NEWLINK GENETICS CORP
Form 10-K
February 29, 2016

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, 2015.
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 x	Accelerated filer o
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, 2015, as reported by the NASDAQ Global Market, was

$929,606,561. 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 a conclusive determination for other purposes.

As of February 23, 2016, there were 28,858,536 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 2016 Annual Meeting of Stockholders (the "2016 Proxy Statement").

NewLink Genetics Corporation
Table of Contents

Table of Contents

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, including the outcomes of both of our Phase 3 clinical trials for our algenpantucel-L cancer immuno-oncology product candidate; 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 other 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.

Table of Contents

PART I

Item 1. BUSINESS

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. Our portfolio includes biologic and small-molecule immuno-oncology product candidates intended to treat a wide range of oncology indications. Our biologic product candidates are based on our proprietary HyperAcute® Cellular Immunotherapy technology, which is designed to stimulate the human immune system. Algenpantucel-L is our most clinically advanced product candidate from this platform with two Phase 3 clinical trials ongoing for patients with pancreatic cancer, one of which is expected to read out data during 2016. Our additional HyperAcute cellular HyperAcute Cellular Immunotherapy product candidates in clinical development include tergenpumatucel-L and dorgenmeltucel-L for patients with advanced lung cancer and melanoma, respectively. Additional product candidates are also under development for patients with other types of cancer. Additionally, we have two small-molecule product candidates currently in clinical development, GDC-0919 and indoximod, which target key immune checkpoints. These product candidates are IDO pathway inhibitors and focus on breaking the immune system's tolerance to cancer. We believe that our immuno-oncology technologies have the potential to lead to multiple product candidates, targeting a wide range of oncology indications that could be used either alone or in combination with other therapies.

Our HyperAcute Cellular Immunotherapy platform consists of novel biologic product candidates designed to stimulate the patient's immune system to recognize and attack cancer cells. To date, our HyperAcute Cellular Immunotherapy platform product candidates have been administered to more than 700 patients with cancer, either as a monotherapy or in combination with other treatments and have been generally well tolerated with limited grade 3/4 adverse events. HyperAcute Cellular Immunotherapy product candidates are composed of human cancer cell lines that are tumor specific, but not patient specific. These cells have been modified to express alpha-Gal, a carbohydrate for which humans have preexisting immunity. These alpha-Gal-modified cancer cells are designed to stimulate an immune response against cancer cells. The objective of HyperAcute Cellular Immunotherapy is to elicit an antitumor response by "educating" the immune system to attack a patient's own cancer cells. HyperAcute Cellular Immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of our HyperAcute Cellular Immunotherapy product candidates have the potential to result in the stimulation of a robust immune response in patients with cancer.

Our most advanced program, algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, is being studied in two randomized Phase 3 clinical trials. Our first Phase 3 clinical trial, IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) completed enrollment of 722 patients with surgically resected pancreatic cancer. The primary endpoint for our IMPRESS trial is overall survival. We expect to report primary IMPRESS results during 2016. Our second Phase 3 clinical trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), has completed enrollment with over 300 patients. The primary endpoint for our PILLAR trial is overall survival. We initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival. Algenpantucel-L has received Fast Track Designation from the FDA for the adjuvant treatment of Stage I/II resected pancreatic adenocarcinoma in combination with adjuvant gemcitabine chemotherapy with or without adjuvant 5-FU-based chemoradiotherapy and Orphan Drug designation from the FDA for the treatment of pancreatic cancer, as well as Orphan Medicinal Product designation from the European Commission for the treatment of pancreatic cancer.

In addition to our HyperAcute Cellular Immunotherapy platform, we have an active drug discovery and clinical development program focused on the IDO (indoleamine-2, 3-dioxygenase) and TDO (tryptophan-2, 3-dioxygenase) pathway. Our small-molecule IDO pathway inhibitor drug candidates currently in clinical development include GDC-0919 (in partnership with Genentech, Inc. a member of the Roche Group or Genentech) and indoximod and are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1 and PD-L1 that represent potential breakthrough approaches to cancer therapy.

The IDO pathway regulates immune response by suppressing T-cell activation, which enables local tumor immune escape. Recent clinical trials conducted by third parties have demonstrated that the IDO pathway is active 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, whereby this pathway promotes 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. We have a number of active programs directed at synthesizing inhibitors that are potential anti-cancer compounds and that could function individually or in combination with IDO inhibition.

Table of Contents

Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that we believe have the potential to be breakthrough approaches for patients with a variety of different cancer types. This type of molecule has the potential to be combined with different standard of care therapeutic approaches such as chemotherapy and radiotherapy or with novel cancer therapeutic approaches such as other immune checkpoint inhibitors, CAR T-cells or anti-tumor vaccination. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of GDC-0919, one of our IDO pathway inhibitors, and a research collaboration for the discovery of next-generation IDO and TDO pathway inhibitors, or the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150.0 million in November 2014. We may be eligible to receive in excess of $1.0 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech. Genentech will fund future research, development, manufacturing and commercialization costs. Genentech also provides us with funding for support of the research collaboration. We will continue to pursue development activities associated with GDC-0919 in combination with our novel HyperAcute Cellular Immunotherapy platform. We retain the option for co-promotion rights for GDC-0919 and potential next-generation IDO/TDO compounds in the United States.

GDC-0919 is currently in Phase 1 development led by our collaborators at Genentech. Two Phase 1 clinical trials are currently underway with GDC-0919. GDC-0919 is being evaluated in a Phase 1b combination clinical trial of GDC-0919 and atezolizumab (MPDL3280A) in patients with locally advanced or metastatic solid tumors. Enrollment began in July 2015 and a total enrollment of up to 224 patients is planned. A second Phase 1 clinical trial of GDC-0919 is ongoing evaluating dosing of GDC-0919 in patients with recurrent advanced solid tumors.
Indoximod, our proprietary IDO pathway inhibitor, is in multiple Phase 2 clinical trials evaluating potential clinical activity in multiple solid tumor indications. These trials feature indoximod in combination with both standard of care immunotherapy treatments for cancer as well as standard of care chemotherapy treatments for cancer. Indications being evaluated in indoximod clinical trials include metastatic breast cancer, refractory malignant brain tumors, advanced melanoma, metastatic pancreatic cancer, and prostate cancer.
In addition to our immuno-oncology programs, we have a team focused on developing vaccines against infectious diseases. Our infectious disease program researches and develops vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism.
Our primary program is a replication-competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Ebola and Marburg viruses. The rVSV-ZEBOV (Ebola) vaccine product candidate was originally developed by the Public Health Agency of Canada and is designed to utilize the rVSV vector to induce immunity against Ebola and Marburg viruses when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck, Sharp and Dohme Corp., or Merck, to develop and potentially commercialize our rVSV-ZEBOV vaccine product candidate and certain other aspects of our vaccine technology. 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. In addition to milestone payments from Merck, the Company was awarded contracts for development of the rVSV-ZEBOV from the BioMedical Research & Development Agency, or BARDA, and the Defense Threat Reduction Agency, or DTRA, totaling $67.0 million during 2014 and 2015. In July 2015, we announced that the international partnership studying the rVSV-ZEBOV vaccine candidate in Guinea released interim data suggesting that it is effective in the prevention of Ebola disease in a large Phase 3 clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days of administration to a person without the infection. The rVSV-ZEBOV product candidate will continue to be studied in clinical trials.

In February 2016, we announced our initiative to develop a vaccine against the Zika virus. We believe that the experience gained in the development of our Ebola vaccine candidate will give us an advantage in this program.

We had a net loss of $40.4 million for the year ended December 31, 2015. We expect our losses to increase 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.

Table of Contents

Founded in 1999 and headquartered in Ames, Iowa and Austin, Texas, we have a clinical, research and development staff dedicated to our pipeline of product candidates for potential commercialization. We currently have a manufacturing facility in Ames, Iowa and have plans to expand our facilities to include a commercial manufacturing facility. Additionally, we have established offices in Austin, Texas, where we are currently building our commercial organization through which we intend to market our oncology products in the United States, and in Devens, Massachusetts, where we manage the development of and strategic relationships relating to our infectious disease program. Finally, we have built a manufacturing and packaging facility in Ankeny, Iowa for the final manufacturing stage of algenpantucel-L, if it is approved, and other potential products we may commercialize. Outside the United States we will either commercialize and distribute approved products independently or establish partnerships to address specific needs as we have with Genentech and Merck for some of our product candidates.

Our HyperAcute Cellular Immunotherapy Platform

Our Technology

Our HyperAcute Cellular Immunotherapy platform consists of novel biologic products designed to stimulate the patient's immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human, tumor-specific cancer cell lines. These cells have been modified to express alpha-Gal, a carbohydrate to which humans have preexisting immunity. These alpha-Gal-modified cancer cells stimulate an immune response that “educates” the immune system to attack a patient's own cancer cells.

We believe our HyperAcute Cellular Immunotherapies operate by exploiting a natural barrier present in humans that protects against infections. This barrier is related to the enzyme alpha (1,3) galactosyltransferase (alpha-GT). The presence of this enzyme results in the expression of a carbohydrate called alpha-Gal on the surface of affected cells. Introducing alpha-Gal expressing cells to the immune system activates an immune response from preexisting antibodies against alpha-Gal.

We believe that, compared to some prior immunotherapy approaches, our proprietary HyperAcute Cellular Immunotherapy technology offers several advantages including:

- a robust inherent immune response that harnesses the human body's naturally protective and rapid immune reaction to the alpha-Gal carbohydrate as a mechanism to fight cancer;
- a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- an allogeneic, tumor-specific, but not patient specific, approach, in which we manufacture products from genetically modified, allogeneic cells from previously established cell lines, which permits an easier scale-up of the manufacturing process compared to an autologous, or patient specific, approach involving a patient's own cells.

Table of Contents

HyperAcute® Cellular Immunotherapy Proposed Mechanism

Unlike some immunotherapies, HyperAcute Cellular Immunotherapies do not require the harvesting of an individual's tissue or cancer cells in order to produce the vaccine. HyperAcute Cellular Immunotherapies are manufactured using established tumor-specific human cell lines. In addition, HyperAcute Cellular Immunotherapies use intact whole cells rather than cell fragments or purified proteins, which we believe results in the stimulation of an enhanced multi-faceted immune response against the patient's cancer.

HyperAcute Cellular Immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes alpha-Gal. Exposure to alpha-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which alpha-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti-alpha-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to TAAs common to both the immunotherapy and the patient's tumor cells.

In the case of a HyperAcute Cellular Immunotherapy, this process results in immune cells that are educated to attack a patient's own cancer cells by virtue of the antigens that the immunotherapy and these tumor cells share and by a more generalized activation of the immune system. Our scientists have shown in mouse models of cancer that the immune system responds after a HyperAcute injection by attacking all similar cancer cells, including those that have no alpha-Gal carbohydrate.

HyperAcute Cellular Immunotherapies are designed to break tolerance and enable longer duration of anti-tumor effect. We believe that our HyperAcute Cellular Immunotherapy technology induces a combination of unique immune responses.

HyperAcute Pipeline

We have multiple HyperAcute Cellular Immunotherapy product candidates currently under clinical development specific to multiple types of cancer.

- Algenpantucel-L is currently being studied in two Phase 3 clinical trials for patients with pancreatic cancer:
  - IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study)
  - PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease)
- Tergenpumatucel-L is being investigated in a Phase 2b clinical trial for patients with advanced non-small cell lung cancer (NSCLC) and is also under investigation in a Phase 1/2 clinical trial evaluating the combination of tergenpumantucel-L with indoximod and docetaxel for patients with advanced NSCLC
- Dorgenmeltucel-L is being investigated in a Phase 2 clinical trial for patients with advanced melanoma

We have also created HyperAcute Cellular Immunotherapies for patients with other cancer indications such as renal and prostate.

Table of Contents

IDO Pathway Inhibitor Platform

Our Technology

The IDO pathway inhibitor platform is focused on developing small molecule drugs that disrupt mechanisms by which tumors evade the patient's immune system. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1 and PD-L1 that represent potential breakthrough approaches to cancer therapy. Inhibition of the IDO pathway has been shown to reduce immunosuppression and enhance immune response offering the potential for enhanced anti-tumor response in preclinical models. IDO pathway inhibition has demonstrated preclinical synergy in combination with other immunotherapies including other checkpoint inhibitors and cancer vaccines as well as chemotherapy or radiation.

The IDO pathway regulates immune response by suppressing T cell function and enabling local tumor immune escape. Recent studies indicate that the IDO pathway is active 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 resulting in peripheral tolerance to TAAs. Certain cancers may use the IDO pathway to facilitate survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system.

We believe that immune system failure is a fundamental reason for the inability of the human body to successfully fight cancer cells. Research into the inability of the immune system to respond to cancerous tumors indicates that tumors can induce the human immune system to tolerate the existence of the tumor. This immune tolerance and suppression represents a major barrier to successful treatment of cancer and is a significant target for new therapeutics. Scientific understanding of the process leading to immune tolerance is in its early stages. We believe IDO is part of a system that may be used by some tumors as a mechanism to evade the immune system. IDO is an enzyme that regulates immune response by suppressing effector T cell function by breaking down the essential amino acid tryptophan. Expression of IDO, either directly by tumors or by dendritic cells in tumor-draining lymph nodes, has been shown in animal studies to induce immune tolerance to tumors, and inhibition of IDO has been shown in these studies to prevent this induction of tolerance. IDO is rarely expressed by the majority of normal tissues, but it is overexpressed in many types of human tumors.

Cytotoxic chemotherapy places substantial stress on established, tumor-induced tolerance. Several factors can potentially contribute to this result: (1) dying tumor cells release waves of TAAs for processing and presentation, (2) many chemotherapeutic regimens induce a period of transient lymphopenia and homeostatic recovery during which T cells may become more susceptible to breaking tolerance, and (3) certain regimens can transiently deplete or inactivate tumor-protective T-regulatory cells. Despite producing these challenges to tolerance, most chemotherapeutic agents do not appear to trigger a protective immune response against established tumors. This shortcoming of traditional chemotherapy has been attributed, in part, to the ability of tumors to

Table of Contents

rapidly reestablish tolerance following each cycle of chemotherapy. We believe a potential mechanism underlying the failed opportunity is IDO expression by APCs in tumor-draining lymph nodes, which are thereby converted to an immunosuppressive and tolerance-inducing milieu. Preclinical data have demonstrated that IDO pathway inhibitors have anti-tumor effects in combination with a number of radiotherapy, chemotherapeutic drugs or other immunotherapy drug candidates and may work better together than either type of treatment alone.

The ability to acutely eliminate the protective IDO mechanism by administering IDO pathway inhibitor drugs, such as GDC-0919 or indoximod, may provide a therapeutic window in which to break tolerance in tumors and reverse the inhibition of immune cells. Additionally, we believe that once immune cells are restored to normal function, they can assist in the rejection of tumors.

We believe our IDO pathway inhibitor technology has the following potential advantages in combating cancers:

- Potential to break immune tolerance. The immune tolerance to cancerous cells represents a key barrier to the treatment of cancer. To date, there are several available therapies that have addressed the immune escape mechanisms of cancer. We believe inhibition of the IDO pathway has the potential to break a key immune escape mechanism of cancer cells and significantly enhance patient outcomes.
- Tolerability. In early-stage clinical development, we have observed an encouraging safety profile. We believe inhibition of the IDO pathway will selectively enhance the immune response against cancer cells given the limited expression of IDO in normal cells.
- Oral bioavailability. Unlike many cancer therapies which require intravenous administration, our IDO pathway inhibitors are orally bioavailable, a significant advantage in ease of administration for patients and physicians.
- Synergy with existing cancer therapies. Inhibiting the IDO pathway in conjunction with immunotherapy or chemotherapy has the potential to enhance the therapeutic effect of these agents. Used in combination with chemotherapy IDO inhibitors have the potential to delay or disrupt the reacquisition of immune tolerance to tumor antigens during the period following chemotherapy. In addition, preclinical studies have demonstrated the synergistic potential of IDO pathway inhibitors in combination with other cancer immunotherapies, including other checkpoint pathway inhibitors as well as cancer vaccines. The safety profile in humans is conducive to exploring combination therapy and the available animal data does not indicate significant additive or synergistic toxicities with many common oncology therapies.

IDO Pathway Pipeline

We are actively developing two IDO pathway inhibitors with broad potential across multiple tumor types. Our IDO pathway inhibitors, GDC-0919 and indoximod, are orally administered small molecules primarily designed to be used in combination with other cancer therapies including other checkpoint inhibitors such as those directed against CTLA-4, PD-1 and PD-L1, cancer vaccines such as our HyperAcute Cellular Immunotherapies and chemotherapy regimens for potential increased activity.

In October 2014, we entered into an exclusive worldwide license agreement with Genentech for the development and commercialization of GDC-0919 and a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors. Under the terms of the Genentech Agreement, we received a non-refundable upfront payment of $150 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating royalties on potential commercial sales of multiple products by Genentech. We did not license indoximod under the Genentech Agreement, and we are continuing its clinical development. Indoximod is in multiple Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic and brain cancers, as well as melanoma.

GDC-0919 and indoximod are being investigated as part of combination regimens including with other checkpoint inhibitors, and chemotherapy for patients with advanced NSCLC, advanced melanoma, metastatic prostate cancer, and other cancers.

Our Strategy

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

- Complete the Phase 3 clinical trials of algenpantucel-L, our lead HyperAcute Cellular Immunotherapy product candidate, and gain regulatory approval.

- Build commercial infrastructure to support a successful product launch of algenpantucel-L in the United States and establish commercial collaborations in other regions.

Table of Contents

- Expand current manufacturing capabilities to establish adequate supply for anticipated commercial demand and future clinical development for algenpantucel-L.
- Establish validated external manufacturing capacity for algenpantucel-L and potential subsequent HyperAcute Cellular Immunotherapy products.
- Seek an expanded indication for algenpantucel-L to include the treatment of patients with locally advanced pancreatic cancer.
- Advance our tergenpumatucel-L and dorgenmeltucel-L product candidates through additional clinical trials.
- Further develop our proprietary IDO pathway inhibitor indoximod.
- Support the strategic alliances with Genentech and Merck.
- Strengthen our pipeline of immune stimulatory drug candidates, including both our oncology and our infectious disease targets.

Cancer Market Overview

Cancer is the second-leading cause of death in the United States; the American Cancer Society estimated that more than 550,000 deaths will occur in 2016. 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 2005-2011 according to the American Cancer Society.

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. Tumors also have various defense mechanisms that may prevent the immune system from fully activating.

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

Table of Contents

- Immune system suppression. Cancer is difficult to treat in part because cancer cells use sophisticated strategies to evade the immune system. Current approaches to cancer treatment generally involve introduction of an agent, such as a chemical, an antibody or radiation. These agents cause 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.

Potential Advantages of HyperAcute Cellular Immunotherapy Over Current Cancer Therapies

We believe our HyperAcute Cellular Immunotherapy has the following potential advantages over existing therapies, which may enable us to develop commercial products that extend both survival and improved quality of life for patients with cancer:

- Robust, innate immune response. Our HyperAcute Cellular Immunotherapy technology is designed to fight cancer by activating the human body's naturally protective and rapid immune response to the alpha-Gal carbohydrate.
- Complex, multi-targeted approach. We believe our HyperAcute Cellular Immunotherapy technology attacks cancer through several mechanisms. Initially, by introducing allogeneic, whole cancer cells incorporating alpha-Gal to the body, our HyperAcute Cellular Immunotherapy is designed to educate the immune system to attack specific cancer cells, such as pancreas, lung or melanoma cancer cells, with both antibody mediated and cellular immune responses. Secondly, by using multiple whole cancer cell lines, our HyperAcute Cellular Immunotherapy targets multiple tumor proteins simultaneously, which we believe increases the probability of stimulating an effective immune response to the heterogeneous cells that are present in cancer.
- Favorable safety profile. We have not observed significant additional systemic toxicities when HyperAcute Cellular Immunotherapy has been added to standard chemotherapy or radiation regimens. Our HyperAcute Cellular Immunotherapy technology is designed to stimulate a strong or robust immune response to specific cancer cells while limiting the risks of off-target effects.
- Broad applicability. We believe that the novel mechanism of action, good tolerability and favorable safety profile will enable our HyperAcute Cellular Immunotherapy product candidates to have potential benefits across multiple disease stages and tumor types and in combination with other therapies.

Table of Contents

Our Product Pipeline

The chart below summarizes our current product candidates and their stages of development. Our product candidate pipeline includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications.

Table of Contents

Algenpantucel-L, Our Lead HyperAcute Cellular Immunotherapy Product Candidate

Our lead HyperAcute Cellular Immunotherapy product candidate, algenpantucel-L, is an investigational immunotherapy for patients with pancreatic cancer. The product consists of two pancreatic cancer cell lines that have been genetically modified to express alpha-Gal carbohydrates on cell surface molecules. We believe that upon injection into the patient, the alpha-Gal stimulates an immune response against pancreatic cancer-specific antigens in the tumor cell lines. The patient's immune system then targets the patient's own pancreatic cancer cells, destroying them. In the adjuvant setting, the immune response targets and eradicates residual tumor cells in conjunction with chemotherapy or chemotherapy and chemoradiation.

