Income tax benefit (expense) consists of (in thousands):

	Current	Deferred	Total
Year Ended December 31, 2017:			
U.S. federal	$332	$ 140	$472
State and local	87	—	87
	$419	$ 140	$559
Year Ended December 31, 2016:			
U.S. federal	$6,469	$ —	$6,469
State and local	(1,113)	—	(1,113)
	$5,356	$ —	$5,356
Year Ended December 31, 2015:			
U.S. federal	$(5,522)	$ —	$(5,522)
State and local	(1,216)	—	(1,216)
	$(6,738)	$ —	$(6,738)

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The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at December 31, 2017 and 2016 are presented below (in thousands):

	Year Ended December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$10,622	$ 654
Federal research and development tax credits	26,327	20,836
Share-based compensation	11,780	11,843
Deferred rent	327	491
Minimum tax credits	—	143
Accrued compensation	789	427
Unearned revenue	17	163
Charitable contributions	39	13
Leasehold improvements and equipment	297	552
Gross deferred tax assets	50,198	35,122
Less valuation allowance	(50,198)	(35,122)
Total deferred tax assets	—	—

The valuation allowance for deferred tax assets as of December 31, 2017 and 2016 was $50.2 million and $35.1 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2017 and 2016 was an increase of $15.1 million and of $14.4 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of December 31, 2017 and 2016, due to the uncertainty of future recoverability.

Federal operating loss carryforwards as of December 31, 2017 of approximately $38.8 million and federal research credit carryforwards of approximately $26.2 million expire at various dates from 2026 through 2035. Sections 382 and 383 of the Internal Revenue Code limit a corporation’s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation’s business, results of operations, financial condition and cash flow.

Based on analysis from its inception through December 31, 2016, the Company experienced Section 382 ownership changes in September 2001 and March 2003 and one of its subsidiaries experienced Section 382 ownership changes in January 2006 and January 2011 and the reported deferred tax assets reflect these expected limitations. These ownership changes limited the Company's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of the Company and one of its subsidiaries. Additional ownership changes may occur in the future as a result of events over which the Company will have little or no control, including purchases and sales of the Company’s equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of the Company’s stock or certain changes in the ownership of any of the Company’s 5% stockholders.

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A reconciliation of income taxes at the statutory federal income tax rate to net income tax expense (benefit) included in the accompanying statements of operations is set forth in the following table:

	Year ended December 31,		
	2017	2016	2015
U.S. federal income tax expense (benefit) at the statutory rate	(35.00)%	(35.00)%	(35.00)%
Available research and experimentation tax credits	—	—	(2.30)
State income taxes, net of federal taxes	(0.03)	0.88	(0.50)
Loss in foreign subsidiary	7.36	15.88	43.60
Valuation allowance, including impact of tax reform	24.10	12.07	13.70
Other	2.80	0.25	0.50
Total	(0.77)%	(5.92)%	20.00 %

The loss in foreign subsidiary reconciling item in the above table is the tax effect of intercompany research and development expenses which are not deductible on the Company's consolidated federal income tax return.

The Company accounts for the effect of any uncertain tax positions based on a more likely than not threshold to the recognition of the tax positions being sustained based on the technical merits of the position under scrutiny by the applicable taxing authority. If a tax position or positions are deemed to result in uncertainties of those positions, the unrecognized tax position is estimated based on a cumulative probability assessment that aggregates the estimated tax liability for all uncertain tax positions. Interest and penalties assessed, if any, are accrued and recorded in either interest expense or miscellaneous expense, respectively in the consolidated statement of operations. During the year ended December 31, 2017, the Company recorded interest and penalties relating to its uncertain tax position of $335,000 in its consolidated statement of operations in interest expense and other expenses. No interest or penalties were recorded for the years ended December 31, 2016 and 2015. The liability for uncertain tax benefits consists of estimated federal and state income tax liabilities in years for which the statute of limitations is open. Open years range from 2014 through 2016.