Algenpantucel-L is currently being studied in combination with standard of care in two Phase 3 clinical trials:

- IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study)
- PILLAR (Pancreatic Immunotherapy with Algenpantucel-L for Locally Advanced non-Resectable)

Algenpantucel-L has received Fast Track Designation from the FDA for the adjuvant treatment of Stage I/II resected pancreatic adenocarcinoma in combination with adjuvant gemcitabine chemotherapy, and Orphan Drug designation from the FDA for the treatment of pancreatic cancer. In May 2010, we initiated IMPRESS, our first Phase 3 clinical trial in patients with surgically-resected pancreatic cancer patients. We completed enrollment in September 2013 with 722 patients. The primary endpoint for our IMPRESS trial with algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer is overall survival. The first interim analysis was conducted when 222 events (deaths) were reported for the clinical trial, which occurred during the first quarter of 2014. As part of this planned interim analysis, the independent data safety monitoring committee, or DSMC, met to review available patient data. As anticipated, following its review, the DSMC recommended that the clinical trial should proceed as planned, without modification. The second interim analysis was completed during the second quarter of 2015 following 333 events, which had occurred prior to February 26, 2015. For the second interim analysis, the DSMC reviewed available patient data and recommended the clinical trial proceed without modification to final analysis. We previously announced that concurrent with the second interim analysis, a Kaplan-Meier estimation of overall median survival calculated from the same data set determined that the estimated blended median overall survival in the trial from the time of randomization was 28.5 months for all patients. This compares with a long-standing Kaplan-Meier estimated survival of patients with resected pancreatic cancer of approximately 20 months. Median time from surgery to randomization was approximately 1.5 months. Therefore, median survival from surgery was estimated to be approximately 30 months for all patients in our IMPRESS clinical trial. The clinical trial is powered to show an improvement in overall survival after 442 events, and we expect to report primary results in 2016.

In 2013, we initiated PILLAR, our second Phase 3 clinical trial for algenpantucel-L in patients whose pancreatic cancer is locally advanced. This trial was fully enrolled as of the end of 2015 with just over 300 patients with borderline resectable or locally advanced unresectable pancreatic disease. The primary endpoint for the PILLAR study is overall survival after treatment with a regimen of chemotherapy (either FOLFIRINOX or gemcitabine/nab-paclitaxel) with or without algenpantucel-L.

We initiated these trials based on encouraging interim data from our Phase 2 clinical trial that was fully enrolled in March 2010. At the time of the interim analysis, all patients in this Phase 2 clinical trial had reached at least 24 months of follow-up with a median follow-up period of approximately 33 months. The study met its primary objective with an established median disease-free survival of 14.1 months. The secondary endpoint of overall survival showed one-year overall survival to be 86%. Efficacy data for the 26 patients receiving high dose therapy demonstrated median disease-free survival of 15.3 months and a one-year overall survival rate of 96 percent. Algenpantucel-L has demonstrated good tolerability and a favorable safety profile in the Phase 2 clinical trial. The most common treatment-related adverse reactions (reported by at least 5 percent of patients) for the product candidate included injection site reactions (40%), induration (19%), injection site pain (10%), pyrexia (9%), erythema (7%), fatigue (19%), nausea (6%), lymphopenia (6%) and pruritus (5%). All of these events were grade three or less. The common terminology criteria, or CTC, of the National Cancer Institute, or NCI, categorizes adverse events into five grades, where grade one is mild, grade two is moderate, grade three is severe, grade four is life-threatening and grade five is death.

Market Opportunity

Pancreatic cancer is the fourth leading cause of cancer death in the United States and is one of the most difficult cancers to treat. Approximately 53,000 Americans are expected to be newly diagnosed with pancreatic cancer in 2016, and the incidence rates have been increasing since 2004. A subset of these patients, which we estimate to be 25 to 30%, may be eligible for surgical resection under current practice in the United States. Adjuvant therapy with chemotherapy or chemoradiation is the standard of care post-resection. Despite improvements in treatments median overall survival is 14 to 19 months and the five-year survival rate for these patients remains low at 12 to 18%. Current treatment recommendations for locally advanced pancreatic cancer usually include combined modality treatments with chemotherapy and radiotherapy. These treatments are rarely effective in shrinking a tumor to the point where it can be

Table of Contents

successfully resected. There is a trend toward using combination regimens that have shown benefits for conversion to resectability and increased survival. However, many of these regimens are associated with considerable toxicity. Treatment recommendations for advanced pancreatic cancer are primarily palliative in nature. There have been limited advances over the past 20 years with the most recent agents approved for use in the United States for patients with advanced pancreatic cancer offering modest survival benefits of approximately two months over previous approaches. There remains a critical need for novel therapies that can improve outcomes for patients with pancreatic cancer.

Phase 3 Clinical Trial (IMPRESS)

In May 2010, we initiated IMPRESS our first Phase 3 clinical trial for algenpantucel-L. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating 722 patients with Stage I and Stage II surgically-resected pancreatic cancer classified according to the American Joint Committee on Cancer classification system, or AJCC system, who have no detectable disease by a CT scan. The primary endpoint of the clinical trial is overall survival, with secondary endpoints of disease-free survival, safety, toxicity and immunological responses. In September 2013, we completed the enrollment of 722 patients in this clinical trial. Based on our discussions with the FDA, we believe this number of patients is adequate to demonstrate statistically significant improvement in overall survival at the end of the trial.

Current adjuvant standard-of-care regimens for post-resection pancreatic cancer patients include gemcitabine alone or a combination of gemcitabine plus 5-FU based chemoradiotherapy. In our Phase 3 clinical trial, 50% of the patients receive standard adjuvant therapy with algenpantucel-L and 50% receive standard adjuvant therapy without algenpantucel-L. Data from our Phase 2 clinical trial demonstrated a statistically significant improvement in disease-free survival at one year for the high dose (300 million cells) arm of the study. Therefore, we selected the 300 million cell dose as the treatment dose for our Phase 3 clinical trial. In addition, considering the observed dose response, we believe a higher number of treatments might provide further benefit. We therefore modified the treatment schedule for all patients receiving algenpantucel-L to increase the number of immunotherapy treatments from 12 to up to 18 treatments given every two weeks over a period of approximately six months followed by six monthly injections. Patients in the study are being monitored with periodic imaging to check for recurrences for at least five years after surgery or until death occurs.

The clinical trial included interim evaluations for overall survival when approximately one-half of the expected number of deaths had occurred and, again when approximately three-quarters of the expected number of deaths had occurred. The first interim analysis occurred in the first quarter of 2014, and the DSMC determined to continue. The second interim analyses of data from this study occurred in the second quarter of 2015, and the DSMC recommended the study proceed without modification until final analysis. We subsequently reported that the projected combined median overall survival of the IMPRESS trial was 28.5 months from randomization and approximately 30 months from surgery. The clinical trial is powered to show an improvement in overall survival after the anticipated 442 events, and we expect to report primary results in 2016.

When initially diagnosed, patients eligible for our Phase 3 clinical trial had localized tumors that could potentially be completely removed based upon strict imaging criteria. In addition, the patients were generally strong enough to survive a major surgical procedure that involves an inherent significant risk of death. Patients were not eligible to participate in this trial until pathology and post-operative imaging studies indicate that they were without clinical evidence of residual tumor as observed by a CT scan. As a result, patients admitted to the trials had minimal residual tumor burden and possessed generally intact immune systems, characteristics that we believe may improve the likelihood of meaningful outcome.

Phase 3 Clinical Trial (PILLAR)

The recent emergence of combination therapy with FOLFIRINOX (leucovorin, 5-FU, oxaliplatin and irinotecan) or gemcitabine / nab-paclitaxel has been promising in the metastatic disease and both regimens are being tested extensively in the locally advanced disease setting. We believe that the addition of algenpantucel-L immunotherapy to FOLFIRINOX or gemcitabine / nab-paclitaxel combination chemotherapy has the potential to improve survival of patients in this population. To assess this potential treatment combination we initiated PILLAR, our second Phase 3 clinical trial that will assess overall survival after treatment with a regimen of FOLFIRINOX or gemcitabine / nab-paclitaxel with or without algenpantucel-L immunotherapy in subjects who have borderline resectable or locally

advanced unresectable pancreatic cancer. In addition to overall survival, secondary endpoints include assessment of progression free survival and correlative scientific studies of subject samples to determine the mechanism of any observed anti-tumor effect. In these studies human humoral and cellular immune responses to algenpantucel-L will be evaluated.

Phase 2 Clinical Trial

We have completed an open-label, two-armed Phase 2 clinical trial, referred to as NLG-0205, in which algenpantucel-L was given in doses of either 100 million cells or 300 million cells approximately twice monthly for six months in combination

Table of Contents

with the standard-of-care treatment regimen, which consisted of gemcitabine chemotherapy plus 5-FU based chemoradiotherapy. We enrolled patients for this clinical trial at 16 different sites in the United States. Patients in this clinical trial had been diagnosed with Stage I and Stage II pancreatic adenocarcinoma, according to the AJCC system, and subsequently underwent surgical resection to remove all visible tumors with curative intent. There were no other exclusion criteria relative to pre-operative disease status. The primary endpoint of this clinical trial was to evaluate disease-free survival with secondary endpoints of overall survival and toxicity. We also wanted to determine if a superior dosing regimen could be identified.

We enrolled 44 patients in the 100 million cell dose cohort, or low dose group, and 26 patients in the 300 million cell dose cohort, or high dose group. The baseline patient characteristics of both cohorts were similar in terms of age, gender and disease state. Patient enrollment was complete in March 2010.

As of June 2012, all patients had reached at least 24 months of follow-up with a median follow-up period of approximately 33 months. To date, algenpantucel-L has demonstrated good tolerability and a favorable safety profile. The most common non-serious adverse events observed were fatigue, local injection site skin reactions and injection site pain. The nature and frequency of the adverse events observed in this clinical trial are consistent with the adverse events observed in all clinical trials for other HyperAcute Cellular Immunotherapies. The study met its primary objective with an established median disease-free survival (DFS) of 14.1 months. The analyses of the secondary endpoint of overall survival for the entire study showed one-year overall survival of 86 percent and a Kaplan-Meier estimate predicts a median overall survival at 24.1 months. Subgroup analysis showed that patients receiving 300 million cells/dose had a 12-month DFS of 81 percent while those receiving 100 million cells/dose had a 12-month DFS of 51 percent (p=0.02, Fisher's exact), and a one-year overall survival rate of 96 percent and 79 percent for the respective cohorts.

These results compare favorably to the outcomes of prior clinical trials in surgically-resected pancreatic cancer patients. Of these clinical trials, we believe the study known as RTOG 97-04, a 538-patient (451 evaluable patients) clinical trial conducted by the Radiation Therapy Oncology Group, is the most comparable with respect to baseline patient characteristics and treatment regimen even though our trial population had a higher frequency of lymphatic node invasion (68% vs. 81% in our trial). One treatment arm in RTOG 97-04 received gemcitabine chemotherapy plus 5-FU based chemoradiotherapy, which is the current standard-of-care treatment regimen, and we believe this treatment arm provides the best comparison to our NLG-0205 study. In RTOG 97-04, the 221 patients in the standard-of-care treatment arm had one-year disease-free survival of less than 50 percent and a one-year overall survival rate of 69 percent based on Kaplan-Meier analysis.

Kaplan-Meier Analysis of Overall Survival in our Phase 2 Clinical Trial

Kaplan-Meier analysis is a statistical method of predicting survival rates using study survival data. Nomogram analysis is a method for determining expected survival rates using patient baseline characteristics and other prognostic indicators. As shown in the graph below, the Kaplan-Meier-calculated overall survival in our Phase 2 clinical trial compares favorably to projected survival calculated by nomogram analysis.

Table of Contents

Kaplan-Meier Plot of Overall Survival for
NLG-0205 Versus Expected Distribution

The dotted line represents projected survival of patients enrolled in NLG-0205 based on the prognostic Brennan et al. Nomogram (Brennan et al., Ann Surg, 2004, 240:293), also known as the Memorial Sloan Kettering Cancer Center nomogram. The solid blue line represents the Kaplan-Meier estimated survival curve for patients enrolled in NLG-0205 as of June 2012. At 12 months after surgery overall survival for the combined patient population in NLG-0205 is 86%. The observed median overall survival is 24.1 months for the combined patient population in NLG-0205 versus 16.6 months predicted by the Brennan et.al. Nomogram.

Data from the NLG-0205 study has been stratified into high dose and low dose groups on the basis of statistically significant differential responses to algenpantucel-L immunotherapy. We believe 300 million cells is the largest practically attainable treatment dose based on clinician observation; however, we have tested a 100 million cell dose as a means to reduce the number of injections needed during therapy. The patterns of response in patients treated with these two doses have become distinct during the study.

Patients in the high dose group of NLG-0205 demonstrated an improved disease-free survival compared to patients in the low dose group or the current standard-of-care RTOG 97-04 chemoradiotherapy protocol alone. The data from NLG-0205 demonstrate a statistically significant difference between high and low dose groups in terms of disease-free survival (p=0.02).

In addition, an increased overall survival at one year for 300 million cell dose patients compared to low dose patients was observed (96% vs. 79%, p=0.053). These data demonstrate that patients in the high dose group have both a higher disease-free survival and a trend towards higher overall survival at one year compared to patients in the low dose group. Notably, patients treated at both dose levels in NLG-0205 compare favorably to the 63% one-year overall survival calculated by the Memorial Sloan Kettering Cancer Center nomogram analysis of the NLG-0205 patient population. Furthermore, both dose levels in NLG-0205 compare favorably to the 69% one-year overall survival observed for the 221 patients who received gemcitabine plus 5-FU based chemoradiotherapy in the RTOG 97-04 study.

Survival Outcome of NLG0205 vs predicted and RTOG 97-04

	Disease-Free Survival at one year	Overall Survival at one year
Predicted Brennan et al., 2005 nomogram	Not Applicable	63%
RTOG 97-04 (221 patients)	<50%*	69%
NLG-0205-100 million cell dose group	51%	79%
NLG-0205-300 million cell dose group	81%	96%

* Disease-free survival at one year was not reported. However, from the median disease-free survival of 11.4 months, we have inferred that disease-free survival at one year is less than 50%.

Table of Contents

Analysis of Historical Controls

Baseline patient characteristics are key factors to consider in reviewing clinical trials. Not all patients have an identical disease state and, in the context of surgically-resected pancreatic cancer patients, certain patient characteristics have been shown to have a significant impact on a patient's prognosis of disease progression and survival. Prognostic indicators for Stage I/II pancreatic cancer have been analyzed during the development of the AJCC system. The principal prognostic indicators have been validated and demonstrate that baseline data on tumors, nodal involvement and metastasis inform meaningful predictions of likely outcomes for patients. These characteristics include:

- Nodal status: refers to the presence of cancer in the nearby lymph nodes. When cancer enters the lymph nodes, there is an increased risk that the cancer will spread, or metastasize, to other regions of the body via the lymphatic system. As such, nodal status is an indicator of disease progression and thereby a prognostic indicator of survival. A study completed by Hsu et al. and published in the Annals of Surgical Oncology in 2010 reported that resected pancreatic cancer patients who received adjuvant chemoradiotherapy with positive lymph nodes prior to resection had a median overall survival 8.5 months less than that of patients with negative nodes. Further, a study conducted by Lim et al. published in Annals of Surgery in 2003 demonstrated that patients with greater than four positive lymph nodes had median overall survival 9.4 months less than that of patients with no positive lymph nodes.
- Degree of local invasion: refers to the extension of tumors into peripancreatic tissues including neural, vascular, or lymphatic structures or surrounding organs. Larger, higher-staged tumors are associated with a higher degree of local invasion, advanced disease and a poorer prognosis. As it relates to pancreatic cancer, patients with smaller, less invasive tumors have a greater median overall survival as reported by Gebhardt et al. in Langenbeck's Archives of Surgery in 2000. In the Gebhardt study, patients with pancreatic cancer that had invaded the lymph vessels, blood vessels and perineural tissues had a median overall survival of 16.8 months, 7.2 months and 4.8 months less, respectively, than patients with cancer that had not invaded these tissues.
- Tumor stage: refers to the size and peripancreatic extension of pancreatic cancer. T1 is defined as less than two centimeters in diameter and limited to the pancreas; T2 is defined as greater than two centimeters in diameter and limited to the pancreas; T3 is defined as a tumor that has extended beyond the pancreas; and T4 tumors are defined as unresectable. The T3 tumor stage is associated with poorer prognosis and increased risk of death compared to T1-T2 tumors in resected pancreatic cancer patients who receive adjuvant chemoradiotherapy as reported by Hsu et al., where T3 patients had a median overall survival that was 8.3 months less than T1-T2 patients.
- Tumor grade: refers to abnormalities of cancer cells relative to healthy cells. Tumor cells considered undifferentiated, or having a higher tumor grade, have little to no resemblance to the cells from which they originated (in this case pancreatic cells). Tumors classified as G1 or G2 are considered low grade tumors with well and moderately differentiated cells, respectively. Tumors classified as G3 or G4 are considered high grade tumors with poorly or undifferentiated cells, respectively. Many factors are considered in determining tumor grade, including the structure and growth pattern of the cells. Tumor grade is determined by a pathologist via biopsy of the tumor. Higher degrees of cancer cell abnormality are associated with a poorer disease prognosis; in fact, high tumor grade is an independent predictor of survival. The study conducted by Lim et al. referred to above showed that patients with poorly differentiated (G3), or higher grade, tumors of the pancreas had median overall survival of 22.8 months less than patients with well differentiated (G1), or lower grade, tumors.
- Ca 19-9 markers: refers to the post-operative concentration of the tumor marker carbohydrate antigen 19-9. The concentration of Ca 19-9 markers is associated with significant risk of early, distant metastasis. A study conducted by Kinsella et al. published in American Journal of Clinical Oncology in 2008 reported that pancreatic cancer patients with high post-operative Ca 19-9 levels, defined as greater than 70 units per milliliter, had a median overall survival 16.8 month less than patients with Ca 19-9 marker levels lower than 70 units per milliliter.

Our Phase 2 clinical trial did not compare the outcomes of patients who received algenpantucel-L plus the standard-of-care treatment regimen to the standard-of-care alone. Therefore, we believe it is important to evaluate the patient characteristics and clinical results of NLG-0205 relative to those of prior clinical trials in surgically-resected pancreatic cancer patients.

17

Table of Contents

Study	Nodal Status (%N+)	Local Invasion	Tumor Stage (T3/T4)	High Tumor Grade	Ca 19-9 (≥ 180 U/mL)	Disease-Free Survival Median (Months)	Overall Survival Median (Months)	Overall Survival at 1 Year
RTOG 97-04 2008(1) Treatment Arm: Gemcitabine + 5FU + Radiation (221 patients)	68 %	Not reported	81 %	32%*	14%(2)	11/4/2003	20.5(3)	69 %
NLG-0205 (4) Gemcitabine + 5-FU + Radiation + Algenpantucel-L (69 patients)	81 %	90%*	83 %	36%*	17%*	14.1	24.1	86 %

(1) Regine et al., JAMA 2008; 299(9): 1019-1026.

(2) Includes only the 124 patients who tested positive for the Lewis antigen (patients who test negative for the antigen do not express Ca 19-9).

(3) Regine et al. study in JAMA only reports overall survival and disease-free survival for patients with pancreatic head tumors. The median overall survival of patients in the standard-of-care treatment arm of RTOG 97-04 is 18.8 months.

(4) Hardacre JM, mulcahy KA, Small EJ, et al: Addition of Algenpantucel-L Immunotherapy to Standard Adjuvant Therapy for Pancreatic Cancer: a Phase 2 Study J Gastrointest Surg DOI 10.1007/s11605-012-2064-6, 2012.

* Calculation excludes unknowns.

U.S.-based comparator studies

In terms of historical comparisons between NLG-0205 and other resectable pancreatic cancer trials with curative intent, we believe RTOG 97-04 represents the most appropriate comparator study. This clinical trial enrolled 538 patients at 164 U.S. and Canadian institutions from July 1998 to July 2002 with follow-up through August 2006. The objective of RTOG 97-04 was to determine if the addition of gemcitabine to adjuvant 5-FU chemoradiation would improve survival for patients with resected pancreatic adenocarcinoma. In their primary analysis of a 451 patient sub-population, 221 of which received gemcitabine, the RTOG 97-04 investigators determined that the addition of gemcitabine to adjuvant 5-FU-based chemoradiation was associated with a survival benefit for patients with resected pancreatic cancer, although this benefit was not statistically significant. Based on the subpopulation analysis of this study, we believe that this study demonstrated limited benefit. The results of RTOG 97-04 were presented at the 2006 American Society of Clinical Oncologists, or ASCO, annual meeting and published in JAMA in March 2008.

Because comparisons between specific studies can have limited validity, researchers have developed statistical tools to evaluate the likely impact of therapies on overall survival. One such tool is the Brennan et. al. Nomogram developed at Memorial Sloan Kettering Cancer Center for surgically resected Stage I/II patients based on the interaction of baseline patient characteristics and other prognostic indicators.

Among the U.S.-based comparator studies, RTOG 97-04 baseline patient characteristics are the most similar to NLG-0205 baseline patient characteristics; both studies enrolled patients primarily at major medical centers in the United States, and NLG-0205 incorporates the addition of algenpantucel-L to a chemoradiotherapy protocol highly similar to that used in RTOG 97-04. As calculated by applying Brennan et. al. Nomogram analysis to the patient characteristics and other prognostic indicators of the respective studies, the projected overall survival of patients in the RTOG 97-04 study is higher than the projected overall survival of patients in the NLG-0205 study.

Tergenpumatucel-L HyperAcute Cellular Immunotherapy Product Candidate

Tergenpumatucel-L is our investigational HyperAcute Cellular Immunotherapy for patients with NSCLC. The product candidate consists of three NSCLC cell lines that have been genetically modified to express alpha-Gal carbohydrates on cell surface molecules. Upon injection into the patient, the alpha-Gal is intended to stimulate a rapid and powerful immune response against NSCLC-specific antigens in the tumor cell lines. We believe the patient’s immune system

then targets the patient's own NSCLC cancer cells, destroying them. In a Phase 2b clinical trial in progressive or relapsed NSCLC, two different dosing schedules of tergenpumatucel-L are currently being compared to docetaxel with a primary endpoint of overall survival. This study is also evaluating the potential for chemosensitization to salvage regimens post tergenpumatucel-L exposure.