The changes in the Company's uncertain income tax positions for the year ended December 31, 2017 consisted of the following (in thousands):

	December 31, 2017
Beginning Balance - uncertain tax positions	$ 653
Increases for tax positions related to current year	—
Decreases due to settlements with taxing authorities	—
Reductions due to lapsed statute of limitations	—
Ending Balance - uncertain tax positions	$ 653

The Company does not anticipate the liability for uncertain tax positions as of December 31, 2017 to significantly change in the next 12 months. The Company is currently under IRS examination for its federal tax returns for the years ending December 31, 2016 and 2014.

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10. Loss Per Share

The following table presents the calculations of loss per share:

	Years Ended December 31,		
	2017	2016	2015
Historical net loss per share			
Numerator			
Net loss attributable to common stockholders	$(71,951)	$(85,155)	$(40,381)
Denominator			
Basic and diluted weighted-average shares outstanding	31,304,309	28,979,327	28,586,585
Basic and diluted loss per share	$(2.30)	$(2.94)	$(1.41)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. For December 31, 2017, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 7,202,221 and 168,221, respectively. For December 31, 2016, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 6,278,542 and 288,964.

11. Licensing Agreements

The Company is a party to a number of licensing agreements with respect to certain of the technologies that underlie its intellectual property. These agreements typically provide that the Company has exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to the Company meeting its financial and other contractual obligations under the agreements. The Company recognizes expense under its licensing agreements in the period the obligation is incurred. These agreements typically provide for a license fee based on a percent of sales and annual minimum royalties. For additional information regarding how the Company records payments under these agreements, see Note 2 above. The Company has incurred expense of approximately $1.4 million, $2.0 million, and $2.0 million, under all of the in-licensing agreements for the years ended December 31, 2017, 2016, and 2015, respectively, which is recorded as a component of general and administrative expenses.

Under certain license agreements the Company is obligated to make potential milestone payments as listed in the following table. In addition to the milestone payments, each license is paid as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined. The milestone payments and royalty payments are in place through at least the expiration of certain of the Company's patents, which is currently 2029 and beyond.

Licensor	Aggregate potential milestone payments
Augusta University Research Institute under AURI IDO	$2.8 million per licensed product
Augusta University Research Institute under the AURI PTEN Agreement	$4.3 million in total
Public Health Agency of Canada	C$475,000

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12. Employee Benefit Plans

The Company sponsors a 401(k) plan, which includes a defined contribution feature. The Company's defined contribution was $361,000, $482,000, $361,000 for the years ended December 31, 2017, 2016 and 2015, respectively. The Company made discretionary contributions to the plan of $401,000, $446,000, and $319,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

The Company has approved employment agreements for certain executives, dated October 29, 2010, as amended January 4, 2016, that provide for the payment of 6 to 24 months of base salary, bonus, and group health insurance premiums plus accrued obligations upon termination of the executive in certain circumstances. The agreements include provisions to accelerate the vesting of stock options subject to certain events including those related to a change in control. The Company entered into the January 2016 amendments to the foregoing agreements, upon recommendation by the Compensation Committee of the Board of Directors, to align the terms of certain termination benefits with termination terms for executive officers at similarly situated companies to the Company.

13. Restructuring Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

In July 2017, the Company undertook an organizational realignment to refocus its clinical development efforts and align the Company's resources to focus on the Company's highest value opportunities. The Company's restructuring activities included a reduction of its workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Restructuring charges recorded during 2017 included $1.7 million, of which $1.1 million is included within general and administrative expenses and $600,000 is included within research and development expenses in the consolidated statement of operations. The charges include employee severance costs of one-time employee termination benefits and certain expenses related to contractual termination benefits for employees with pre-existing severance arrangements.

In May 2016, the Company announced that its Phase 3 clinical trial Immunotherapy for Pancreatic RESectable cancer Study, or IMPRESS, of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint and in order to reduce costs associated with algenpantucel-L and the HyperAcute® Cellular Immunotherapy platform technology, the Company's management adopted a restructuring plan in May 2016 which included a reduction in the Company's workforce; the exit or reduction of certain leased facilities; and the renegotiation or termination of contracts with certain third parties. As a result of the restructuring, the Company also impaired fixed assets which management determined had no or limited future use. The fair value of impaired fixed assets was determined based on management’s estimate of market resale value. Restructuring charges recorded during 2016 were $11.6 million, of which $500,000 is included general and administrative expenses and $11.1 million is included within the research and development expenses in the consolidated statement of operations. Included in the $11.6 million of charges is non-cash asset impairment charges of $4.0 million. There were no restructuring charges recorded in 2015.