Market Opportunity

According to the American Cancer Society, NSCLC is the leading cause of cancer death among both men and women in the United States, with more than 150,000 Americans expected to die from this devastating disease in 2016. Of more than 200,000

Table of Contents

newly diagnosed patients expected in 2016, approximately 57% will present with metastatic disease, for which there are significant limitations in treatment options. Despite advancements being made with new treatment strategies in NSCLC, survival outcomes remain poor. The five-year survival rate for Stage IIIA NSCLC is about 14%. For stage IIIB cancers the survival rate is about 5%. NSCLC that has spread to other parts of the body is often hard to treat. Metastatic, or Stage IV NSCLC, has a five-year survival rate of about 1%, which underscores a need for innovative therapies.

Phase 1/2 Clinical Trial

Tergenpumatucel-L was studied in a Phase 1/2, single-arm, open-label clinical trial that fully enrolled with 54 patients at the National Cancer Institute, or NCI. This clinical trial was for patients with refractory, recurrent or metastatic NSCLC. Its primary endpoint was to assess tumor response rate after administration of tergenpumatucel-L, and the secondary endpoint was to assess overall survival. For the Phase 1 portion of this clinical trial, a positive response included stable disease for 16 weeks in patients who had enrolled after having previously shown progressive disease. A total of 17 patients were enrolled in the Phase 1 portion and 37 patients in the Phase 2 portion. Of the 37 patients enrolled in Phase 2, only 28 were evaluated for clinical response. In Phase 1, four cohorts of patients each received injections of 3 million, 10 million, 30 million, or 100 million cells every four weeks for four doses, and one cohort of three patients received an initial dose of 500 million cells, followed by injections of 300 million cells every two weeks for up to seven doses. In Phase 2, the 28 patients evaluated received injections of 300 million cells every two weeks for up to eight doses.

The Phase 1 results of our Phase 1/2 clinical trial for our tergenpumatucel-L immunotherapy reported a favorable safety profile, with no dose limiting toxicities at any of the five escalating dose levels. There have been no reported CTC grade four adverse events attributed to tergenpumatucel-L. The most common treatment-related adverse reactions (reported by at least 5% of patients) for tergenpumatucel-L, were injection site reaction (88%), induration (51%), fatigue (25%), urticaria (10%), anemia (5%), pruritus (7%), lymphopenia (7%), elevated serum amylase (5%), edema (5%), skin pain (5%) and dyspnea (5%). The clinical trial involved a dose escalation from approximately three million up to 300 million cells in repeat dosing. Only a single dose escalation has been required by the FDA in all subsequent clinical trials of our other HyperAcute candidates conducted to date.

Results of our Phase 1/2 clinical trial for tergenpumatucel-L, based on the analysis of 45 patients, were encouraging. As of January 2012, the results for the 28 patients evaluated in the Phase 2 clinical trial group showed a median progression-free survival of 3.4 months, median overall survival of 11.3 months, and a one-year survival rate of 46%. Median overall survival data from the Phase 2 clinical trial group was better than the Phase 1 clinical trial group (11.3 versus 7.6 months), a comparison that would be consistent with study drug dose dependency.

Immunological studies showed that tergenpumatucel-L induced the increase of IFN-gamma secreted post immunization by peripheral blood lymphocytes in 11 of 18 tested patients. Patients that responded with increased IFN-gamma secretion post immunization had significantly increased overall survival when compared to non-responding patients (21.9 vs 7.2 months p=0.044).

Prior Phase 3 clinical trials suggest that in the refractory, recurrent or metastatic NSCLC setting (second line therapy), the median overall survival of patients receiving best supportive care was 4.6 months and the median overall survival of patients receiving pemetrexed or docetaxel therapy was approximately eight months. The following table shows comparative results for second-line treatment in advanced NSCLC with pemetrexed, docetaxel and tergenpumatucel-L.

Treatment Options and Clinical Outcomes in Second Line Advanced Stage NSCLC

Therapy	Overall Survival (Months)	12 Month Survival	Serious Adverse Events (CTC Grade 3 or 4) Attributed to Therapy							
			Nausea		Fatigue		Anemia		Neutropenia	
Best supportive care(1)	4.6	11 %	—		—		—		—	
Docetaxel(1)	7.5	37 %	1.8	%	5.4	%	4.3	%	40.2	%
Pemetrexed(2)	8.3	30 %	2.6	%	5.3	%	4.2	%	5.3	%
Tergenpumatucel-L(3)	11.3	46 %	—	%	—	%	—	%	—	%

(1) Prospective Randomized Trial of Docetaxel versus Best Supportive Care in Patients with Non-Small-Cell Lung Cancer Previously Treated With Platinum-Based Chemotherapy. Shepherd et al., Journal of Clinical Oncology, Volume 18, No. 10 (May), 2000: pp 2095-2103

(2) Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients with Non-Small-Cell Lung Cancer Previously Treated with Chemotherapy. Hanna et al., Journal of Clinical Oncology 2004 May 1; 22(9):1589-97

(3) Data from NLG-0101 tergenpumatucel-L clinical trial, Patients 18-45

Table of Contents

Given the favorable safety profile of tergenpumatucel-L, and the 11.3 month median overall survival observed in the Phase 2 study, tergenpumatucel-L compares favorably to current standard-of-care cytotoxic chemotherapy.

In 2013, enrollment started on our Phase 2b clinical trial in NSCLC. Additionally, we have begun enrollment in a second trial evaluating tergenpumatucel-L. This Phase 1b/2 clinical trial is evaluating the combination of tergenpumatucel-L with indoximod and docetaxel for patients with advanced NSCLC.

Dorgenmeltucel-L HyperAcute Cellular Immunotherapy Product Candidate

Dorgenmeltucel-L is our investigational HyperAcute Cellular Immunotherapy for patients with advanced melanoma. The product consists of three melanoma tumor cell lines that have been genetically modified to express alpha-Gal carbohydrates on cell surface molecules. Upon injection into the patient, the alpha-Gal stimulates a rapid and powerful immune response against melanoma-specific antigens in the tumor cell lines. We believe the patient’s immune system then targets the patient's own melanoma cancer cells, destroying them. Dorgenmeltucel-L was studied in an investigator-initiated Phase 2 clinical trial in 25 patients with advanced melanoma. In this trial, dorgenmeltucel-L was administered intradermally with an eight-week course of PEG-Intron, a man-made immune modulator that has been tested for the treatment of melanoma.

Market Opportunity

According to the American Cancer Society, the incidence of melanoma in the United States has been increasing for the last 30 years. Most cases of melanoma (84%) are diagnosed at an early stage, when curative treatment with surgical excision is possible. However, melanoma can recur after surgery, and about 13% of patients present with regionally advanced or metastatic disease. For patients with stage IIIC disease, five-year survival has been reported to be 40%. Only 15-20% of patients with metastatic disease will survive for five years or more.

Phase 2 Clinical Trial

We provided drug and financial support for a Phase 2 investigator-initiated clinical trial studying the combination of dorgenmeltucel-L with an eight week course of PEG-Intron for patients with advanced melanoma. The trial completed enrolling 25 patients in September 2010. The treatment consisted of 12 weekly intradermal injections of dorgenmeltucel-L at 150 million cells per dose with PEG-Intron co-administered in weeks five through 12. This was the first time that one of our HyperAcute immunotherapies was combined with another approved immunotherapy, in this case PEG-Intron. The primary objective of this clinical trial was to conduct correlative scientific studies of patient tumor and peripheral blood samples to determine the mechanism of any observed anti-tumor effect involving the innate and cell-mediated host immune response to dorgenmeltucel-L alone and combined with PEG-Intron. Although the number of patients in this clinical trial is modest, the results to date are encouraging.

As of June 2012, vitiligo had been observed in four out of 25 (16%) patients. Vitiligo is an autoimmune condition in which the patients immune system attacks melanoctyes, the cells responsible for skin pigmentation and potential melanoma cancer cells. Two prior clinical trials of immunotherapies conducted by others suggest that the development of vitiligo was correlated with a favorable response to therapy in melanoma patients. All patients evaluated developed autoimmune antibodies. Other than vitiligo, no other clinically apparent autoimmune disorder has been reported in any patient to date. These observations suggest an immunological response to the dorgenmeltucel-L.

Dorgenmeltucel-L has been reported as well tolerated, with no systemic, drug-related serious adverse events characterized by the investigators as possibly or probably attributable to our product candidate. The most common treatment-related adverse events reported, regardless of relationship to drug, included injection site reactions (92%), induration (76%), pruritis (16%), fatigue (52%), fever (32%), diarrhea (52%), nausea (44%), vomiting (8%), rigors or chills (8%), head pain (52%), muscle pain (52%) and anorexia (28%). By Response Evaluation Criteria in Solid Tumors, or RECIST criteria, of 16 stage IV melanoma patients, there were two complete responders (CR), two with stable disease (SD) and two with no evidence of disease (NED) after resection. For the one stage II and eight stage III patients, three of nine (3/9) remain NED, with one patient with slowly progressive disease remaining alive at 30 months. The median overall survival is 29 months, with 50% of the patients surviving for two years. In conclusion, combination immunotherapy with dorgenmeltucel-L plus PEG-Intron shows signs of clinical efficacy with tumor regression and concomitant immune activation.

We are currently enrolling a Phase 2 clinical trial of dorgenmeltucel-L in combination with commercially available checkpoint inhibitors ipilimumab, nivolumab, or pembrolizumab for patients with advanced melanoma. The design is

a randomized Phase 2 design that compares dorgenmeltucel-L combined with the current standard of care checkpoint inhibitors to checkpoint inhibitors alone. We used the statistically significant improvements in outcomes resulting from higher doses in our Phase 2 clinical trials with algenpantucel-L to inform our Phase 2 combination trial. Specifically, in the Phase 2 clinical trial of dorgenmeltucel-L, we employed a weekly dose of 150 million cells for 12 weeks during the course of the treatment. Due to the statistically significant improvement in disease free survival reported with high versus low dose in our trials of algenpantucel-L for patients

Table of Contents

with resected pancreatic cancer, we are now using a higher dose and a longer treatment duration in our current dorgenmeltucel-L clinical trials.

Other HyperAcute Cellular Immunotherapy Product Candidates and Indications

We believe we have developed a process to efficiently discover and develop new tumor-specific HyperAcute Cellular Immunotherapies for patients with other solid tumor types. We initiated development for our HyperAcute Prostate, HyperAcute Breast and HyperAcute Renal product candidates and are developing our HyperAcute Cellular Immunotherapy technology for other indications.

IDO Pathway Inhibitor Product Candidates

We have an active drug discovery and clinical development program focused on the IDO and TDO pathways. Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. In October 2014, we entered into an exclusive worldwide license agreement with Genentech, for the development and commercialization of GDC-0919, and a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating royalties on potential commercial sales of multiple products by Genentech. We did not license indoximod under the Genentech Agreement, and we expect to continue its development. Indoximod is in multiple clinical trials for the treatment of patients with breast, prostate, pancreas and brain cancers.

Phase 1B/2 Clinical Trials

Indoximod has successfully completed initial Phase 1 development. Phase 1 studies evaluating indoximod were done in cooperation with the National Cancer Institute's Division of Cancer Treatment and Diagnosis and enrolled a total of 65 patients. Indoximod was well tolerated and a Ready for Phase 2 Dose (RP2D) was determined. No dose limiting toxicities were observed. Under the same partnership, a Phase 1b clinical trial of indoximod in combination with docetaxel for patients with advanced solid tumors was performed. The combination was well tolerated, a Phase 2 dose for the combination was determined, and clinical responses were observed.

Currently, indoximod is in being developed by us in a variety of combinations across several cancer indications:

- NLG2101 Phase 2 clinical trial of indoximod in combination with taxane chemotherapy for patients with metastatic breast cancer was fully enrolled as of the end of 2015. We expect to report additional progress in 2016.
- NLG2102 Phase 1b/2 clinical trial of indoximod in combination with temozolomide for patients with refractory malignant brain tumors.

Phase 1b portion results were reported in 2015 and confirmed the combination has an acceptable safety profile and demonstrated preliminary clinical activity of the combination therapy.

Phase 2 portion is currently enrolling. We expect to report additional progress in 2016.

- NLG2103 Phase 1b/2 clinical trial of indoximod in combination with ipilimumab for patients with advanced melanoma.

Phase 1b portion results were reported in 2015 and confirmed the combination has an acceptable safety profile.

- NLG2014 Phase 1b/2 clinical trial of indoximod in combination with gemcitabine or nab-paclitaxel for patients with metastatic pancreatic cancer.

Phase 1b portion results were reported in 2016 and confirmed the combination has an acceptable safety profile and demonstrated preliminary clinical activity.

- NLG2105 Phase 1 clinical trial of indoximod in combination with temozolomide for pediatric patients with refractory malignant brain tumors.

Infectious Disease

Our infectious disease program is based upon two core technologies, each of which can be leveraged into the infectious disease or biodefense fields. The first technology is replication competent recombinant Vesicular Stomatitis Virus, or rVSV, an advanced vaccine technology developed for the Ebola and Marburg viruses and licensed from the Public Health Agency of Canada, or PHAC. In November 2014, we entered into the Merck Agreement to develop and potentially commercialize our Ebola vaccine product candidate and certain other aspects of our vaccine technology.

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 Merck successfully commercializes it. The Company announced on July 31, 2015 that

Table of Contents

the international partnership studying the rVSV-EBOV vaccine candidate in Guinea released interim data suggesting that it is effective in the prevention of Ebola in a large Phase 3 clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days of administration to a person without the infection. The rVSV-EBOV product candidate will continue to be studied in clinical trials.

The second technology is our HyperAcute immunotherapy technology, which is currently focused on enhancing vaccines for influenza. We have been investigating HyperAcute recombinant vaccine product candidates using H1N1, H5N1 and H7N9 influenza viruses in animal experiments. Other HyperAcute recombinant infectious disease vaccines are currently under investigation.

In February 2016, we announced our initiative to develop for a vaccine against the Zika virus. The Zika virus is a mosquito-borne flavivirus related to dengue, yellow fever, and West Nile virus. In January 2016, the World Health Organization declared the Zika virus an international public health emergency. There is no current vaccine and no course of treatment for the Zika virus.

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 three fiscal years. In December 2014, we announced that BARDA had awarded us a contract, as the prime contractor, in the amount of $30 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 October 2015, we announced that BARDA had exercised an $18 million option on our existing contract to support the scale-up of the manufacturing process related to our Ebola vaccine product candidate. 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.

Manufacturing

We manufacture our HyperAcute Cellular Immunotherapies at our facilities in Ames, Iowa. We believe this facility is adequate to supply all of the Phase 3 clinical trial drug requirements for at least two HyperAcute product candidates. In addition, we have entered into an agreement with WuXi to produce algenpantucel-L in bulk quantities for the commercial market. When and if algenpantucel-L is approved, we expect to manufacture it in bulk quantities at our Ames facility. WuXi is building capacity and working with us to validate its processes and equipment in the event that clinical data will support an application to FDA for approval of algenpantucel-L. We have established our own facility in Ankeny, Iowa to manage the final production steps, including irradiation and packaging, and to distribute our potential vaccine drug products, if any are approved.

We currently contract with Regis Technologies, Inc. and with University of Iowa Pharmaceuticals for the manufacture of our indoximod drug substance and drug product, respectively. We believe that many suppliers would be available for the production of this product, if required. We currently have no plans to build our own manufacturing capacity to support this product.

Genentech will be responsible for the manufacturing of GDC-0919 and any other drug candidate developed in accordance with the Genentech Agreement.

We have entered into an agreement with an established contract manufacturing organization to produce our Ebola vaccine product candidate. After a transition period and subject to conditions, Merck will assume 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 our HyperAcute Cellular Immunotherapy and indoximod product candidates. We are currently building a commercial infrastructure to support any of these products, should they receive FDA authorization for marketing and sales in the United States. In 2014, we established an office in Austin, Texas to serve as the headquarters for our commercial organization. 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 in the U.S. market. Our

Table of Contents

lead product candidate, algenpantucel-L is anticipated to be approved for patients with resected pancreatic cancer. We anticipate that a moderately sized, focused and highly experienced sales team will be sufficient to reach key institutions and cancer centers treating this subset of patients with resected pancreatic cancer. Additional support for our commercialization efforts may be provided by both medical affairs and market access professionals, who will provide the needed medical education, reimbursement support and other key functions needed to support an oncology product launch in the United States. We anticipate the need to hire personnel in advance of the approval of any of our product candidates and in 2015, hired key personnel in medical and clinical affairs, market access, and marketing to prepare for a possible launch of algenpantucel-L.

Outside the United States we will either commercialize and distribute approved products independently or establish partnerships to address specific needs as we have with Genentech and Merck for our other product candidates.

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 partners, 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 approaches to cancer have been approved in recent years. As a class of therapeutics, only one FDA-approved active cellular immunotherapy product has been approved to date. Three drugs classified as checkpoint inhibitors have been approved since 2011 targeting either CTLA-4 or PD-1 via antibody blockade. Additionally, one oncolytic virus therapy has been approved. The indications for which these agents have been approved include some indications which we are pursuing such as melanoma and NSCLC. Other indications, such as pancreatic cancer, breast cancer, and malignant brain tumors, do not currently have any FDA approved immunotherapy approaches.

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. The competitors of which we are aware that have initiated a Phase 3 clinical trial or have obtained marketing approval for a potentially competitive drug to our lead product candidate, algenpantucel-L for the adjuvant treatment of patients with resected pancreatic cancer, include Astra-Zeneca, Celgene Corporation, Merrimack Pharmaceuticals and Aduro Biotech. Our competitors in the field of immuno-oncology and cancer vaccines include AdaptImmune LLC, Aduro Biotech, Advaxis, Inc., AstraZeneca PLC, Bristol Myers-Squibb Company, Celgene Corporation, GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Immune Design Corp., Incyte Corporation, Merck & Co., Inc., Merrimack Pharmaceuticals, Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd, and Sanofi SA, among others. Many other 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 drug candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have

Table of Contents

significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of drug 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. If we obtain regulatory approval and launch commercial sales of our drug 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

Genentech Agreement

In October 2014, we entered into the Genentech Agreement for the development and commercialization of GDC-0919, 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 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined development, regulatory and sales milestones, as well as escalating royalties on potential commercial sales of multiple products by Genentech. The rates of such royalties will vary based on the stage of the compound at the signing of the Collaboration Agreement, regulatory exclusivity, intellectual property status, and other considerations.

Genentech will be responsible for and will fund future research, development, manufacturing and commercialization of GDC-0919 and next generation IDO/TDO compounds. Genentech will also provide us with funding to support our participation in the research collaboration. We have the right to continue to pursue development activities associated with the combination of GDC-0919 with our novel HyperAcute Cellular Immunotherapy platform. Additionally, we have retained the option under the Genentech Agreement to co-promote GDC-0919 and next generation IDO/TDO products with Genentech in the United States, subject to certain conditions, if and when such products are approved for sale.

Under the Genentech Agreement, we granted to Genentech an exclusive, sublicensable, royalty-bearing license under certain of our patents and know-how relating to IDO/TDO, and we have agreed to work exclusively with Genentech with respect to IDO/TDO compounds for a specified number of years.

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 of the Genentech Agreement or the other party’s bankruptcy or insolvency. After the end of the research collaboration, Genentech may terminate the Genentech Agreement for convenience upon 180 days written notice.

We have retained all rights to indoximod, our proprietary IDO pathway inhibitor, including the ability to develop, commercialize, license and divest indoximod in our discretion.

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 million in 2014 and a milestone payment of $20 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 rVSV-ZEBOV (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. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days of administration to a person without the infection. The rVSV-ZEBOV product candidate will continue to be studied in clinical trials.

Under the terms of the Merck Agreement, Merck is granted the exclusive rights to the Ebola vaccine product candidate, as well as any follow-on products. The Ebola vaccine product candidate is under an exclusive licensing arrangement with BioProtection Systems, our wholly owned subsidiary and a licensee of PHAC. Under these license arrangements, PHAC retains non-commercial rights pertaining to the vaccine candidate.

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

Table of Contents

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 HyperAcute technology and our IDO pathway inhibitor technology in the United States and abroad. As of December 31, 2015, our patent portfolio included ten patent families relating to our HyperAcute technology and twenty-two patent families relating to our IDO pathway inhibitor technology.

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 23 registered U.S. and foreign patents related to the HyperAcute technology. This patent family is expected to provide 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 7,763,641, US 8,551,474 and US 8,535,658), 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 includes issued patents relating to gene therapy technology and the use of xenogeneic cells having alpha-Gal expiring in 2016 (US 7,005,126); and four applications issued in the United States (US Patents No. 7,998,486, 8,357,777, 8,916,169 and 9,090,643) and two pending applications in both the United States and Europe covering isolated tumor antigens comprising alpha-Gal residues. The issued United States patents expire in 2029, 2027, 2028 and 2017, respectively, while the pending applications are projected to expire in 2027. Additional patent applications have been filed covering the use of carbohydrate-modified glycoproteins (PCT/US2014/025702, PCT/US2013/026271) and US 13/463,420, and correlates of efficacy to tumor vaccine (PCT/US2014/038231).

A family of patents, which relate to the use of alpha-Gal in viral and cancer vaccines and which was previously a second principal family of patents for our HyperAcute product candidates and HyperAcute technology, has mostly expired. The last remaining patent in such family, U.S. Patent No. 5,879,675, will expire in March 2016 and our exclusive license from Drexel University to such patent family will automatically terminate at such time.

Our IDO pathway inhibitor technology patent portfolio contains several key U.S. patent families exclusively licensed from Augusta University Research 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 five 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 three 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 and US 8,580,844 expires in 2027and 2025, respectively). Related applications directed to the use of indoximod to activate T cells are granted in Australia and Canada (AU 2008200315 B2 and CA 2483451 C).

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 are fully owned by us: 1) PCT/US2008/085167 with granted applications in Europe (EP2227233), China, Japan and Hong Kong; 2) PCT/US2010/054289, with granted patents in the US (8,722,720), and pending in Europe and Canada; and 3)

PCT/US2012/033245, which covers the IDO inhibitor compound GDC-0919, currently in clinical development, and its national counterparts are set to provide protection at least until 2032. This patent has been granted in Australia, New Zealand and Japan and allowed in US, Europe and Israel 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

Table of Contents

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, China 102083429 and pending applications in Europe and Japan).

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 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

Following are licensing agreements covering technologies and intellectual property rights useful to our HyperAcute product candidates and technologies:

Central Iowa Health System License Agreement

We are a party to a license agreement, or the CIHS Agreement, dated August 2, 2001, as amended on December 30, 2013 with the Central Iowa Health System, or CIHS. The CIHS Agreement grants to us an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information or know-how relating to our HyperAcute immunotherapy technology. The license is subject to CIHS's retained right to use, and to permit other academic and research institutions to use, the CIHS patent rights and information for non-commercial bona fide research purposes. The license is also subject to certain rights of and obligations to the United States government under applicable law, to the extent that such intellectual property was created using funding provided by a United States federal agency. We may grant sublicenses under the license, so long as the sublicense is subordinate to, and complies with, the CIHS Agreement.

In partial consideration of the license under the CIHS Agreement, we entered into a stock purchase agreement with CIHS, under which we issued to CIHS shares of our common stock and granted CIHS certain rights related to ownership of such shares. In addition, we must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If we or our sublicensees commercialize a licensed product, we also have the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments we must make to third parties. If we grant a sublicense under the licenses granted by CIHS, we must pay to CIHS, in addition to the royalties described above, a percentage of certain consideration paid by the sublicensee to us. We have no obligation to pay fees to CIHS as a result of payments between us and our affiliates.

Under the CIHS Agreement, we must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets. As

part of such efforts, we must deliver to CIHS certain information including an annual progress report detailing our progress towards commercial use of licensed products. At specific dates after the effective date we must satisfy certain obligations to conduct specified development on the licensed product, expend specified amounts on development of the licensed technology, or raise specific minimum amounts of equity capital. We are obligated to use commercially reasonable efforts to negotiate appropriate sponsored research programs with researchers at CIHS. If CIHS concludes that we have not met any of these obligations, and we fail to cure such failure, CIHS may either terminate the agreement or convert the license to a non-exclusive license. In addition, if CIHS determines that we have

Table of Contents

failed to use commercially reasonable efforts to, or to grant sublicenses to, develop or commercialize a licensed product in a particular field within the licensed field of use and we fail to cure such failure, CIHS may terminate, or convert the license to a non-exclusive license with respect to such particular field.

Unless terminated earlier, the CIHS Agreement will remain in effect until the expiration of all of our royalty obligations under the agreement. Our royalty obligations expire on a country-by-country and a licensed product-by-licensed product basis upon the later of (1) the expiration of the last to expire valid claim within the licensed patents covering a licensed product in a country or (2) 12 years following the first commercial sale of a licensed product in a country. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect that the last patent will expire under this agreement in 2023, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. Upon expiration of the CIHS Agreement we will retain a fully-paid, nonexclusive license under the licensed technology to make, have made, use, sell, offer for sale, and import licensed products. We may terminate the agreement, or specific patents covered by the agreement, after written notice to CIHS or for CIHS' uncured material breach of the agreement. CIHS has the right to terminate for our uncured material breach of the agreement after written notice. Upon termination of the agreement we may sell our existing inventory of licensed products for a period of three months after such termination. We have the right to assign the CIHS Agreement to any affiliate or in connection with the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires CIHS' written consent, which consent shall not be unreasonably withheld.

On December 30, 2013, we entered into an amendment to the CIHS Agreement, or the CIHS Amendment. Under the terms of the CIHS Amendment, certain provisions of the CIHS Agreement were amended, in part to clarify that we are not obligated to pay fees to CIHS as a result of payments between us and our affiliates with respect to the intellectual property rights licensed by CIHS to us pursuant to the CIHS Agreement. The CIHS Amendment includes, without limitation, clarifications to (1) the definitions of “Third Party(ies)” and “Net Sales”, (2) provisions with respect to our obligations to take actions to enable CIHS to meet its obligations under certain federal statutes and (3) provisions with respect to the sublicensing fee payable by us to CIHS. In addition, the CIHS Amendment updates the list of patents that are licensed to us under the CIHS Agreement. We entered into the CIHS Amendment in connection with our sublicensing of certain intellectual property to our wholly owned foreign subsidiary.

Drexel University License Agreement

Our license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel,will automatically terminate in March 2016 upon the expiration of the last of the Drexel patent rights licensed to us pursuant to the Drexel Agreement. While the Drexel Agreement remains in force, we and our affiliates have an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on alpha-Gal epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease. Upon termination of the Drexel Agreement, this license will terminate, and we and our affiliates will not have any right to use the Drexel technical information or to make, have made, use, import, sell or offer for sale products that use the Drexel technical information.

Following are licensing agreements covering technologies and intellectual property rights useful to our IDO pathway inhibitor technology and product candidate:

LIMR Exclusive License Agreement (IDO-1)

We are a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, and sell products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics. Such license is subject to LIMR's retained right to use such LIMR patent rights and technology for its non-commercial educational and research purposes, and LIMR agrees to notify and provide us with a first look at any additional research findings that directly result from such use of the technology. We may grant sublicenses under the LIMR Licenses, provided that each sublicense materially conforms to the IDO-1 Agreement and is expressly subject to its terms.

In consideration of such license grant, we are obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential one time milestone payments in an aggregate amount up to approximately $1.36 million, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the IDO-1 Agreement, we must to pay to LIMR a percentage of the consideration received by us from the sublicensee.

Table of Contents

Under the IDO-1 Agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If we breach our obligations and fail to cure such breach, LIMR may reduce our license to a non-exclusive license or revoke the license in its entirety. We have the responsibility, at our expense, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement.

Unless terminated earlier, the IDO-1 Agreement shall remain in effect until the expiration of the last licensed LIMR patents. Pending the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2024, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. LIMR may terminate the agreement for our failure to make payments due, bankruptcy or similar proceedings, and we may terminate the agreement upon a specified period of notice. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We have the right to assign the IDO-1 Agreement in connection with an acquisition, merger, consolidation, operation of law or the transfer of all or substantially all of our assets or equity relating to the agreement, but any other assignment requires the express prior written consent of LIMR, not to be unreasonably withheld.

Augusta University Research Institute License Agreement

We are a party to a License Agreement dated September 13, 2005, or the AURI 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 Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013 and July 10, 2014. The AURI 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.

Such license 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, 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.

Under the agreement, we are obligated to make certain investments toward the further development of licensed products within specified time periods. If we fail to make the required investment, AURI may convert our license in the oncology field to a non-exclusive license. In addition, 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 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.

LIMR Exclusive License Agreement (IDO-2)

We are a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target Indoleamine 2,3 Dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. Such license is subject to LIMR's retained non-exclusive right to use such LIMR patent rights and technical information for internal non-commercial, educational and research purposes only. In addition, the license is subject to certain rights of and obligations to the U.S. government

Table of Contents

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 the LIMR IDO-2 license, provided that each sublicense complies with the terms of the LIMR IDO-2 Agreement.

In consideration of such license grant, we have paid to LIMR an upfront license fee and annual license maintenance fees, and are obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately $1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of “net sales” of the licensed product, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us. The payment provisions of the LIMR IDO-2 Agreement provide that, in the event a product for which we have payment obligations under the LIMR IDO-2 Agreement is also covered by payment obligations under the LIMR IDO-1 Agreement, we will not be obligated to pay both such obligations but rather will pay to LIMR the higher of the amounts owed under the two agreements.

Under the LIMR IDO-2 Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license. We have the obligation, at our expense and in our reasonable discretion, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement. In addition, LIMR granted us the exclusive option to obtain exclusive, worldwide licenses on commercially reasonable terms to future inventions and discoveries of LIMR related to IDO-2 or inhibitors of IDO-2.

Concurrently with, and as an obligation under, the LIMR IDO-2 Agreement, we entered into a cooperative research and development agreement with LIMR, or the CRADA Agreement. Under the CRADA Agreement, we agreed to provide funding to LIMR in support of IDO research for one year and renewable at our option.

Unless terminated earlier, the LIMR IDO-2 Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. 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. We may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for our uncured breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We may assign the LIMR Agreement in connection with the transfer of all or substantially all of our assets or equity, or by reason of acquisition, merger, consolidation or operation of law, but any other assignment requires LIMR's written consent, which shall not be unreasonably withheld.

LIMR Exclusive License Agreement (IDO)

We are a party to a license agreement, or the LIMR IDO Agreement, dated April 23, 2009 with LIMR. The LIMR IDO Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. Such license is subject to LIMR's retained non-exclusive right to use such LIMR patent rights and technical information for internal non-commercial, educational and research purposes only. 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 the LIMR IDO license, provided that each sublicense complies with the terms of the LIMR IDO Agreement.

In consideration of such license grant, we are obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately $610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of “net sales” of the licensed product, subject to reduction for our royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Under the LIMR IDO Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license. We have the right and responsibility, at our expense and in our reasonable discretion,

to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement. Unless terminated earlier, the LIMR IDO Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. 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 2029, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. We may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for our uncured breach, bankruptcy or similar

Table of Contents

proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We may assign the LIMR IDO Agreement in connection with the transfer of all or substantially all of our assets or equity, or by reason of acquisition, merger, consolidation or operation of law, but any other assignment requires LIMR's written consent, which shall not be unreasonably withheld.

Bresagen License Agreement

We entered into a patent license agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen, which expired in March 2014 when the licensed patents expired, and on April 1, 2014 we entered into a license agreement with Bresagen, or the Bresagen Agreement, that is an extension of the original agreement and grants us a non-exclusive, non-sublicensable license to a mouse strain controlled by Bresagen for use in testing microbial and cancer vaccines in the U.S. In consideration of such license grant, we are obligated to pay Bresagen an annual license fee.

Unless terminated earlier, the Bresagen Agreement shall continue for one year and will be automatically renewed for additional one year periods. Either party may terminate the Agreement with prior written notice to the other party. Bresagen also has the right to terminate for our uncured breach, repeated breach, or insolvency, change of control without consent or similar proceedings. Upon termination of the agreement, all of our rights under the license are terminated. We may assign the Bresagen Agreement to an affiliate, but any other assignment requires Bresagen's written consent.

Following are licensing agreements to which BPS is a party covering technologies and intellectual property rights applicable to BPS’s development of vaccines for the biodefense field:

The Ohio State University License Agreement

We are a party to a license agreement dated June 28, 2013 with The Ohio State University, or OSU. This agreement grants us exclusive rights in the United States and its territories, in all fields of use, to patents related to pharmaceutical compositions and vaccines comprising antigens associated with L-Rhamnose and Forssman epitopes, including patent application US 13/463,420, which is co-owned by us and OSU.

In consideration of the license grant, we are obligated to pay OSU specified license fees and are obligated to pay to OSU specified annual license maintenance fees, patent prosecution and maintenance costs, potential milestone payments in an aggregate amount up to approximately $2.75 million for the first licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized, with minimum royalties for the first three years in which a licensed product generates revenue. In addition, if we grant a sublicense under this agreement, we must also pay to OSU a percentage of certain consideration received by us from the sublicensee. Under this agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products and to use commercially reasonable efforts to achieve certain milestones by agreed-upon deadlines.

Unless terminated earlier, the agreement will continue until the expiration of the last licensed patent rights which extend until 2024. We may terminate the agreement at any time for any reason with 90 days prior written notice. OSU may immediately terminate the agreement if we materially breach our obligations to OSU and do not cure the breach within the specified period, or if we or our affiliates or sublicensees participates in a challenge to the validity, enforceability or scope of the licensed patents. The agreement will also terminate if we agree with OSU that the agreement should be terminated or if we cease business operations or become involved in any bankruptcy, insolvency or liquidation-related activities. If the agreement is terminated, we will lose our license from OSU to the licensed patents but we will retain our rights as owners of all licensed patents that are co-owned by us and OSU.

Public Health Agency of Canada License Agreement

BPS is a party to a license agreement dated May 4, 2010, with PHAC, or the PHAC License. The PHAC License grants BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license for commercialization of specified Canada patent rights relating to technology based on rVSV. The license is subject to Canada's retained right to use the PHAC patent rights and technology to improve the patent rights, carry out educational purposes, and development of the patent rights where BPS cannot obtain regulatory approval or meet demand. BPS may 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.

In consideration of the license grant, BPS must pay to Canada specified patent and signing fees, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$205,000 per licensed product, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, which royalty rate varies depending on the type of licensed product. In addition, if BPS grants a sublicense under the licenses granted by Canada,

Table of Contents

BPS is required to pay to Canada a percentage of certain consideration BPS receives from the sublicensee. 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 expiration of the last of the PHAC patent rights. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we currently expect the last patent will expire under this agreement in 2023, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. Canada may terminate this agreement for BPS's failure to use commercially reasonable efforts to 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 we assign the PHAC License without prior written consent or if BPS files for bankruptcy or similar proceedings.

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.

Table of Contents

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. We have been informed that one of the approximately 70 clinical trial sites participating in the IMPRESS trial may not be in compliance with certain GCP requirements. The site in question self-reported certain violations to both us and the FDA. The site is conducting an internal investigation, and is implementing a plan to remediate the violations. There can be no assurance that the site will complete such remediation to the satisfaction of the FDA and us, or that the FDA will not ultimately require that some or all of the patients from such site enrolled in the IMPRESS trial be excluded from the final analysis of the study. 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.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the 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. Before proceeding with a Phase 3 clinical trial, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment, or SPA. SPAs help establish up front agreement with the FDA about the adequacy of the design of a clinical trial to support a regulatory approval, but the agreement is not binding if new circumstances arise. In addition, even if an SPA remains in place and the trial meets its endpoints with statistical significance, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses or approval with restricted distribution or other burdensome post-approval requirements or limitations.

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 ten 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 assurance 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, is satisfactory 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

Table of Contents

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.

Fast Track Designation

A Fast Track product is a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the FDA's Fast Track program, the sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a Fast Track product at any time during the development of the product, prior to a new drug or biologic license application submission. Fast Track designation enables a company to file their application for approval on a rolling basis and potentially qualify for priority review.

The FDA may condition approval of an application for a Fast Track product for accelerated approval on a commitment to do post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and require prior review of all promotional materials. In addition, the FDA may withdraw approval of a Fast Track product in an expedited manner on a number of grounds, including the sponsor's failure to conduct any required post-approval study in a timely manner.

Orphan Drug Designation

The FDA grants Orphan Drug designation to drugs intended to treat a rare disease or condition, which for this program is defined as having a prevalence of less than 200,000 individuals in the United States.

Orphan drug designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives the first approval for the indication for which it has designation, the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the United States. Orphan Drug exclusive marketing rights may be lost if the FDA determines that our request for designation was materially defective or if we are unable to assure sufficient quantity of our drug.

Additional benefits of Orphan Drug designation include clinical tax research incentives and exemption from application filing fees. Although obtaining approval to market a product with orphan drug exclusivity may be advantageous, we cannot be certain:

- that we will be the first to obtain approval for any other drugs or indications for which we obtain Orphan Drug designation;
- that Orphan Drug designation will result in any commercial advantage or reduce competition; or
- that the limited exceptions to this exclusivity will not be invoked by the FDA.

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, 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.

Table of Contents

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.

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.

Table of Contents

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 Payment 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; and 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. 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.

Similar to the United States, a system for Orphan Drug designation exists in the E.U. Orphan designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has designation, the relevant regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for ten years in the E.U.

Price Controls

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.

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.

Table of Contents

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

We are not currently a party to any legal proceedings that are expected to have a material impact on our business, financial condition, results of operations or prospects.

Employees

As of December 31, 2015 we had approximately 210 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. In June 2010, we completed the expansion of approximately 23,500 square foot facility, which includes executive offices as well as approximately 14,000 feet dedicated to manufacturing, testing and product storage. The manufacturing portion of the facility became operational on October 17, 2010. The lease expires January 31, 2020, and we have the option to extend the lease for two additional five-year periods upon the same terms as the base lease. In addition, we continue to occupy a small pilot manufacturing and office facility in the same research park under the terms of a lease that expires October 31, 2016.

On November 14, 2011, we entered into a Memorandum of Agreement, or the Memorandum, with Iowa State University Research Park Corporation, or ISURP. The Memorandum is an addendum to the lease, or the Lease, dated September 30, 2009 between us and ISURP covering our facilities in Ames, Iowa. The Memorandum added approximately 26,600 square feet of additional space to the Lease. During 2012 operating rents to ISURP increased by $211,000. During 2012, ISURP provided a building allowance of $622,000 and assisted in securing an additional $456,000 in debt financing for us. This lease expires on February 28, 2017.

On December 29, 2014, we added an additional 6,770 square feet of offices located in the Iowa State University Research Park in Ames, Iowa. On July 9, 2015 we added 2,070 square feet of offices adjacent to the 6,770 square feet. Both leases expire January 31, 2018.

On February 24, 2014, we signed a lease for a 6,430 square foot commercial facility and additional executive offices in Austin, Texas and amended the lease in February 2015. We anticipate conducting activities at this location associated with expansion of our commercialization efforts as well as supporting the continued growth of our clinical operations activities. On February 16, 2015, we added an additional 3,468 square feet to the Austin facility. The lease expires September 30, 2016.

On August 25, 2014, we entered into a lease for 47,250 square feet of space in Ankeny, Iowa where we plan to manage the final production steps, including irradiation and packaging, and to distribute our potential vaccine drug products, if any are approved. The lease expires October 31, 2017.

On December 15, 2014, we entered into a lease for 1,310 square feet of office space in Devens, Massachusetts to support our development efforts related to our Ebola vaccine product candidate. The lease expired December 14, 2015 and we are in discussions to renegotiate the terms of the renewal.

Corporate Information

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

Available Information

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

Table of Contents

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.

Table of Contents

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

Our near-term prospects are highly dependent on algenpantucel-L for patients with surgically resected pancreatic cancer. 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 algenpantucel-L, our business would be harmed and the value of our securities would likely decline.

We must be evaluated in light of the uncertainties and complexities affecting a development stage biopharmaceutical company. We have not completed clinical development for any of our product candidates. Our most advanced oncology product candidate is algenpantucel-L. The FDA must approve algenpantucel-L before it can be marketed or sold. Our ability to obtain FDA approval of algenpantucel-L depends on, among other things, completion of one or both of our Phase 3 clinical trials, whether our Phase 3 clinical trials of algenpantucel-L demonstrate statistically significant achievement of the applicable clinical trial endpoints with an acceptable safety and tolerability profile and whether the FDA agrees that the data from either of our Phase 3 clinical trials of algenpantucel-L are sufficient to support approval. In addition, there are multiple methods of statistical analysis that could be used to evaluate the data from our algenpantucel-L IMPRESS Phase 3 clinical trial and other clinical trials, and the methods that we use, or that the FDA uses or permits us to use, may demonstrate lower, or no, statistical significance in achieving the applicable clinical trial endpoints, or may require an extended period of time to demonstrate statistical significance, if at all, as compared to other methods of statistical analysis that we could use.

The final results of our Phase 3 clinical trials of algenpantucel-L may not meet the FDA’s requirements to approve the product for marketing, and the FDA may otherwise determine that our manufacturing processes, facilities or raw materials are insufficient to warrant approval. We may need to conduct more clinical trials than we currently anticipate. Furthermore, even if we do receive FDA approval, we may not be successful in commercializing algenpantucel-L. If any of these events occur, our business could be materially harmed and the value of our common stock would likely decline.

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.

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.

38

Table of Contents

In particular, there have been no control groups in our algenpantucel-L clinical trials completed to date. While comparisons to results from other reported clinical trials can assist in predicting the potential efficacy of algenpantucel-L, there are many factors that affect the outcome for patients in clinical trials, some of which are not apparent in published reports, and results from two different trials cannot always be reliably compared. As a result, we are studying algenpantucel-L in combination with the current standard-of-care in direct comparison to the current standard-of-care alone in the same trial and will need to show a statistically significant benefit when added to the current standard-of-care in order for algenpantucel-L to be approved as a marketable drug. Patients in our Phase 3 clinical trial who do not receive algenpantucel-L may not have results similar to patients studied in the other clinical trials we have used for comparison to our Phase 2 clinical trials. If the patients in our Phase 3 clinical trial who receive standard-of-care without algenpantucel-L have results that are better than the results predicted by the other large clinical trials, we may not demonstrate a sufficient benefit from algenpantucel-L to allow or convince the FDA to approve it for marketing.

Our HyperAcute Cellular Immunotherapy product candidates are based on a novel technology, which may raise development issues we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our product candidates.

Our HyperAcute Cellular Immunotherapy product candidates are based on our novel HyperAcute Cellular Immunotherapy technology. In the course of developing this technology and these product candidates, we have encountered difficulties in the development process. There can be no assurance that additional development problems, which we may not be able to resolve or which may cause significant delays in development, will not arise in the future.