The following table shows the amount accrued for restructuring activities which is recorded within Accrued Expenses in the consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as of December 31, 2016	$ 42	$42
Expensed	1,735	1,735

Cash Payments	1,570	1,570
Adjustments	—	—
Balance as of December 31, 2017	$ 207	$ 207

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14. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint which asserts claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. In particular, the lead plaintiffs allege that the Defendants made material misstatements or omissions related to the Phase II and III trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs do not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they seek to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. On April 27, 2017, the Court granted the parties' request for leave to brief a motion to dismiss the amended complaint, and ordered the parties to file a stipulation and proposed order setting forth a schedule for the briefing of that motion. On May 15, 2017, the Court ordered the following briefing schedule: motion to dismiss due July 14, 2017, opposition due September 12, 2017, and reply due September 26, 2017. The Defendants filed a motion to dismiss on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision. The Company disputes the claims in the Securities Action and intends to defend against them vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth, or collectively, the Morrow Defendants, captioned Morrow v. Link., et al., Case 1:17-cv-03039, or the Morrow Action. The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase II and III trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court

temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise resolved. Under the terms of the stay, the plaintiff in the Ely Action will be provided with any discovery that is provided in the Securities Action, and given an opportunity to participate in any mediation or settlement efforts in the Securities Action. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

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15. Quarterly Financial Information (Unaudited)

	First	Second	Third	Fourth
	(In thousands, except per share data)			
Year Ended December 31, 2017				
Grant and licensing revenue	$2,761	$10,370	$5,482	$10,098
Loss from operations	(21,198)	(16,727)	(20,905)	(14,051)
Net loss	(20,913)	(16,726)	(20,626)	(13,686)
Basic and diluted loss per share	$(0.72)	$(0.57)	$(0.69)	$(0.37)
Year Ended December 31, 2016				
Grant and licensing revenue	$5,708	$2,012	$15,345	$12,703
Loss from operations	(25,393)	(34,528)	(16,687)	(13,970)
Net loss [(1)]	(23,720)	(32,389)	(15,540)	(13,506)
Basic and diluted loss per share	$(0.82)	$(1.12)	$(0.54)	$(0.46)

(1) In the fourth quarter of 2016, the Company adopted ASU 2016-09 which required adoption as of January 1, 2016. In the second and third quarter of 2016, the Company recorded an income tax benefit and an increase to additional paid in capital of $127,000 and $513,000, respectively, which is reflected in the above quarterly financial information (unaudited) as reported. Adoption allows for the recognition of excess tax benefits in the income tax provision rather than as paid-in capital. This resulted in the reversal of the prior quarter entries, including tax expense of $640,000 recorded in the fourth quarter of 2016.

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Index to Exhibits

The following exhibits are filed with this form 10-K or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

Exhibit Number		Description	Incorporated By Reference			Filed Herewith
			Form	Filing Date	Number	
2.1		Asset Purchase Agreement, dated March 19, 2017, between Bluelink Pharmaceuticals, Inc. and Cerulean Pharma, Inc.	8-K	3/20/2017	2.1	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2		Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3		Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1		Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2		Reference is made to Exhibits 3.1, 3.2 and 3.3				
4.3		Amended and Restated Investor Rights Agreement by and between the Registrant and certain holders of the Registrant's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1	†	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers	S-1/A	11/8/2011	10.11	
10.2	†	2000 Equity Incentive Plan	S-1	12/21/2010	10.2	
10.3.1	†	Form of Stock Option Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.3	
10.3.2	†	Form of Stock Option Grant Notice under 2000 Equity Incentive Plan	S-1	12/21/2010	10.4	
10.3.3	†	Form of Stock Bonus Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.5	
10.4	†	Amended and Restated 2009 Equity Incentive Plan	S-1	12/21/2010	10.6	
10.4.1	†	Form of Stock Option Agreement under 2009 Equity Incentive Plan	S-1	12/21/2010	10.7	
10.4.2	†	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan	S-1	12/21/2010	10.8	
10.4.3	†	Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.6	
10.4.4	†	Form of Restricted Stock Unit Grant Notice [Four Year Annual Vesting] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.7	
10.4.5	†	Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.8	
10.5	†	2010 Employee Stock Purchase Plan	8-K	5/14/2013	10.2	
10.6	†	2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	11/8/2016	10.2	
10.6.1	†	Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.4	
10.6.2	†	Form of Restricted Stock Unit Grant Notice under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.5	
10.7	*	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46	
10.7.1	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research	S-1/A	11/8/2011	10.47	

		Institute, Inc.			
10.7.2	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48
10.7.3	*	Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49
10.7.4	*	Amendment to License Agreement dated March 28, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3
10.7.5	*	Amendment to License Agreement dated July 10, 2014 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4
10.8	*	Patent License Agreement dated March 1, 2006 by and between the Registrant and Bresagen Xenograft Marketing Ltd.	S-1/A	11/8/2011	10.50

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10.9	*	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and BioProtection Systems Corporation	S-1/A	11/8/2011	10.66
10.10	*	Letter of Intent for Cooperative Research and Development Agreement (CRADA #2166) dated May 7, 2007 by and between the Registrant and National Cancer Institute	S-1/A	11/8/2011	10.38
10.10.1		Amendment No. 1 to Letter of Intent for CRADA #2166 dated January 17, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.39
10.10.2		Amendment No. 2 to Letter of Intent for CRADA #2166 dated July 7, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.40
10.10.3		Amendment No. 3 to Letter of Intent for CRADA #2166 dated March 24, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.41
10.10.4		Amendment No. 4 to Letter of Intent for CRADA #2166 dated October 28, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.42
10.10.5		Amendment No. 5 to Letter of Intent for CRADA #2166 dated December 16, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.43
10.10.6		Amendment No. 6 to Letter of Intent for CRADA #2166 dated June 29, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.44
10.10.7		Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.45
10.10.8		Amendment No. 8 to Letter of Intent for CRADA #2166 dated June 2, 2011 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.79
10.11		Memorandum of Agreement dated December 6, 2005 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.48
10.12		Memorandum of Agreement dated April 13, 2006 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.49
10.13		Memorandum of Agreement dated February 20, 2008 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.50
10.14		Memorandum of Agreement dated May 1, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.51
10.15		Memorandum of Agreement dated March 24, 2010 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.52
10.16		Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53
10.17		Lease dated August 10, 2005 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.82
10.18		Memorandum of Agreement dated September 29, 2011 by and between the Registrant and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.84
10.19		Memorandum of Agreement dated September 29, 2011 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.83
10.20		Memorandum of Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Iowa State University Research Park Corporation	8-K	11/18/2011	10.1
10.21		Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54
10.22		Iowa Values Fund Agreement dated March 18, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.56
10.23		Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58
10.24			S-1	12/21/2010	10.59

	Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development			
10.25	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57
10.26	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.60
10.27	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77