Regulatory approval of novel product candidates such as ours can be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical products due to our and regulatory agencies' lack of experience with them. This may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, including post-approval studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. For example, the two cell lines that comprise algenpantucel-L are novel and complex therapeutics that we have endeavored to better characterize so that their identity, strength, quality, purity and potency may be compared among batches created from different manufacturing methods. We currently lack the manufacturing capacity necessary for large-scale production. If we make any changes to our current manufacturing process and cannot design assays that satisfy the FDA's expectations regarding product comparability, the FDA may require us to undertake additional clinical trials.

The novel nature of our product candidates also means that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel for research, development and manufacturing positions.

Our SPA with the FDA relating to our algenpantucel-L IMPRESS Phase 3 clinical trial does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.

The protocol for our algenpantucel-L IMPRESS Phase 3 clinical trial was reviewed by the FDA under its SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a Biologics License Application, or BLA, and provides an agreement that the clinical trial design, including trial size, clinical endpoints and/or data analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. However, the SPA agreement is not a guarantee of approval, and any methods of data analysis that we may propose to use that are not specifically set forth in the SPA may be rejected by the FDA. Alternatively, we may propose to use statistical methods that result in the termination of the SPA. The FDA retains the right to require additional Phase 3 testing, and we cannot be certain that the design of, or data collected from, the IMPRESS Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of algenpantucel-L for the treatment of patients with surgically resected pancreatic cancer, or otherwise be sufficient to support FDA or any foreign regulatory approval. In addition, the survival rates, duration of response and safety profile required to support FDA approval are not specified in the IMPRESS Phase 3 clinical trial protocol and will be subject to FDA review. Further, the SPA agreement is not binding on the FDA if public health concerns

unrecognized at the time the SPA agreement was entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed-upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the IMPRESS Phase 3 clinical trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the IMPRESS Phase 3 clinical trial, how it will view our analysis of such data and results or whether algenpantucel-L will receive any regulatory approvals as a result of the IMPRESS Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer.

Table of Contents

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;
- 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;
- 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;
- 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 competition with ongoing clinical trials and 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

Table of Contents

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;
- 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.

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.

41

Table of Contents

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 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.

We have been informed that one of the approximately 70 clinical trial sites participating in the IMPRESS trial may not be in compliance with certain GCP requirements. The site in question self-reported certain violations to both us and the FDA. The site is conducting an internal investigation, and is implementing a plan to remediate the violations. There can be no assurance that the site will complete such remediation to the satisfaction of the FDA and us, or that the FDA will not ultimately require that some or all of the patients from such site enrolled in the IMPRESS trial be excluded from the final analysis of the study.

Table of Contents

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, our HyperAcute Cellular Immunotherapy product candidates, indoximod 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.

Indoximod, our proprietary IDO pathway inhibitor product candidate, has been studied in two Phase 1b/2 clinical trials co-sponsored by the National Cancer Institute. We are currently supplying indoximod 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 is being 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.

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.

We have received Fast Track and Orphan Drug Designations for algenpantucel-L and may seek one or more of these or other special designations from regulatory authorities for our other product candidates. These designations may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

Sponsors of biologic or pharmaceutical product candidates may seek designations from the FDA designed to accelerate the FDA’s review and approval of marketing applications. For example, we have received Fast Track Designation for algenpantucel-L. Fast Track Designation may be granted to a drug intended for treatment of a serious or life-threatening disease or condition that has potential to address unmet medical needs for the disease or condition. The key benefits of Fast Track Designation include potential eligibility for priority review, rolling review (submission of portions of an application before the complete marketing application is submitted), and accelerated approval, if relevant criteria are met. Under the accelerated approval program, the FDA may approve a product candidate on the

basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the product's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

Table of Contents

The FDA has broad discretion over whether or not to grant these designations, so even if we believe a particular product candidate is eligible for a particular designation, we cannot assure you that the FDA would decide to grant it. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree and instead determine not to make such a designation. In any event, the receipt of a particular designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. Further, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from a clinical development program.

We have also received Orphan Drug Designation for algenpantucel-L. The FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population of greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, or the EU, the European Medicines Agency’s, or the EMA's, Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition when the prevalence of the condition is not more than five in 10,000 persons in the EU or when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the product. Additionally, there must be no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for algenpantucel-L in the United States and EU, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing biologic and pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a competing product can be approved for a different indication. Even after an orphan drug is approved, the FDA or EMA can subsequently approve another drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

Even if approved, the HyperAcute Cellular Immunotherapy product candidates, indoximod, GDC-0919, 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 no 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.

Table of Contents

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 plan to increase our manufacturing capacity, which may include negotiating and entering into arrangements for third-party contract manufacturing for some or all of our commercial manufacturing requirements. We plan to seek FDA approval for our production process in connection with our BLA for algenpantucel-L. Should we not receive timely approval of our production process, our ability to produce the immuno-oncology products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

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 Genentech Agreement in October 2014 for the sales, marketing and distribution of GDC-0919, and we entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if GDC-0919 or our Ebola vaccine product candidate are approved by regulators for marketing and sale, Genentech or Merck may be unsuccessful in their efforts to commercialize GDC-0919 or 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 GDC-0919 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 or persuade adequate numbers of physicians to prescribe 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 towards 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, particularly Dr. Charles J. Link, Jr. and Dr. Nicholas N. Vahanian. The loss of services by either of these leaders 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.

45

Table of Contents

We will need to recruit a significant number of 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. If the personnel who have contingently agreed to join us choose, not join us it will be difficult or impossible for us to execute our business plan in a timely manner. Additionally, our most significant facilities are 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.

Risks Relating to Manufacturing Activities

We have never manufactured our product candidates at commercial scale, and there can be no assurance that such products can be manufactured in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have no experience in commercial-scale manufacturing, the management of large-scale information technology systems or the management of a large-scale distribution system. In June 2014, we granted WuXi, a non-exclusive right to use certain of our starting materials and confidential information for the commercial manufacturing of cell material for the production of algenpantucel-L, pursuant to the WuXi Agreement. The WuXi Agreement is intended to establish an expanded source of supply for algenpantucel-L for commercial sale, if and when that product is approved by the FDA. We will incur significant expense under the WuXi Agreement or under similar commercial manufacturing arrangements, and our commercial manufacturing programs may not result in the manufacture of algenpantucel-L to the required quality standards or in quantities or at a cost that allows any future commercial sales to be profitable or commercially viable for many reasons, including the following:

- the FDA may not approve our facilities or the facilities used by, or the manufacturing processes developed by, us or WuXi or other manufacturers, or the FDA may impose additional requirements that result in unforeseen expense or delay;
- we have no experience managing relationships with commercial manufacturing organizations, and we may make decisions in connection with our relationship with other manufacturers that result in unforeseen delays, expenses or other difficulties, or that later prove to be less advantageous than other decisions we could have made;
- we or such other manufacturers may encounter unforeseen difficulties in attempting to manufacture biological materials related to algenpantucel-L at a larger scale than we have previously attempted;
- other manufacturers may not be able to devote sufficient resources or facilities to manufacture cell materials in the quantities we may require;
- the manufacturing processes may produce low or variable quality or quantities of manufactured cell materials, and we may expend considerable resources attempting to identify or remedy factors causing such problems, or we may not be able to identify or remedy such factors;
- WuXi is currently our sole contract manufacturer for cell materials, and any unforeseen difficulties or work slow down or stoppage resulting from economic, labor, governmental, political or environmental factors, among others, may result in increased costs or delay, or a reduction or elimination of WuXi's ability to manufacture cell material for algenpantucel-L; and
- the FDA may not approve algenpantucel-L for the treatment of patients with surgically resected pancreatic cancer, or any subset of such patients, which would not relieve our obligation for certain costs under the WuXi Agreement or other such agreements, if any.

We may develop additional or alternative manufacturing capacity by expanding our current facilities, by entering into additional third-party contract manufacturing arrangements, or by some combination of the foregoing. Expanding our current facilities would require substantial additional funds, and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing

facilities that are sufficient to produce materials for additional later-stage clinical trials or commercial use. Contracting for additional third-party commercial manufacturing would require expertise and qualified personnel to manage the added complexity of such additional relationships and regulatory compliance at multiple manufacturing sites operated by different third-parties and may further increase our expenses related to, and decrease our direct control over, procuring a sufficient supply of our product candidates for commercial sale.

If we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes or our relationships with WuXi or other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of

Table of Contents

product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business, financial condition and results of operations. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of each BLA and each New Drug Application, or NDA, on a timely basis and must adhere to Good Laboratory Practice, or GLP, and current Good Manufacturing Practice, or cGMP, regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA approval of the products will not be granted.

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 Genentech and Merck in their respective capacities as our licensees, 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.

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.

We currently rely on relationships with third-party contract manufacturers, a circumstance that limits our ability to control the availability of, and manufacturing costs for, our product candidates in the near term. The loss of any of these manufacturers, some of which are our only current source for components of our product candidates, or delays or problems in the supply or manufacture of components of our product candidates, could materially and adversely affect our business, financial condition and results of operations.

We intend to rely in whole or in part on contract manufacturers or strategic partners for the manufacture of all of our product candidates, including algenpantucel-L, for commercial sale, if any are approved for sale. In addition, we currently rely on contract manufacturers for supply of our Ebola vaccine product candidate 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 antigen, components of HyperAcute Cellular Immunotherapy product candidates, indoximod, or our Ebola vaccine product candidate, or finished products. This could delay or reduce commercial sales and materially harm our business. We do not currently have experience with the manufacture of products at commercial scale or the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to manufacture products at commercial scale or to negotiate and enter into relationships with third-party contract manufacturers. Any prolonged delay or interruption in the operations of our facilities or our current or future contract manufacturers' facilities could result in

Table of Contents

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 drug 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.

Further, 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.

We replicate all biological cells for clinical trials of our product candidates internally and utilize a single manufacturing site to manufacture our HyperAcute Cellular Immunotherapy clinical product candidates. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture product candidates for clinical testing and would result in increased costs and losses.

We have thus far elected to replicate all biological cells for our HyperAcute Cellular Immunotherapy clinical product candidates for clinical testing internally using a complex process. The disruption of our operations could result in manufacturing delays due to the inability to purchase the cell lines from outside sources. Currently, we have only one manufacturing facility in which we can manufacture HyperAcute Cellular Immunotherapy clinical product candidates. In the event of a physical catastrophe at our manufacturing or laboratory facilities, we could experience costly delays in reestablishing manufacturing capacity, due to a lack of redundancy in manufacturing capability.

Our current HyperAcute Cellular Immunotherapy manufacturing facility contains highly specialized equipment and utilizes complicated production processes developed over a number of years, which would be difficult, time-consuming and costly to duplicate or may be impossible to duplicate. Any prolonged disruption in the operations of our HyperAcute Cellular Immunotherapy manufacturing facility would have a significant negative impact on our ability to manufacture HyperAcute Cellular Immunotherapy product candidates for clinical testing on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. We may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or any losses may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

We have experienced bacterial and mycoplasma contaminations in lots produced at our facilities, and we destroyed the contaminated lots and certain overlapping lots. We may experience additional contaminations at our facilities, and we will destroy any contaminated lots that we detect, which could result in significant delay in our ability to produce material for clinical trials, or if approved, products for commercial sale or additional expense in our operations.

We rely on a single manufacturer for a key component used in the manufacture of our HyperAcute Cellular Immunotherapy product candidates, which could impair our ability to manufacture and supply our products.

The manufacturing process for our HyperAcute Cellular Immunotherapy product candidates has one component that we obtain from a single manufacturer. If our current supplier is unable to continue supplying the component for our clinical trials, or to supply the component at quantities insufficient for commercial sale, we may need to utilize an alternative manufacturer. If we utilize an alternative manufacturer, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use. The loss of our current supplier could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays.

48

Table of Contents

Our facilities are 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 facilities are located in Ames, Iowa, which is susceptible to floods and tornados, and our facilities are 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.

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. To date, the FDA has approved only one active cellular cancer

immunotherapy product, even though several have been, and currently are, in clinical development.

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:

Table of Contents

- 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
- 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 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 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 reimbursement to the consumer from third-party payers, such as government and private insurance plans. 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

Table of Contents

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.

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 recent years. 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 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. Recently, 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.

Table of Contents

- 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; 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; and 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, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, 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.

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. There has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices over the course of 2015, 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 bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In the United States, the pharmaceutical industry has already been significantly affected by major legislative initiatives, including, for example, the Affordable Care Act, or ACA. The ACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. The ACA, compounded by the intense public scrutiny of drug pricing in the United States, is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding. In the future, there will likely continue to be additional 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.

Table of Contents

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 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. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

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 ten 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.

Algenpantucel-L and certain other of our product candidates may be regulated as biological products, or biologics, which may subject them to competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the ACA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. To be considered biosimilar, a product candidate must be highly similar to the reference product notwithstanding minor differences in clinically inactive components. In addition, there can be no clinically meaningful differences between the product candidate and the reference product in terms of the safety, purity and potency of the product. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological product candidates.

Under the BPCIA, no approval of an application for a biosimilar product may be made effective until 12 years after the original branded product is first licensed by the FDA pursuant to the approval of a BLA. We believe that if the FDA approves a BLA for algenpantucel-L, algenpantucel-L should qualify for this 12-year period of market exclusivity, known as reference product exclusivity, such that no approval of a biosimilar version of our product could become effective prior to the expiration of that 12-year period. However, these exclusivity provisions have been subject to various interpretations that have not yet been fully addressed by the FDA, and there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider algenpantucel-L to be eligible for reference product exclusivity, potentially creating the opportunity for competition sooner than anticipated. In addition, even if algenpantucel-L were to receive reference product exclusivity, a competitor may seek approval of a product candidate under a full BLA rather than a biosimilar product application. In such a case, although the competitor would not enjoy the benefits of the abbreviated pathway for biosimilar approval created under the BPCIA, the FDA would not be precluded from making effective an approval of the competitor

product pursuant to a BLA prior to the expiration of our 12-year period of marketing exclusivity.

In addition, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear. In particular, it is unclear at this juncture whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies. Such substitution will depend on a number of marketplace and regulatory factors that are still developing.

Table of Contents

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.

Financial Risks

Despite our profitable fiscal year ended December 31, 2014, we have a history of net losses. We incurred a net loss in 2015 and expect to continue to incur increasing 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 depend on our achievement of specific milestones, and any royalties depend on successful commercialization of GDC-0919 or other 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 $40.4 million in 2015 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. In addition, prior to the year ended December 31, 2014, we have incurred significant net losses in each year including net losses of $31.2 million and $23.3 million for the years ended December 31, 2013 and 2012, respectively. Our losses have resulted principally from costs incurred in our research activities. We anticipate that our operating losses will substantially increase 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;

Table of Contents

- 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, build commercial capabilities, develop our pipeline and expand our corporate infrastructure. We believe that our existing cash and cash equivalents and certificates of deposit will allow us to fund our operating plan through the end of 2016, although not through commercialization and launch of revenue-producing products. 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 $2.8 million per license (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.

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

Table of Contents

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.

Despite our incurred net losses for the year ended December 31, 2015, we were subject to federal income taxes in the United States. As a result of our profitability for the year ended December 31, 2014, we were subject to income taxes, and we may become subject to income taxes in future years in the United States or foreign jurisdictions. 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, 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.

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 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 partner with collaborators 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

Table of Contents

of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. The competitors of which we are aware that have initiated a Phase 3 clinical trial or have obtained marketing approval for a potentially competitive drug to our lead product candidate, algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer, include Astra-Zeneca, Celgene Corporation, Incyte Corporation, Merrimack Pharmaceuticals, and Threshold Pharmaceuticals. Our competitors in the field of immuno-oncology and cancer vaccines include AdaptImmune LLC, Aduro Biotech, Advaxis, Inc., AstraZeneca PLC, Bristol Myers-Squibb Company, Celgene Corporation, GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Immune Design Corp., Incyte Corporation, Merck & Co., Inc., Merrimack Pharmaceuticals, Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd, and Sanofi SA, among others. Many other 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 drug 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 drug 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. If we obtain regulatory approval and launch commercial sales of our drug 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 our HyperAcute Cellular Immunotherapy product candidates, indoximod, GDC-0919 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.

Our infectious disease product candidates face significant competition for United States government funding for both development and procurement of vaccines against infectious diseases, medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. Public and private biopharmaceutical companies, academic institutions, government agencies, private research organizations and public research organizations are conducting research and filing patents toward commercialization of products. In particular, given the widespread media attention on the recent Ebola epidemic, there are competitive efforts by public and private entities to develop an Ebola vaccine as fast as possible, including by GlaxoSmithKline and Johnson &

Johnson. Those other entities may develop Ebola vaccines that are more effective than any we may develop in collaboration with Merck, or may develop an Ebola vaccine at a lower cost or earlier than we or Merck are able to develop any Ebola vaccine, or they may be more successful at commercializing an Ebola vaccine. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our Ebola vaccine development efforts. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to infectious disease or biodefense products.

Table of Contents

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 partners and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Genentech and Merck are responsible for clinical trials of GDC-0919 and our Ebola vaccine product candidate, respectively, 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, respectively. If either company does not succeed in advancing any product candidate to final approval, such failure 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 in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

Table of Contents

If we enter into a collaboration agreement we consider acceptable, including the Genentech Agreement to commercialize GDC-0919 and the Merck Agreement to 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 future 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, disputes that 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. For example, Genentech has the right to terminate the Genentech Agreement for any reason after October 16, 2016, and Merck has the right to terminate the Merck Agreement for any reason 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 commercialization efforts. The occurrence of any of these events could adversely affect the 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, 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 Genentech Agreement and the Merck Agreement, and we may be required under future 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 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;
- 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,

Table of Contents

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 hereunder 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.

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.

Table of Contents

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 file patent applications in the United States that claim technology also claimed by us, 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 become 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.

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 Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidate and may initiate legal action against us.

Table of Contents

We currently carry clinical trial liability insurance in the amount of $5.0 million in the aggregate for claims related to our drug 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 may become involved in securities class-action litigation that could divert management’s attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biopharmaceutical companies. These broad market fluctuations as well as broad range of other factors, including the realization of any of the risks described in the “Risk Factor,” section of this Annual Report on Form 10-K, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management’s attention and resources, which could adversely affect our business. Any adverse determination in any such litigation, or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

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 this Annual Report on Form 10-K and the following:

- 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, including our Phase 3 IMPRESS clinical trial of algenpantucel-L, 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;

Table of Contents

- 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 and Merck;
- 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. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

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, 2015 our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 52.7% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after December 31, 2015. 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.

Table of Contents

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, our ability to pay cash dividends is currently prohibited by the terms of one of our debt financing arrangements, and 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;
- 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.

Table of Contents

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, 2014, 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.

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.

Table of Contents

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, research and development, and manufacturing	58,940	2020
Austin, Texas	Commercial and administrative offices	9,898	2016
Ankeny, Iowa	Packaging and distribution	47,250	2017
Devens, Massachusetts	Administrative offices	1,310	2015

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

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

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, LLC under the symbol "NLNK." The following table sets forth the range of high and low sales prices for our common stock on The NASDAQ Stock Market, LLC for the periods indicated since November 11, 2011.

	High	Low
Fiscal 2015		
First Quarter	$57.63	$31.70
Second Quarter	58.73	36.02
Third Quarter	56.16	34.11
Fourth Quarter	46.34	31.56
Fiscal 2014		
First Quarter	$53.48	$20.99
Second Quarter	29.54	18.28
Third Quarter	29.48	20.01
Fourth Quarter	42.00	17.32

As of February 23, 2016, we had 94 stockholders of record of our common stock.

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.

Table of Contents

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
NewLink Genetics Corporation	$100	$99	$177	$311	$561	$514
NASDAQ Composite	$100	$97	$113	$156	$177	$187
NASDAQ Biotechnology	$100	$110	$145	$240	$322	$358

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

* 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.

Table of Contents

Recent Sales of Unregistered Securities

None

Repurchases of Equity Securities

During the first quarter of 2015 the Company repurchased 6,248 shares of its common stock at an average price of $43.59 per share. During the second quarter of 2015 the Company repurchased 1,701 shares of its common stock at an average price of $42.06 per share. During the fourth quarter of 2015 the Company repurchased 4,199 shares of its common stock at a price of $35.32 per share and 2,035 shares of its common stock at a price of $34.93 per share.

Use of Proceeds

Not applicable.

Table of Contents

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, 2015, 2014, and 2013 and the balance sheet data as of December 31, 2015 and 2014 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, 2011 and 2012 and the balance sheet data as of December 31, 2011, 2012 and 2013 from our audited consolidated financial statements not included in this annual report.

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

	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands, except per share data)				
Statement of operations data:					
Grant revenue	$32,358	$6,642	$1,093	$1,687	$1,872
Licensing and collaboration revenue	36,143	165,950	—	—	—
Total operating revenue	68,501	172,592	1,093	1,687	1,872
Operating expenses:					
Research and development	71,414	35,691	22,713	17,838	14,255
General and administrative	30,689	19,328	9,521	7,108	5,679
Total operating expenses	102,103	55,019	32,234	24,946	19,934
(Loss) income from operations	(33,602)	117,573	(31,141)	(23,259)	(18,062)
Other income and expense:					
Miscellaneous (expense) income	(14)	—	112	(38)	5
Interest income	78	86	12	14	11
Interest expense	(105)	(26)	(33)	(38)	(42)
Other (expense) income, net	(41)	60	91	(62)	(26)
Net (loss) income before taxes	(33,643)	117,633	(31,050)	(23,321)	(18,088)
Income tax expense	(6,738)	(21,616)	(130)	—	—
Net (loss) income	(40,381)	96,017	(31,180)	(23,321)	(18,088)
Less net loss attributable to noncontrolling interest	—	—	—	—	1
Net (loss) income attributable to NewLink stockholders	$(40,381)	$96,017	$(31,180)	$(23,321)	$(18,087)
Basic (loss) earnings per share	$(1.41)	$3.45	$(1.23)	$(1.12)	$(2.98)
Diluted (loss) earnings per share	$(1.41)	$3.09	$(1.23)	$(1.12)	$(2.98)
Basic average shares outstanding	28,587	27,839	25,275	20,779	6,065
Diluted average shares outstanding	28,587	31,025	25,275	20,779	6,065

	As of December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Balance sheet data:					
Cash, cash equivalents, and certificates of deposit	$197,800	$202,797	$61,540	$21,744	$41,980
Working capital	193,302	198,601	60,094	20,470	32,124
Total assets	218,542	231,221	70,557	29,429	48,379
Royalty obligations, notes payable and obligations under capital leases	6,381	7,133	7,222	7,382	7,156
Accumulated deficit	(80,353)	(39,960)	(135,977)	(104,797)	(81,476)

Total stockholders' equity	195,744	196,936	58,327	17,927	36,773

(1) The Statement of Operations data for the year ending December 31, 2014 and Balance Sheet Data as of December 31, 2014 have been revised to reflect the immaterial error correction relating to income tax expense. See further discussion of this error in Note 2 to the Consolidated Financial Statements.

Table of Contents

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 biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. Our portfolio includes biologic and small-molecule immuno-oncology product candidates intended to treat a wide range of oncology indications. Our biologic product candidates are based on our proprietary HyperAcute® Cellular Immunotherapy technology, which is designed to stimulate the human immune system. Algenpantucel-L is our most clinically advanced product candidate from this platform with two Phase 3 clinical trials ongoing for patients with pancreatic cancer, one of which is expected to read out data during 2016. Our additional HyperAcute Cellular Immunotherapy product candidates in clinical development include tergenpumatucel-L and dorgenmeltucel-L for patients with advanced lung cancer and melanoma, respectively. Additional product candidates are also under development for patients with other types of cancer. Additionally, we have two small-molecule product candidates currently in clinical development, GDC-0919 and indoximod, which target key immune checkpoints. These product candidates are IDO pathway inhibitors and focus on breaking the immune system's tolerance to cancer. We believe that our immuno-oncology technologies have the potential to lead to multiple product candidates, targeting a wide range of oncology indications that could be used either alone or in combination with other therapies.

Our HyperAcute Cellular Immunotherapy platform consists of novel biologic product candidates designed to stimulate the patient's immune system to recognize and attack cancer cells. To date, our HyperAcute Cellular Immunotherapy platform product candidates have been administered to more than 700 patients with cancer, either as a monotherapy or in combination with other treatments and have been generally well tolerated with limited grade 3/4 adverse events. HyperAcute Cellular Immunotherapy product candidates are composed of human cancer cell lines that are tumor specific, but not patient specific. These cells have been modified to express alpha-Gal, a carbohydrate for which humans have preexisting immunity. These alpha-Gal-modified cancer cells are designed to stimulate an immune response against cancer cells. The objective of HyperAcute Cellular Immunotherapy is to elicit an antitumor response by "educating" the immune system to attack a patient's own cancer cells. HyperAcute Cellular Immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of our HyperAcute Cellular Immunotherapy product candidates have the potential to result in the stimulation of a robust immune response in patients with cancer.

Our most advanced program, algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, is being studied in two randomized Phase 3 clinical trials. Our first Phase 3 clinical trial, IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) completed enrollment of 722 patients with surgically resected pancreatic cancer. The primary endpoint for our IMPRESS trial is overall survival. We expect to report primary IMPRESS results during 2016. Our second Phase 3 clinical trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), has completed enrollment with over 300 patients. The primary endpoint for our PILLAR trial is overall survival. We initiated these trials based on encouraging Phase 2 data

that suggest potential to improve both disease-free and overall survival. Algenpantucel-L has received Fast Track Designation from the FDA for the adjuvant treatment of Stage I/II resected pancreatic adenocarcinoma in combination with adjuvant gemcitabine chemotherapy with or without adjuvant 5-FU-based chemoradiotherapy and Orphan Drug designation from the FDA for the treatment of pancreatic cancer, as well as Orphan Medicinal Product designation from the European Commission for the treatment of pancreatic cancer.

In addition to our HyperAcute Cellular Immunotherapy platform, we have an active drug discovery and clinical development program focused on the IDO (indoleamine-2, 3-dioxygenase) and TDO (tryptophan-2, 3-dioxygenase) pathway. Our

Table of Contents

small-molecule IDO pathway inhibitor drug candidates currently in clinical development include GDC-0919 (in partnership with Genentech, Inc. a member of the Roche Group or Genentech) and indoximod and are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1 and PD-L1 that represent potential breakthrough approaches to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell activation, which enables local tumor immune escape. Recent clinical trials conducted by third parties have demonstrated that the IDO pathway is active 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, whereby this pathway promotes 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. We have a number of active programs directed at synthesizing inhibitors that are potential anti-cancer compounds and that could function individually or in combination with IDO inhibition.

Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that we believe have the potential to be breakthrough approaches for patients with a variety of different cancer types. This type of molecule has the potential to be combined with different standard of care therapeutic approaches such as chemotherapy and radiotherapy or with novel cancer therapeutic approaches such as other immune checkpoint inhibitors, CAR T-cells or anti-tumor vaccination. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of GDC-0919, one of our IDO pathway inhibitors, and a research collaboration for the discovery of next-generation IDO and TDO pathway inhibitors, or the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150.0 million in November 2014. We may be eligible to receive in excess of $1.0 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech. Genentech will fund future research, development, manufacturing and commercialization costs. Genentech also provides us with funding for support of the research collaboration. We will continue to pursue development activities associated with GDC-0919 in combination with our novel HyperAcute Cellular Immunotherapy platform. We retain the option for co-promotion rights for GDC-0919 and potential next-generation IDO/TDO compounds in the United States.

GDC-0919 is currently in Phase 1 development led by our collaborators at Genentech. Two Phase 1 clinical trials are currently underway with GDC-0919. GDC-0919 is being evaluated in a Phase 1b combination clinical trial of GDC-0919 and atezolizumab (MPDL3280A) in patients with locally advanced or metastatic solid tumors. Enrollment began in July 2015 and a total enrollment of up to 224 patients is planned. A second Phase 1 clinical trial of GDC-0919 is ongoing evaluating dosing of GDC-0919 in patients with recurrent advanced solid tumors.

Indoximod, our proprietary IDO pathway inhibitor, is in multiple Phase 2 clinical trials evaluating potential clinical activity in multiple solid tumor indications. These trials feature indoximod in combination with both standard of care immunotherapy treatments for cancer as well as standard of care chemotherapy treatments for cancer. Indications being evaluated in indoximod clinical trials include metastatic breast cancer, refractory malignant brain tumors, advanced melanoma, metastatic pancreatic cancer, and prostate cancer.

In addition to our immuno-oncology programs, we have a team focused on developing vaccines against infectious diseases. Our infectious disease program researches and develops vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism.

Our primary program is a replication-competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Ebola and Marburg viruses. The rVSV-ZEBOV(Ebola) vaccine product candidate was originally developed by the Public Health Agency of Canada and is designed to utilize the rVSV vector to induce immunity against Ebola and Marburg viruses when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck, Sharp and Dohme Corp., or Merck, to develop and potentially commercialize our

rVSV-ZEBOV vaccine product candidate and certain other aspects of our vaccine technology. 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. In addition to milestone payments from Merck, the Company was awarded contracts for development of the rVSV-ZEBOV rom the BioMedical Research & Development Agency, or BARDA, and the Defense Threat Reduction Agency, or DTRA, totaling $67.0 million during 2014 and 2015. In July 2015, we announced that the international partnership studying the rVSV-ZEBOV vaccine candidate in Guinea released interim data suggesting that it is effective in the prevention of Ebola disease in a large Phase 3 clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days

Table of Contents

of administration to a person without the infection. The rVSV-ZEBOV product candidate will continue to be studied in clinical trials.

In February 2016, we announced our initiative to develop a vaccine against the Zika virus. We believe that the experience gained in the development of our Ebola vaccine candidate will give us an advantage in this program.

We had a net loss of $40.4 million for the year ended December 31, 2015. We expect our losses to increase 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 $68.5 million for the year ended December 31, 2015. We had grant revenues of $32.4 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 $36.1 million which consisted of revenues recognized under the license and collaboration agreements with Merck and Genentech that we entered into during 2014, and a milestone payment of $20.0 million from Merck in February 2015.

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.

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 increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidates, and to further advance our earlier-stage research and development projects. For the years ended December 31, 2015, 2014 and 2013 we incurred $71.4 million, $35.7 million, and $22.7 million, respectively, in research and development expenses. The following tables summarize our research and development expenses for the periods indicated:

Table of Contents

Research and Development Expenses by Product
(In thousands)

	Years Ended December 31,		
	2015	2014	2013
HyperAcute cellular immunotherapy technology	$30,326	$21,681	$16,241
IDO pathway inhibitor technology	13,210	6,962	4,772
Other research and development	27,878	7,048	1,700
Total research and development expenses	$71,414	$35,691	$22,713

Research and Development Expenses by Category
(In thousands)

	Years Ended December 31,		
	2015	2014	2013
Compensation	$21,558	$13,951	$9,273
Equipment, supplies and occupancy	9,827	5,859	5,846
Outside clinical and other	40,029	15,881	7,594
Total research and development expenses	$71,414	$35,691	$22,713

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.

We anticipate that our general and administrative expenses will continue to increase over the next several years for, among others, the following reasons:

- we expect our general and administrative expenses to increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, auditing and tax services and investor relations costs; and director compensation;
- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect to expand as we continue to advance the clinical development of our product candidates; and
- we expect to incur increased expenses related to the planned sales and marketing of our product candidates, which may include recruiting a specialty sales force, in anticipation of commercial launch before we receive regulatory approval, if any, of a product candidate.

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.

Table of Contents

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.

Tax Loss and Credit Carryforwards

The valuation allowance for deferred tax assets as of December 31, 2015 and 2014 was $20.7 million and $14.6 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2015 and 2014 was an increase of $6.1 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. Valuation allowances have been established for the entire amount of the net deferred tax assets as of December 31, 2015 and 2014, due to the uncertainty of future recoverability.

As of December 31, 2015 and December 31, 2014, we had federal net operating loss carryforwards of $1.4 million and $2.3 million and federal research credit carryforwards of $10.9 million and $6.5 million, respectively, which expire at various dates from 2026 through 2031. We utilized $905,000 in federal net operating loss and federal research credit carryforwards in 2015. 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, 2014, we experienced Section 382 ownership changes in September 2001 and March 2003 and our subsidiary 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 subsidiary.

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.

Income tax expense was $6.7 million, $21.6 million, and $130,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Income tax expense 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 changes in the valuation allowance for deferred taxes.

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

Table of Contents

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. 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 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. Generally, we have issued employee awards that vest over time. For these awards, we record compensation cost on a straight-line basis over the vesting period. We issue awards, which typically vest 20% to 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 months, 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.

We have 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.

We recorded noncash share-based compensation expense for employee and nonemployee stock options and restricted stock awards of $15.9 million, $8.6 million and $4.4 million during 2015, 2014 and 2013, respectively. As of December 31, 2015, the total compensation cost related to unvested option awards and restricted stock awards not yet recognized was $35.8 million and the weighted average period over which it is expected to be recognized was 3 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,		
	2015	2014	2013
Exercise price	$32.49-$56.87	$20.26-$46.76	$11.79-$22.61
Risk-free interest rate	1.51%-2.00%	1.73%-2.24%	.89%-2.14%
Expected dividend yield	—	—	—
Expected volatility	62.5%-67.3%	57.4%-68.3%	61.4%-67.3%
Expected term (in years)	5.9-7.0	6.0-7.0	4.8-7.0

Exercise Price. Subsequent to our IPO, options have been granted with an exercise price of the fair value of our common stock on the date of grant based on the current market price.

Table of Contents

Expected Volatility. We estimate future expected volatility for each stock option valuation utilizing volatility rates of similar publicly traded companies considered to be in the same peer group. Prior to 2015, we used a combination of our own data and peer group data to compute our volatility. Beginning in 2015, we began to 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 have a large number of options outstanding. We use historical exercise and option expiration data to estimate the expected term assumption for the Black-Scholes grant-date valuation. We believe this historical data is currently the best estimate of the expected term of awards.

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 was determined by the Board of Directors in good faith until November 16, 2011, when our common stock initiated trading on the NASDAQ Global Market. Following that date, the fair value of the common stock has been the quoted market price as listed on the public exchange. Based on the per share closing price of our common stock on the NASDAQ Global Market of $36.39 per share on December 31, 2015 , the intrinsic value of stock options outstanding at December 31, 2015, was $126.2 million, of which $115.0 million and $11.2 million related to stock options that were vested and unvested, respectively, at that date.

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

Table of Contents

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 5 – 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 expense was 20.0% of loss before income taxes in 2015. A valuation allowance of $20.7 million as of December 31, 2015 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.

Immaterial Error Correction

During the third quarter of 2015, we identified an immaterial error in our 2014 income tax provision expense. Included in the consolidated balance sheet as of December 31, 2014 and the consolidated statement of operations and statement of cash flows for the year ending December 31, 2014 is an immaterial error correction related to the provision for income taxes. The income tax receivable as of December 31, 2014 has been decreased by $6.8 million and the income tax expense has been increased by $6.8 million. Due to this error, our net income and stockholders' equity were both correspondingly overstated for the year ending December 31, 2014 by $6.8 million. The impact to basic and diluted earnings per share was a decrease of $0.25 and $0.22, respectively, for the year ending December 31, 2014. There was no impact to the net cash provided by operating activities in the consolidated statement of cash flows for the year ending December 31, 2014. The immaterial error correction also resulted in an increase in our deferred tax asset and a corresponding increase to the valuation allowance as there is a full valuation allowance against net deferred tax assets due to the uncertainty of future recoverability.

Management concluded that correcting the error would be immaterial to the fourth quarter results for 2014 and had no effect on the trend of financial results. Management also evaluated the impact of this error on our assessment of the effectiveness of internal control over financial reporting and concluded that our evaluation of controls as of December 31, 2014 remains effective.

Results of Operations

Comparison of the Years Ended December 31, 2015 and 2014

Revenues. Revenues for the year ended December 31, 2015 were $68.5 million, as compared to $172.6 million in 2014, a decrease of $104.1 million. Licensing and collaboration revenues decreased by $129.8 million in 2015. In 2014, we received an upfront payment from Genentech for $150.0 million and an upfront payment from Merck for $30.0 million. Our licensing and collaboration revenues decreased in 2015 as we did not receive similar upfront

payments. Licensing and collaboration revenues in 2015 are comprised primarily of a Merck milestone payment received in February 2015 for $20.0 million and revenues recognized

Table of Contents

in 2015 that were previously deferred as of December 31, 2014. Grant revenues increased by $25.7 million primarily due to revenues received under our BARDA government contract for our work with the Ebola vaccine.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2015 were $71.4 million, increasing from $35.7 million for the same period in 2014. The $35.7 million increase was due to an $11.2 million increase in outside clinical and other expenses, a $11.4 million increase relating to contract manufacturing costs for our clinical trials and the Ebola vaccine product candidate, a $4.0 million increase in supplies and equipment, and a $7.6 million increase in personnel-related expenses due to increased staffing levels and compensation increases. The remaining $1.5 million increase is due to increases in supplies and equipment-related expenses incurred for our clinical trial activities.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2015 were $30.7 million, increasing from $19.3 million for the same period in 2014. The $11.4 million increase was due to a $3.4 million increase in other costs including legal and consulting fees, travel, licensing expense, a $500,000 increase in supplies, equipment and rent expense, and accompanied by a $7.5 million increase in personnel-related expenses due to increased staffing levels and compensation increases.

Income tax expense. Income tax expense for the year ended December 31, 2015 was $6.7 million decreasing from $21.6 million for the same period in 2014. The decrease was primarily due to the Company having net loss before taxes of $33.6 million in 2015 and net income before taxes of $117.6 million in 2014. We incurred income tax expense for the year ended December 31, 2015 due to the net income generated by our domestic entities and the net loss generated by our foreign subsidiary, NewLink International, which is not deductible on the Company's consolidated federal income tax return.

Net (Loss) Income. Net loss for the year ended December 31, 2015 was $40.4 million, decreasing from net income of $96.0 million for the same period in 2014 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 2015 were 28.6 million, resulting in diluted loss per share of $1.41, as compared to 31.0 million average shares outstanding and $3.09 diluted earnings per share for 2014.

Comparison of the Years Ended December 31, 2014 and 2013

Revenues. Revenues for the twelve months ended December 31, 2014 were $172.6 million, increasing from $1.1 million for the same period in 2013. The increase in revenue of $171.5 million was due to an increase of $166.0 million in licensing revenue, and a $5.5 million increase in grant revenue under various government contracts.

Research and Development Expenses. Research and development expenses for the twelve months ended December 31, 2014 were $35.7 million, increasing from $22.7 million for the same period in 2013. The $13.0 million increase was due to an $8.3 million increase in outside clinical and other expenses including contract development costs for GDC-0919, contract manufacturing costs for indoximod and the Ebola vaccine product candidate, consulting fees, and direct development expenses for our clinical trial activities, accompanied by a $4.7 million increase in personnel-related expenses due to increased staffing levels and compensation increases.

General and Administrative Expenses. General and administrative expenses for the twelve months ended December 31, 2014 were $19.3 million, increasing from $9.5 million for the same period in 2013. The $9.8 million increase was due to a $5.8 million increase in other costs including legal and consulting fees, travel, and licensing expense, accompanied by a $4.0 million increase in personnel-related expenses due to increased staffing levels and compensation increases, which includes $1.7 million in share-based compensation resulting from the vesting in full of one employee's options upon the employee's termination during the year ended December 31, 2014.

Income tax expense. Income tax expense for the year ended December 31, 2014 was $21.6 million, increasing from $130,000 for the same period in 2013. The increase was primarily due to an increase of $166.0 million in licensing revenue offset by increases in operating expense in 2014.

Net Income (Loss). For the year ended December 31, 2014 we had net income of $96.0 million, increasing from a net loss of $31.2 million for the same period in 2013 primarily due to the increase in licensing revenue, offset by an increase in operating expenses of $22.8 million and income tax expense of $21.6 million. The diluted average shares outstanding for 2014 were 31.0 million, resulting in diluted earnings per share of $3.09, as compared to 25.3 million average shares outstanding and a $1.23 diluted loss per share for 2013. The increase in the number of diluted average

shares outstanding was primarily attributable to shares issued in our ATM Offering during the first quarter of 2014.

Table of Contents

Liquidity and Capital Resources

Before our IPO, we funded our operations principally through the private placement of equity securities, debt financing and interest income. As of December 31, 2015, we had 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, we have funded our operations principally through public offerings of common stock. On November 16, 2011, we received proceeds, net of offering costs, of $37.6 million from the issuance of 6,200,000 shares of common stock in our IPO. On February 4, 2013, we received proceeds, net of offering costs, of $49.0 million from the issuance of 4,600,000 shares of common stock in our follow-on offering. Under our ATM Offering, we sold 2,163,240 shares of common stock, raising a total of $58.7 million in net proceeds.

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,		
	2015	2014	2013
Net cash (used in) provided by operating activities	$(24,087)	$109,068	$(25,818)
Net cash provided by (used in) investing activities	6,218	(13,844)	(141)
Net cash provided by financing activities	23,085	33,889	67,000
Net increase in cash and cash equivalents	$5,216	$129,113	$41,041

For the year ended December 31, 2015, we used cash of $24.1 million in our operating activities. For the year ended December 31, 2015, the sources and uses of cash in this period primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities. The net loss for this period was primarily due to a decrease in licensing and collaboration revenues income and an increase in operating expenses, offset by an increase in grant revenues. For the year ended December 31, 2014, 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 year ended December 31, 2013, the sources and uses of cash in this period primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities.

For the years ended December 31, 2015, 2014 and 2013, our investing activities generated cash of $6.2 million and used cash of $13.8 million, and $141,000, respectively. The cash generated 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. The cash used by investing activities in the year ended December 31, 2014 was due to $1.7 million in purchases of property and equipment along with the combined net purchase of certificates of deposit for $12.1 million. The cash used by investing activities in the year ended December 31, 2013 was due to $1.4 million in purchases of property and equipment offset by the combined net sale of investments for $1.2 million.

For the years ended December 31, 2015, 2014 and 2013, our financing activities provided $23.1 million, $33.9 million, and $67.0 million, respectively. 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. The cash provided by financing activities in the year ended December 31, 2014 was primarily due to the sale and issuance of common stock for net proceeds of $29.9 million accompanied by $4.3 million from excess tax benefit from employee stock plan awards, offset by the repurchase of common stock of $222,000 and net payments on long-term obligations of $89,000. The cash provided by financing activities in the year ended December 31, 2013 was primarily due to the sale and issuance of common stock for net proceeds of $67.2 million and offset by payments on long-term obligations of $215,000.

Table of Contents

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 $246,000 and $348,000 at December 31, 2015 and December 31, 2014, 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 $284,000 and $339,000 at December 31, 2015 and December 31, 2014, 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 are 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. 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. If, as of March 10, 2016, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2016, we have failed to create or retain at least 150 full-time jobs in Ames, Iowa, we will be required to repay approximately $3,100 per job not created as of or retained following as of such date. As of

December 31, 2015, $397,000 of the total $400,000 forgivable loan was advanced to us. As of December 31, 2015 we had created 150 full-time jobs in Ames, Iowa. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

Table of Contents

Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses related to the research and development of our HyperAcute Cellular Immunotherapy and IDO pathway inhibitor product candidates, build commercial capabilities and expand our corporate infrastructure.