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10.28		Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78
10.29		Contract No. W911NF-08-C-0044 dated May 5, 2008 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.68
10.29.1		Amendment to Contract No. W911NF-08-C-0044 dated February 12, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.69
10.30	*	Contract No. HDTRA1-09-C-0014 dated September 25, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	11/8/2011	10.70
10.30.1		Amendment of Contract No. HDTRA1-09-C-0014 dated September 20, 2011 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	10/4/2011	10.80
10.31		Contract No. W911NF-09-C-0072 dated July 31, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.71
10.31.1		Amendment to Contract No. W911NF-09-C-0072 dated April 21, 2010 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.72
10.32		Grant Number 5U01AI066327-05 issued August 26, 2009 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.73
10.33		Grant Number 1R43AI084350-01A1 issued April 6, 2010 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.74
10.34		Grant Number 5R43AI084350-02 issued March 24, 2011 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	10/4/2011	10.81
10.35		NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2
10.36		NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3
10.37		Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4
10.38		Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2012	8-K	3/28/2012	10.1
10.39	*	Cooperative Research and Development Agreement between the Registrant and the National Cancer Institute, effective as of March 27, 2012	10-Q	5/10/2012	10.6
10.40		Memorandum of Agreement dated May 7, 2012 by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/15/2013	10.1
10.41		Memorandum of Agreement dated May 7, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.2
10.42		Memorandum of Agreement dated November 6, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.3
10.43		Memorandum of Agreement dated April 15, 2013 by and between the Registrant and Iowa State University Research Park Corporation	10-Q	5/8/2013	10.1
10.44		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and the Registrant dated March 1, 2010	10-Q	8/8/2013	10.2
10.45		Amendment of Contract No. HDTRA1-09-C-0014, by and between BioProtection Systems Corporation and the United States Department of Defense, dated as of September 18, 2013	10-Q	11/12/2013	10.1
10.46		License Agreement Amendment, by and between NewLink Genetics Corporation and Georgia Health Sciences University Research Institute, dated as of July 13,	10-Q	11/12/2013	10.2

		2013			
10.47		Memorandum of Agreement, dated January 4, 2014, by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/12/2014	10.93
10.48	*	License and Collaboration Agreement dated November 21, 2014 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.	10-K	3/16/2015	10.105

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10.48.1	*	Amendment to License and Collaboration Agreement dated December 5, 2017 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.				X
10.49		Memorandum of Agreement dated October 25, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005	10-K	3/16/2015	10.106	
10.49.1		Memorandum of Agreement dated July 9, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005	10-K	2/29/2016	10.62.1	
10.50		Memorandum of Agreement dated December 29, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	3/16/2015	10.107	
10.50.1		Memorandum of Agreement dated February 12, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	3/16/2015	10.108	
10.50.2		Memorandum of Agreement dated September 21, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	10-K	2/29/2016	10.63.2	
10.51	†	2015 Bonus Awards	8-K	1/7/2016	10.1	
10.52	†	2016 Salaries, Bonus Targets and Equity Awards	8-K	1/7/2016	10.2	
10.53	*	Sixth Amendment, effective March 15, 2016, to the License Agreement between Augusta University Research, Inc., the Georgia Health Sciences University Research Institute, Inc., and Medical College of Georgia Institute and the Registrant, dated September 13, 2005.	10-Q/A	11/3/2016	10.8	
10.54	*	License Agreement, effective March 15, 2016, by and between Augusta University Research Institute, Inc. and the Registrant	10-Q/A	11/3/2016	10.9	
10.55	*	Research Services Agreement, dated March 18, 2016, between the Registrant and Augusta University Research Institute, Inc.	10-Q/A	11/3/2016	10.10	
10.56		Controlled Equity Offering Sales Agreement, dated November 29, 2016, between the Registrant and Cantor Fitzgerald & Co.	8-K	11/29/2016	10.1	
10.57	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Charles J. Link	8-K	1/7/2016	10.3	
10.58	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Dr. Nicholas N. Vahanian	8-K	1/7/2016	10.4	
10.59	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Carl Langren	8-K	1/7/2016	10.5	
10.60	†	Employment Agreement, dated January 4, 2016, by and between the Registrant and Brian Wiley	8-K	1/7/2016	10.6	
10.61	*	Amended and Restated License Agreement by and between BioProtection Systems Corporation and Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, acting through the Public Health Agency of Canada, dated December 5, 2017.				X
21.1		Subsidiary Information				X
23.1		Consent of KPMG LLP, independent registered public accounting firm				X
24.1		Power of Attorney (included on signature page hereto)				X
31.1		Rule 13a-14(a)/15d-14(a) Certification				X
31.2		Rule 13a-14(a)/15d-14(a) Certification				X
32.1	#	Section 1350 Certification				X
101.INS		XBRL Instance Document (filed electronically herewith)				X

101.SCH	XBRL Taxonomy Extension Schema Document (filed electronically herewith)	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (filed electronically herewith)	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (filed electronically herewith)	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed electronically herewith)	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (filed electronically herewith)	X

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† Indicates management contract or compensatory plan.

* Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 19434, as amended.

The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.