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, including out costs under the WuXi agreement, whether or not a sufficient quantity of cell material is manufactured under that agreement;
- 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, 2015:

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)	$6,969	$532	$321	$6,116	$—
Operating lease obligations	3,516	1,479	1,523	514	—
Capital lease obligations	13	13	—	—	—
Total contractual cash obligations	$10,498	$2,024	$1,844	$6,630	$—

(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 2005 and March 2012 Iowa Department of Economic Development Loan” above.

Table of Contents

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
Lankenau Institute for Medical Research under the IDO-1 Agreement (1)	$1.36 million per licensed product
Lankenau Institute for Medical Research under the LIMR IDO-2 Agreement (1)	$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement
Lankenau Institute for Medical Research under the 2009 LIMR Agreement (1)	$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement
Augusta University Research Institute	$2.8 million per licensed product
The Ohio State University	$2.75 million for first licensed product
Public Health Agency of Canada	C$205,000 per licensed product

(1) As defined below under the heading “Financial Obligations Related to Licensing and Development—In-Licensing Agreements”.

We incurred expense of approximately $2.0 million, $3.1 million, and $88,000, under all of the in-licensing agreements for the years ended December 31, 2015, 2014, and 2013, respectively, which are listed below under the heading “Financial Obligations Related to Licensing and Development—In-licensing Agreements."

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:

Central Iowa Health Systems. We are a party to a license agreement, or the CIHS Agreement, dated August 2, 2001, as amended December 30, 2013, with the Central Iowa Health System, or CIHS. The CIHS Agreement grants to us an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information or know-how relating to our HyperAcute Cellular Immunotherapy technology. In partial consideration of the license under the CIHS Agreement, we entered into a stock purchase agreement with CIHS, under which we issued to CIHS shares of our common stock and granted CIHS certain rights related to ownership of such shares.

In addition, we must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If we or our sublicensees commercialize a licensed product, we also have the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments we must make to third parties. If we grant a sublicense under the licenses granted by CIHS, we must pay to CIHS, in addition to the royalties described above, a percentage of certain consideration paid by the sublicensee to us. Under the CIHS Agreement, we must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets. We have no obligation to pay fees to CIHS as a result of payments between us and our affiliates.

Lankenau Institute for Medical Research—IDO-1. We are a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of IDO and

Table of Contents

related LIMR technology, to make, have made, use, and sell products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics.

In consideration of the license grant, we are obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if we grant a sublicense under the IDO-1 Agreement, we must to pay to LIMR a percentage of the consideration received by us from the sublicensee. Under the IDO-1 Agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines.

LIMR—IDO-2. We are a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target IDO and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses.

In consideration of the license grant, we have paid to LIMR an upfront license fee and annual license maintenance fees, and are obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately $1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of “net sales” of the licensed product, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us. Under the LIMR IDO-2 Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license.

2009 LIMR Exclusive License Agreement. We are a party to a license agreement, or the 2009 LIMR Agreement, dated April 23, 2009 with LIMR. The 2009 LIMR Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses.

In consideration of such license grant, we are obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately $610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of “net sales” of the licensed product, subject to reduction for our royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Augusta University Research Institute. We are a party to a License Agreement dated September 13, 2005, or the AURI 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 Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013 and July 10, 2014. The AURI 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 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, 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. Under the agreement, we are obligated to make certain investments toward the further development of licensed products within specified time periods.

The Ohio State University License Agreement. We are a party to a license agreement dated June 28, 2013 with The Ohio State University, or OSU. This agreement grants us exclusive rights in the United States and its territories, in all

fields of use, to patents related to pharmaceutical compositions and vaccines comprising antigens associated with L-Rhamnose and Forssman epitopes including patent application US 13/463,420, which is co-owned by us and OSU. In consideration of the license grant, we were obligated to pay OSU specified license fees and are obligated to pay to OSU specified annual license maintenance fees, patent prosecution costs and maintenance costs, potential milestone payments in an aggregate amount up to approximately $2.75 million for the first licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized, with minimum royalties for the first three years in

Table of Contents

which a licensed product generates revenue. In addition, if we grant a sublicense under this agreement, we must also pay to OSU a percentage of certain consideration received by us from the sublicensee. Under this agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products and to use commercially reasonable effort to achieve certain milestones by agreed-upon deadlines.

Public Health Agency of Canada Agreement. BPS is a party to the PHAC License, dated May 4, 2010. The PHAC License grants BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license for commercialization of specified PHAC patent rights relating to technology based on rVSV.

In consideration of the license grant, BPS must pay to Canada a specified patent and signing fees, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$205,000 per licensed product, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, which royalty rate varies depending on the type of licensed product. In addition, when BPS grants a sublicense under the licenses granted by Canada, BPS is required to pay to Canada a percentage of certain consideration BPS receives from the sublicensee, including a percentage of certain consideration received pursuant to such sublicense. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products.

Bresagen License Agreement. We are a party to a license agreement, or the Bresagen Agreement, dated April 1, 2014 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants us a non-exclusive, non-sublicensable license to a mouse strain controlled by Bresagen for use in testing microbial and cancer vaccines in the U.S. In consideration of such license grant, we are obligated to pay Bresagen an annual license fee.

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, 2015, 2014 and 2013, we incurred expenses related to the filing, maintenance, and initiation of our patent portfolio of $489,000, $794,000 and $651,000, respectively, for a decrease of 38% for the 2015 period as compared to the same period in 2014, and an increase of 22% for the 2014 period as compared to the same period in 2013. Decreased costs in 2015 compared to 2014 were due to decreased activity on pending cases.

BioProtection Systems Corporation

We formed BioProtection Systems Corporation, or BPS, as a subsidiary in 2005 to research, develop and commercialize vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid response prophylactic and therapeutic treatment for pathogens that might be targeted to the human population through acts of bioterrorism. At December 31, 2010, we owned shares of BPS Series A common stock representing approximately 64% of BPS's common stock on an as-converted basis, assuming conversion into BPS Series B common stock of all outstanding BPS Series A and BPS Series B preferred stock. On December 1, 2010, we entered into an agreement to acquire all of the noncontrolling interest in BPS, as described in more detail below.

Acquisition of BioProtection Systems Corporation

On January 7, 2011, we acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of ours with BPS, with BPS as the surviving corporation. In connection with this transaction, we issued an aggregate of 276,304 shares of our Series E preferred stock to the former holders of BPS Series B common stock, BPS Series A preferred stock and BPS Series B preferred stock (other than us). As a result of this transaction, BPS became a wholly owned subsidiary of us and our note was converted into Series B preferred stock of BPS. All options to purchase shares of BPS stock became options to purchase a total of 50,513 shares of our common stock.

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 November 2015, the Financial Accounting Standards Board, or FASB, issued FASB Accounting Standards Update (ASU) No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This ASU is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earli er application is permitted as of the beginning of an interim or annual reporting period. The Company early adopted this ASU on a prospective basis in the fourth quarter of fiscal 2015. Prior periods were not retrospectively adjusted. As of December 31, 2015 and 2014, all deferred taxes were fully offset by a valuation allowance, therefore adoption of this guidance did not have an impact on the presentation of our consolidated financial statements.

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; however, early adoption at January 1, 2017, is permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method, nor has it determined the effect of the standard on its ongoing financial reporting.

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, 2015 and December 31, 2014, we had cash and cash equivalents and certificates of deposit of $197.8 million and $202.8 million, respectively, consisting of money market funds, and bank certificates of deposit. 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, 2015. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2015, 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

86

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, 2015 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, 2015, 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.

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, 2015, 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 2015 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.

Table of Contents

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 2016 Annual Meeting of Stockholders, or the 2016 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 2016 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 our 2016 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, 2015:

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	5,875,452	$15.88	1,112,531	(1)(2)
Equity compensation plans not approved by security holders	—	$0.00	—	
Total	5,875,452	$15.88	1,112,531	

(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, 2015, 774,499 shares remained available under the 2009 Equity Incentive Plan, 106,640 shares remained available under the 2010 Non-Employee Directors' Stock Award Plan and 231,392 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 our 2016 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 our 2016 Proxy Statement.

Table of Contents

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
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 Company and certain holders of the Company'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	10-Q	8/5/2014	10.7	

amended

89

Table of Contents

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	8/5/2014	10.3
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 July 7, 2005 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.30
10.7.1	*	First Amendment to License Agreement dated May 22, 2006 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.31
10.7.2	*	Second Amendment to License Agreement September 11, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.32
10.8	*	Exclusive License Agreement executed December 21, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.33
10.9	*	Exclusive License Agreement effective April 23, 2009 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.34
10.10	*	License Agreement dated August 2, 2001 by and between the Registrant and Central Iowa Health System	S-1/A	11/8/2011	10.37
10.11	*	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
10.11.1	*	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
10.11.2	*	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
10.11.3	*	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
10.11.4	*	Amendment to License Agreement dated March 28, 2006 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3
10.11.5	*	Amendment to License Agreement dated July 10, 2014 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4
10.12	*	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
10.13	*	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and	S-1/A	11/8/2011	10.66

		BioProtection Systems Corporation			
10.14	*	Sole License Agreement executed May 4, 2010 by and between Public Health Agency of Canada in Right of Canada and BioProtection Systems Corporation	S-1/A	11/8/2011	10.67
10.15		Amendment dated July 31, 2014 to the Sole License Agreement by and between BioProtection Systems Corporation and Public Health Agency of Canada in Right of Canada as Represented by the Minister of Health dated May 4, 2010	10-Q	11/10/2014	10.5
10.16	*	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
10.16.1		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
10.16.2		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
10.16.3		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
10.16.4		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

Table of Contents

10.16.5	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
10.16.6	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
10.16.7	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
10.16.8	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
10.17	Lease dated September 1, 2000 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.46
10.18	Sublease Agreement effective February 1, 2001 by and between the Registrant and Iowa State Innovation System	S-1	12/21/2010	10.47
10.19	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
10.20	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
10.21	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
10.22	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
10.23	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
10.24	Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53
10.25	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
10.26	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
10.27	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
10.28	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
10.29	Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54

10.30	Forgivable Loan Agreement dated March 10, 2010 by and between the Registrant and City of Ames, Iowa	S-1	12/21/2010	10.55
10.31	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
10.32	Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58
10.33	Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.59
10.34	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57
10.35	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.60
10.36	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77
10.37	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78
10.38	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
10.38.1	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

Table of Contents

10.39	*	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
10.39.1		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
10.40		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
10.40.1		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
10.41		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
10.42		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
10.43		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
10.44		NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2
10.45		NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3
10.46		Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4
10.47		Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2013	8-K	3/28/2012	10.1
10.48	*	Cooperative Research and Development Agreement between the Company and the National Cancer Institute, effective as of March 27, 2012	10-Q	5/10/2012	10.6
10.49		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
10.50		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
10.51		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
10.52		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
10.53		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation Dated March 1, 2010	10-Q	8/8/2013	10.2
10.54		Amendment of Contract No. HDTRA1-09-C-0014, by and between BioProtection Systems Corporation and the United	10-Q	11/12/2013	10.1

		States Department of Defense, dated as of September 18, 2013			
10.55		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
10.56		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
10.57	*	Amendment to License Agreement dated December 30, 2013, by and between Registrant and Central Iowa health System	10-K	3/12/2014	10.94
10.58	*	Development and Process Transfer Program Leading to Commercial Manufacturing for algenpantucel-L HyperAcute Pancreas by and between the Company and WuXi AppTec, Inc. dated June 19, 2014	10-Q	8/5/2014	10.2
10.59		Amendment dated September 30, 2014 to the Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec. Inc. dated June 19, 2014	10-Q	11/10/2014	10.2
10.60	*	License and Collaboration Agreement dated October 16, 2014 by and among the Company, NewLink Global, Genentech, Inc. and F. Hoffmann-LaRoche Ltd.	10-Q	11/10/2014	10.1

Table of Contents

10.61	*	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	
10.62		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	
10.62.1		Memorandum of Agreement dated July 9, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005				X
10.63		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	
10.63.1		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	
10.63.2		Memorandum of Agreement dated September 21, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010				X
10.64	†	2014 Bonus Awards	8-K	1/6/2015	10.1	
10.65	†	2015 Salaries, Bonus Targets and Equity Awards	8-K	1/6/2015	10.2	
10.66		First Amendment dated March 31, 2015 to the License and Collaboration Agreement by and between the Company, NewLink Global, Genentech, Inc. and F. Hoffmann-La Roche Ltd. dated as of October 16, 2014	10-Q	5/11/2014	10.1	
10.67	†	Separation and Release Agreement between the Company and W. Jay Ramsey, dated as of May 22, 2015	10-Q	8/6/2015	10.3	
10.68	*	Amended and Restated Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec, Inc. dated January 4, 2016				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

---

† 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.

Table of Contents

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.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)
Date: February 29, 2016

By: /s/ John B. Henneman, III
John B. Henneman, III
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: February 29, 2016

By: /s/ Carl W. Langren
Carl W. Langren
Vice President Finance
(Principal Accounting Officer)
Date: February 29, 2016

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.

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. Charles J. Link, Jr.	Chief Executive Officer, Chairman of Board of Directors and Director (Principal Executive Officer)	February 29, 2016
/s/ John B. Henneman, III John B. Henneman, III	Chief Financial Officer and Secretary (Principal Financial Officer)	February 29, 2016
/s/ Thomas A. Raffin Thomas A. Raffin	Director	February 29, 2016
/s/ Ernest J. Talarico, III Ernest J. Talarico, III	Director	February 29, 2016
/s/ Lota Zoth Lota Zoth	Director	February 29, 2016
/s/ Joseph Saluri Joseph Saluri	Director	February 29, 2016
/s/ Paul R. Edick Paul Edick	Director	February 29, 2016
/s/ Paolo Pucci	Director	February 29, 2016

Paolo Pucci		
/s/ Nicholas N. Vahanian Nicholas N. Vahanian	Director	February 29, 2016

Table of Contents

Report of Independent Registered Public Accounting Firm
The Board of Directors and Stockholders
NewLink Genetics Corporation:

We have audited the accompanying consolidated balance sheets of NewLink Genetics Corporation and subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations, equity, and cash flows for each of the years in the three-year period ended December 31, 2015. We also have audited the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. 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 included in Item 9A. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

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.

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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NewLink Genetics Corporation and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also in our opinion, NewLink Genetics Corporation and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ KPMG LLP
Des Moines, Iowa
February 29, 2016

F-1

Table of Contents

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

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 195,620	$ 190,404
Certificates of deposit	2,180	12,393
Prepaid expenses and other current assets	4,954	8,333
State research and development credit receivable	—	13
Income tax receivable	—	8,763
Other receivables	5,388	3,716
Total current assets	208,142	223,622
Leasehold improvements and equipment:		
Leasehold improvements	7,427	6,022
Computer equipment	2,582	1,399
Lab equipment	5,832	4,110
Contract manufacturing organization equipment	1,075	1,023
Total leasehold improvements and equipment	16,916	12,554
Less accumulated depreciation and amortization	(6,516)	(4,955)
Leasehold improvements and equipment, net	10,400	7,599
Total assets	$ 218,542	$ 231,221

See accompanying notes to consolidated financial statements.

Table of Contents

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

	December 31, 2015	December 31, 2014
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,661	$ 2,412
Accrued expenses	8,761	9,367
Income taxes payable	859	—
Current portion of unearned revenue	892	12,966
Current portion of deferred rent	96	84
Current portion of obligations under capital leases	13	35
Current portion of notes payable	558	157
Total current liabilities	14,840	25,021
Long term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	368	941
Unearned revenue	407	1,085
Deferred rent	1,153	1,238
Total long-term liabilities	7,928	9,264
Total liabilities	22,768	34,285
Stockholders' Equity		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at December 31, 2015 and 2014; issued and outstanding shares — 0 at December 31, 2015 and 2014	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at December 31, 2015 and 2014; issued 28,838,176 and 27,991,242 at December 31, 2015 and 2014 and outstanding 28,814,142 and 27,980,849 at December 31, 2015 and December 31, 2014	288	280
Additional paid-in capital	276,610	236,838
Treasury stock, at cost: 24,034 and 10,393 shares at December 31, 2015 and 2014	(771)	(222)
Accumulated deficit	(80,353)	(39,960)
Total stockholders' equity	195,774	196,936
Total liabilities and stockholders' equity	$ 218,542	$ 231,221

See accompanying notes to consolidated financial statements.

Table of Contents

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

	Year Ended December 31,		
	2015	2014	2013
Grant revenue	$32,358	$6,642	$1,093
Licensing and collaboration revenue	36,143	165,950	—
Total operating revenues	68,501	172,592	1,093
Operating expenses:			
Research and development	71,414	35,691	22,713
General and administrative	30,689	19,328	9,521
Total operating expenses	102,103	55,019	32,234
(Loss) income from operations	(33,602)	117,573	(31,141)
Other income and expense:			
Miscellaneous (expense) income	(14)	—	112
Interest income	78	86	12
Interest expense	(105)	(26)	(33)
Other (expense) income, net	(41)	60	91
Net (loss) income before taxes	(33,643)	117,633	(31,050)
Income tax expense	(6,738)	(21,616)	(130)
Net (loss) income	$(40,381)	$96,017	$(31,180)
Basic (loss) earnings per share	$(1.41)	$3.45	$(1.23)
Diluted (loss) earnings per share	$(1.41)	$3.09	$(1.23)
Basic average shares outstanding	28,586,585	27,838,873	25,275,179
Diluted average shares outstanding	28,586,585	31,025,099	25,275,179

See accompanying notes to consolidated financial statements.

Table of Contents

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, 2012	20,985,192	$210	$122,514	$—	$ (104,797)	$ 17,927
Share-based compensation	—	—	4,365	—	—	4,365
Exercise of stock options	107,541	1	441	—	—	442
Sale of shares under stock purchase plan	63,669	1	415	—	—	416
Issuance of 4,600,000 shares of common stock (net of offering costs of $3,524,405) (February 4, 2013)	4,600,000	46	48,870	—	—	48,916
Issuance of shares under at the market offering (net of offering costs of $402,542)	816,621	8	17,433	—	—	17,441
Net loss	—	—	—	—	(31,180)	(31,180)
Balance at December 31, 2013	26,573,023	266	194,038	—	(135,977)	58,327
Share-based compensation	—	—	8,613	—	—	8,613
Exercise of stock options and vesting of restricted stock awards	375,834	4	1,857	—	—	1,861
Sales of shares under stock purchase plan	25,168	—	466	—	—	466
Issuance of common stock under the ATM Offering (net of offering costs of $692, January and February 2014)	1,017,217	10	27,562	—	—	27,572
Shares withheld for statutory tax withholding (September 30, 2014)	(10,393)	—	—	(222)	—	(222)
Tax benefit from employee stock plan awards	—	—	4,302	—	—	4,302
Net income	—	—	—	—	96,017	96,017
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)	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

See accompanying notes to consolidated financial statements.

Table of Contents

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

	Year Ended December 31,		
	2015	2014	2013
Cash Flows From Operating Activities			
Net (loss) income	$(40,381)	$96,017	$(31,180)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Share-based compensation	15,940	8,613	4,365
Depreciation and amortization	1,592	1,097	891
Loss on sale of fixed assets	—	—	2
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	3,379	(7,561)	134
State research and development credit receivable	13	316	213
Other receivables	(1,672)	(2,388)	(1,132)
Accounts payable and accrued expenses	245	7,898	843
Income taxes (receivable) payable	9,622	(8,892)	130
Unearned revenue	(12,752)	14,051	—
Deferred rent	(73)	(83)	(84)
Net cash (used in) provided by operating activities	(24,087)	109,068	(25,818)
Cash Flows From Investing Activities			
Purchase of certificates of deposit	—	(17,377)	(249)
Maturity of certificates of deposit	10,213	5,233	1,494
Purchase of equipment	(3,995)	(1,700)	(1,386)
Net cash provided by (used in) investing activities	6,218	(13,844)	(141)
Cash Flows From Financing Activities			
Issuance of common stock, net of offering costs	13,534	27,572	66,357
Issuance of common stock under share-based compensation plans	4,206	2,327	858
Excess tax benefits from share-based compensation awards	6,100	4,302	—
Repurchase of common stock	(561)	(222)	—
Proceeds from notes payable	—	97	—
Principal payments on notes payable	(158)	(154)	(149)
Payments under capital lease obligations	(36)	(33)	(66)
Net cash provided by financing activities	23,085	33,889	67,000
Net increase in cash and cash equivalents	5,216	129,113	41,041
Cash and cash equivalents at beginning of year	190,404	61,291	20,250
Cash and cash equivalents at end of year	$195,620	$190,404	$61,291
Supplemental disclosure of cash flows information:			
Cash paid for interest	$105	$26	$34
Cash paid for taxes	4,814	26,443	—
Proceeds from income tax refunds	13,796	—	—
Noncash financing and investing activities:			
Purchased leasehold improvements and equipment in accounts payable and accrued expenses	398	409	—
Assets acquired under capital lease	$—	$—	$54

See accompanying notes to consolidated financial statements.

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

1. Description of Business Activities

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

In 2005, NewLink created a partially owned subsidiary, BioProtection Systems Corporation, or BPS. NewLink contributed certain licensing agreements and other intangible assets for BPS to create vaccines against potential biological terror threats. On January 7, 2011, NewLink acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of NewLink with BPS, with BPS as the surviving corporation resulting in NewLink owning all the outstanding capital stock of BPS.

In 2013, NewLink created a wholly owned subsidiary, NewLink International, or NI. NewLink plans to conduct all or a portion of its operations outside of the United States through NI. During 2014, NewLink created another wholly-owned subsidiary, NewLink Global, or NG, which was subsequently merged into NewLink during 2014.

NewLink and its subsidiaries, or 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, 2015 have been prepared assuming the Company will continue as a going concern. The Company successfully 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, raised an additional $58.7 million in net proceeds from the ATM Offering prior to March 31, 2015. 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 into 2017, although not through commercialization and launch of revenue producing products. 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

(a) 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.

(b) Principles of Consolidation

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

(c) Immaterial Error Correction

During the third quarter of 2015, we identified an immaterial error in the Company's 2014 income tax provision expense. Included in the consolidated balance sheet as of December 31, 2014 and the consolidated statement of operations and statement of cash flows for the year ending December 31, 2014 is an immaterial error correction related to the provision for income taxes. The income tax receivable as of December 31, 2014 has been decreased by $6.8 million and the income tax expense has been increased by $6.8 million. Due to this error, the Company’s net income and stockholders’ equity were both correspondingly overstated for the year ending December 31, 2014 by $6.8 million. The impact to basic and diluted earnings per share was a decrease of $0.25 and $0.22, respectively, for the year ending December 31, 2014. There was no impact to the net cash provided

by operating activities in the consolidated statement of cash flows for the year ending December 31, 2014. The immaterial error correction also resulted in an increase in the Company's deferred tax asset and a corresponding increase to the valuation allowance as there is a full valuation allowance against net deferred tax assets due to the uncertainty of future recoverability.

Management concluded that correcting the error would be immaterial to the fourth quarter results for 2014 and had no effect on the trend of financial results. Management also evaluated the impact of this error on our assessment of the effectiveness of internal control over financial reporting and concluded that our evaluation of controls as of December 31, 2014 remains effective.

(d) 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 $195.6 million and $190.4 million at December 31, 2015 and 2014, respectively, consist of checking accounts, money market accounts and treasury bills.

(e) Certificates of Deposit

Certificates of deposit have original maturities of greater than three months. Certificates of deposit are classified as held-to-maturity with due dates through 2016 and are presented at amortized cost, which approximates fair value.

(f) 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 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 $1.2 million and $1.3 million as of December 31, 2015 and 2014, respectively.

(g) 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.

(h) 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 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 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.

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.

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, 2015, 2014, and 2013, the Company has earned $32.4 million, $6.6 million, and $1.1 million in grant revenue, respectively. We had $4.1 million and $3.7 million of receivables from the government contracts recorded in other receivables and $3.6 million and $7.5 million of unbilled expenses relating to the government contracts recorded in prepaid expenses and other assets on the balance sheet for the years ended December 31, 2015 and 2014, respectively.

(i) 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.

(j) Research and Development

Research and development costs are expensed as incurred. Certain research and development expenses are refundable from the state of Iowa without regard to income. State research and development credits of $450,000 and $748,000 at December 31, 2015 and 2014, respectively, are reflected as a reduction in income taxes on the accompanying consolidated statements of operations.

State research and development credits of $329,000 at December 31, 2013, are reflected as a reduction of research and development expenses on the accompanying consolidated statements of operations.

(k) 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.

(l) 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. Income tax expense was 20.0% of loss before income taxes in 2015. A valuation allowance of $20.7 million as of December 31, 2015 offsets our net deferred tax assets.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. As of December 31, 2015 and 2014, the Company has not recognized any uncertain tax positions.

(m) Share-Based Compensation

The Company is 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. 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. Generally, the Company has issued employee awards that vest over time. For these awards, the Company records compensation cost on a straight-line basis over the vesting period. The Company issues awards, which typically vest 20% to 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 months, as determined by the Board of Directors at the time of grant. 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.

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’s stock options granted prior to the IPO were granted with an exercise price as determined by the NewLink Board of Directors in good faith with the assistance of a third-party appraisal report and an evaluation of milestones achieved. Subsequent to the IPO, 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 estimates future expected volatility for each stock option valuation utilizing volatility rates of similar publicly traded companies considered to be in the same peer group. Prior to 2015, the Company used a combination of its own data and peer group data to compute our volatility. Beginning in 2015, the Company began to use its historical stock price volatility. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

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.

(n) Segments

The Company operates in one segment. The Company conducts research and development activities based from facilities located in Ames, Iowa. NewLink and BPS have 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.

(o) Financial Instruments and Concentrations of Credit Risk

The fair values of cash and cash equivalents, certificates of deposit, 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 $941,000 and $1.1 million as of December 31, 2015 and 2014, respectively, and was determined using Level 2 inputs. 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, and certificates of deposit. 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.

(p) 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.

(q) Concentration of Revenue

Prior to 2014, the Company's revenue was primarily obtained from government research grants. Genentech and Merck accounted for 21.5% and 31.3%, respectively, of the $68.5 million of revenue for the year ended December 31, 2015. Genentech, a member of the Roche Group and Merck Sharpe and Dohme Corp., or Merck, accounted for 78.9% and 17.2%, respectively, of the $172.6 million of revenue earned for the year ended December 31, 2014, with the remainder obtained from government grants.

(r) Recent Accounting Pronouncements

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

In November 2015, the Financial Accounting Standards Board, or FASB, issued FASB Accounting Standards Update (ASU) No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This ASU is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual reporting period. The Company early adopted this ASU on a prospective basis in the fourth quarter of fiscal 2015. Prior periods were not retrospectively adjusted. As of December 31, 2015 and 2014, all deferred taxes were fully offset by a valuation allowance, therefore adoption of this guidance did not have an impact on the presentation of our consolidated financial statements.

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; however, early adoption at January 1, 2017, is permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method, nor has it determined the effect of the standard on its ongoing financial reporting.

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	2015	2014
Lab equipment	$489	$489
Leasehold improvements	27	27
Computer equipment	54	54
Total property under capital leases	570	570
Less accumulated depreciation and amortization	(472)	(384)
Capital leased assets, net	$98	$186

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 by years of the future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of December 31, 2015 (in thousands):

Year ending December 31:	
2016	$13
2017	—
Total minimum lease payments	13
Less amount representing interest	(1)
Present value of net minimum lease payments	$12

(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, 2015, 2014 and

2013, was $1.7 million, $1.2 million, and $766,000 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, 2015 are as follows (in thousands):

Year ending December 31:	
2016	$1,417
2017	991
2018	509
2019	452
2020	38
Thereafter	—
Total	$3,407

4. 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, 2015.

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 $246,000 and $348,000 at December 31, 2015 and December 31, 2014, 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 $284,000 and $339,000 at December 31, 2015 and

December 31, 2014, 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 provides the Company with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until March 10, 2016.

The project calls for the Company to create or retain at least 150 full-time positions located in Ames, Iowa. The agreement also 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, 2105 deadline. If, as of March 10, 2016, the Company has fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2016, the Company has failed to create or retain at least 150 full-time jobs in Ames, Iowa, the Company will be required to repay approximately $3,100 per job not created or retained following such date. As of December 31, 2015, $397,000 of the total $400,000 forgivable loan was advanced to the Company. As of December 31, 2015, the Company had created 150 full-time jobs in Ames, Iowa. In the event of default, including failure to repay any amounts under the loan when due, the Company will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

5. 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 GDC-0919, one of NewLink's clinical stage IDO pathway inhibitors. The parties also entered into 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 and is eligible to receive additional payments of over $1.0 billion upon achieving certain GDC-0919 and Next Generation Product Development regulatory development, international patent acceptance, country marketing approval, and sales-based milestones. The Company is also eligible to receive escalating double-digit royalty payments on potential commercial sales of multiple products by Genentech.

The Company is obligated to deliver multiple non-contingent deliverables related to the GDC-0919 upfront cash payment. These deliverables include the GDC-0919 development and commercialization license, research license, program materials and technology, clinical supply of GDC-0919 product, manufacturing technology, participation in a joint research committee, or JRC, and providing an alliance manager. The GDC-0919 development and commercialization license and research license are separate deliverables, but without the ability to develop GDC-0919, 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 GDC-0919, participation in a JRC and participation of an alliance manager are expected to be 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 $14.7 million for the year ended December 31, 2015. This amount includes the recognition of $9.4 million for program materials and technology transfer, $2.5 million for the clinical supply of GDC-0919 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 recognized revenue under this agreement of $136.2 million for the year ended December 31, 2014 associated with license and manufacturing technology transfer deliverables, which were completed in their entirety. In accordance with the Company’s continuing performance obligation, $13.8 million of the initial $150.0 million upfront payment was deferred as of December 31, 2014. Per the agreement, the up-front payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

The Company will apply the contingency-adjusted performance model to recognize revenue related to potential future milestones under the agreement, therefore, revenue will only be recognized upon the achievement of a milestone.

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 rVSV-ZEBOV, 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 rVSV-ZEBOV 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 rVSV-ZEBOV vaccine product as one arm of the trial. In February 2015, this milestone was achieved and the Company received the milestone payment. In addition, 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 rVSV-ZEBOV license agreement product sales and escalating royalties on potential commercial sales by Merck of products other than current products within the Company's patent rights ranging from low to high single-digit, on increasing levels of annual net sales worldwide. Merck will lead the development of rVSV-ZEBOV and any other rVSV-based viral hemorrhagic fever, or VHF, vaccine product candidates in order to create a marketable product safe for human use.

The Company is obligated to deliver multiple non-contingent deliverables related to the rVSV-ZEBOV upfront cash payment. These deliverables include the license, information and know-how, technology transfer, participation in a joint steering committee, or JSC, and providing a project leader. These 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 allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of service. The determination of the best estimated selling price required the use of significant estimates. To determine the stand alone value of the license, the Company considered the negotiation discussions that led to the final terms of the agreement. The Company used historical cost plus an estimated gross margin to estimate the selling price for information and know-how, technology transfer, participation in the JSC, and providing a project leader. The technology transfer, participation in the JSC and providing a project leader are expected to be delivered throughout the duration of the agreement. The license and information and know-how was delivered shortly after the effective date of the agreement.

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 the Ebola clinical trials not reimbursed under its government contracts. Revenue of $53,800 remains deferred as of December 31, 2015 and will be recognized in future years as delivery occurs.

The Company recognized revenue under this agreement of $29.6 million for the year ended December 31, 2014 associated with license and information and know-how, which were completed in their entirety, and also recognized an additional $170,000 associated with the remaining deliverables. In accordance with the Company's continuing performance obligations, $232,000 of the $30.0 million upfront payment was deferred as of December 31, 2014. Per the agreement, the up-front payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

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 rVSV-ZEBOV 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.

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

6. 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.

7. Preferred Stock

As of December 31, 2015 and 2014, 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, 2015 there were 7,919,109 shares of common stock authorized for the 2009 Plan and 774,499 shares remained available for issuance. As of December 31, 2014 there were 6,799,854 shares of common stock authorized for the 2009 Plan and 654,935 shares remained available for issuance.

On January 7, 2011, stockholders authorized an increase of 714,286 shares of common stock available for issuance under the 2009 Plan. On January 1, 2013, an additional 838,375 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. On January 1, 2014, an additional 1,066,340 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. On January 1, 2015 an additional 1,119,255 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. Subsequent to year end, on January 1, 2016, an additional 1,152,565 shares of common stock were added to the shares reserved for future issuance under the 2009 plan. The shares added to the reserve on January 1, 2013, January 1, 2014, January 1, 2015, and January 1, 2016 were added 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, 2015, 106,640 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, 2015, 231,392 shares remained available for issuance under the plan. During the years ended December 31, 2015 and 2014, 40,248 and 25,168 shares of common stock, respectively, were purchased under the terms of the 2010 Purchase Plan.

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

Share-based Compensation

Share-based employee compensation expense for the years ended December 31, 2015, 2014 and 2013, was $15.9 million, $8.6 million, and $4.4 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations. As of December 31, 2015, the total compensation cost related to unvested option awards not yet recognized was $35.8 million and the weighted average period over which it is expected to be recognized was 3 years. The total income tax benefit recognized in the consolidated statements of operations for stock-based compensation arrangements was $7.8 million, $3.7 million and $0 for the years ended December 31, 2015, 2014 and 2013, respectively.

Stock Options

The Company's Board of Directors determines the vesting period for each stock option award. Stock options awarded to date under the 2009 Plan vest monthly or vest 20% or 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 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, 2015:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	5,098,311	$9.46	
Options granted	1,019,445	42.57	
Options exercised	(422,767)	7.94	
Options forfeited	(48,403)	36.70	
Options expired	(106)	14.19	
Outstanding at end of period	5,646,480	$15.11	6.0
Options exercisable at end of period	4,039,770	$8.04	4.9

Based on the December 31, 2015 price of $36.39 per share, the intrinsic value of stock options outstanding at December 31, 2015, was $126.2 million, of which $115.0 million and $11.2 million related to stock options that were vested and unvested, respectively, at that date.

The following table summarizes options that were granted during the years ended December 31, 2015, 2014 and 2013, 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,		
	2015	2014	2013
Number of options granted	1,019,445	974,555	860,250
Risk-free interest rate	1.51%-2.00%	1.73%-2.24%	.89%-2.14%
Expected dividend yield	—	—	—
Expected volatility	62.5%-67.3%	57.4%-68.3%	61.4%-67.3%
Expected term (in years)	5.9-7.0	6.0-7.0	4.8-7.0
Weighted average grant-date fair value per share	$26.36	$14.80	$7.50

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

The following table summarizes the intrinsic value of options exercised and the fair value of awards vested during the years ended December 31, 2015, 2014 and 2013:

	Years Ended December 31,		
	2015	2014	2013
Intrinsic value of options exercised	$16.7 million	$8.5 million	$1.6 million
Fair value of awards vested	$9.6 million	$7.5 million	$3.0 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. The fair value of options vested for the year ended December 31, 2014, includes $1.7 million in share-based compensation resulting from the vesting in full of one employee's options upon the employee's termination that occurred during 2014.

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, 2015 and 2014, there were 137,780 and 204,209 shares of restricted stock granted, respectively. These restricted stock grants had a weighted average fair value (per share) at date of grant of $43.27 at December 31, 2015. At December 31, 2015 and 2014 there were 228,972 and 153,509 shares of unvested restricted stock outstanding, respectively. Compensation expense is determined for the issuance of restricted stock by amortizing on a straight-line basis 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, 2015 and changes during the year ended December 31, 2015 is as follows:

	Restricted Stock	Weighted Average Grant Date Fair Value
Unvested at beginning of period	153,509	$ 23.63
Granted	137,780	43.27
Vested	(54,517)	22.94
Forfeited/cancelled	(7,800)	43.65
Unvested restricted stock at end of period	228,972	$ 34.94

As of December 31, 2015, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $6.1 million and is expected to be recognized over a weighted-average period of 2.8 years. The grant date fair value of awards granted during the year ended December 31, 2015 was $6.0 million. The fair value of awards vested during the year ended December 31, 2015 was $2.3 million.

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

On January 4, 2016, the Company approved grants of restricted stock unit awards to certain of the named executive officers for extraordinary performance in 2015. These are recognized as 2016 grants.

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

9. Income Taxes

Income tax expense consists of (in thousands):

	Current	Deferred	Total
Year Ended December 31, 2015:			
U.S. federal	$5,522	$—	$5,522
State and local	1,216	—	1,216
	$6,738	$—	$6,738
Year Ended December 31, 2014:			
U.S. federal	$14,592	$—	$14,592
State and local	7,024	—	7,024
	$21,616	$—	$21,616
Year Ended December 31, 2013:			
U.S. federal	$130	$—	$130
State and local	—	—	—
	$130	$—	$130

The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at December 31, 2015 and 2014 are presented below (in thousands):

	Year Ended December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$654	$1,042
Federal research and development tax credits	10,928	6,550
Share-based compensation	8,327	5,191
Deferred rent	519	550
Minimum tax credits	143	143
Accrued compensation	363	1,041
Unearned revenue	540	—
Accrued expenses	—	62
Leasehold improvements and equipment	26	—
Gross deferred tax assets	21,500	14,579
Less valuation allowance	(20,691)	(14,552)
Net deferred tax assets	809	27
Deferred tax liability:		
Leasehold improvements and equipment	(809)	(27)
Total net deferred tax assets	$—	$—

The valuation allowance for deferred tax assets as of December 31, 2015 and 2014 was $20.7 million and $14.6 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2015 and 2014 was an increase of $6.1 million and a decrease of $10.6 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, 2015 and 2014, due to the uncertainty of future recoverability.

Federal operating loss carryforwards as of December 31, 2015 of approximately $1.4 million and federal research credit carryforwards of approximately $10.9 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, 2014, NewLink experienced Section 382 ownership changes in September 2001 and March 2003 and BPS 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 NewLink's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of NewLink and our subsidiary. 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.

Income tax expense was $6.7 million, $21.6 million, and $130,000 for the years ended December 31, 2015, 2014 and 2013.

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,		
	2015	2014	2013
U.S. federal income tax expense/(benefit) at the statutory rate	(35.0)%	35.0 %	(35.0)%
Available research and experimentation tax credits	(2.3)	(7.0)	—
State income taxes, net of federal taxes	(0.5)	4.7	—
Loss in foreign subsidiary	43.6	8.4	—
Valuation allowance	13.7	(21.6)	38.3
Other	0.5	(1.1)	(2.9)
Total	20.0 %	18.4 %	0.4 %

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.

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

10. Earning Per Share (EPS)

The following table presents the calculations of earnings (loss) per share:

	Years Ended December 31,		
	2015	2014	2013
Historical net income (loss) per share			
Numerator			
Net (loss) income attributable to common stockholders	$(40,381)	$96,017	$(31,180)
Denominator			
Basic weighted-average shares outstanding	28,586,585	27,838,873	25,275,179
Dilutive effect of stock option and restricted stock shares	—	3,186,226	—
Diluted weighted-average shares outstanding	28,586,585	31,025,099	25,275,179
Basic earnings (loss) per share	$(1.41)	$3.45	$(1.23)
Diluted earnings (loss) per share	$(1.41)	$3.09	$(1.23)

For December 31, 2015, potentially dilutive stock options to purchase 1,091,492 shares of common stock had exercise prices that were greater than the average market price were excluded from our calculation of diluted net income per share because to do so would be anti-dilutive. For December 31, 2014, and 2013, respectively, potentially dilutive common stock options of 5,098,311, and 4,486,564 were not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive.

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(j) above. The Company has incurred expense of approximately $2.0 million, $3.1 million, and $88,000, under all of the in-licensing agreements for the years ended December 31, 2015, 2014, and 2013, 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.

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

Licensor	Aggregate potential milestone payments
Lankenau Institute for Medical Research under the IDO-1 Agreement	$1.36 million per licensed product
Lankenau Institute for Medical Research under the LIMR IDO-2 Agreement	$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement
Lankenau Institute for Medical Research under the 2009 LIMR Agreement	$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement
Augusta University Research Institute	$2.8 million per licensed product
Public Health Agency of Canada	C$205,000 per licensed product
The Ohio State University	$2.75 million for first licensed product

Table of Contents
NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

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, $303,000, $198,000 for the years ended December 31, 2015, 2014 and 2013, respectively. The Company made discretionary contributions to the plan of $319,000, $299,000, and $144,000 for the years ended December 31, 2015, 2014 and 2013, 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. Quarterly Financial Information (Unaudited)

	First	Second	Third	Fourth
	(In thousands, except per share data)			
Year Ended December 31, 2015				
Grant and licensing revenue	$39,195	$7,445	$14,209	$7,652
Income (loss) from operations	12,848	(15,942)	(15,683)	(14,825)
Net income (loss)	11,190	(14,091)	(15,906)	(21,574)
Basic earnings (loss) per share	0.40	$(0.49)	$(0.55)	$(0.75)
Diluted earnings (loss) per share	$0.35	$(0.49)	$(0.55)	$(0.75)
Year Ended December 31, 2014				
Grant and licensing revenue	$334	$212	$2,801	$169,245
Income (loss) from operations	(9,304)	(9,127)	(13,026)	149,030
Net income (loss) (1)	(9,236)	(9,163)	(5,598)	120,014
Basic earnings (loss) per share (1) (2)	(0.33)	(0.33)	(0.20)	4.29
Diluted earnings (loss) per share (1) (2)	$(0.33)	$(0.33)	$(0.20)	$3.83

(1) During the third quarter of 2015, the Company corrected an immaterial error in the Company's 2014 income tax provision expense resulting in an increase to the Company's income tax expense and a decrease in net income of $6.8 million and a reduction of basic and diluted earnings per share for the three-month period ended December 31, 2014 of $0.25 and $0.22.

(2) The Company identified an error relating to the basic and diluted loss per share amounts reported in Quarterly Financial Information Note to the Annual Report on Form 10-K for the year ended December 31, 2014 of $0.33 and $0.66 for the three-month periods ended June 30, 2014 and September 30, 2014, respectively. Management evaluated the impact of the error on the previously reported consolidated financial statements and notes and concluded the impact was not material. The Company has revised the per share amounts reported above to correctly report the quarter-to-date basic and diluted loss per share for these periods.

Table of Contents

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	
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 Company and certain holders of the Company'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	8/5/2014	10.3	
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 July 7, 2005 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.30	
10.7.1	*		S-1/A	11/8/2011	10.31	

		First Amendment to License Agreement dated May 22, 2006 by and between the Registrant and Lankenau Institute for Medical Research			
10.7.2	*	Second Amendment to License Agreement September 11, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.32
10.8	*	Exclusive License Agreement executed December 21, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.33
10.9	*	Exclusive License Agreement effective April 23, 2009 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.34
10.10	*	License Agreement dated August 2, 2001 by and between the Registrant and Central Iowa Health System	S-1/A	11/8/2011	10.37
10.11	*	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
10.11.1	*	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

Table of Contents

10.11.2	*	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
10.11.3	*	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
10.11.4	*	Amendment to License Agreement dated March 28, 2006 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3
10.11.5	*	Amendment to License Agreement dated July 10, 2014 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4
10.12	*	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
10.13	*	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
10.14	*	Sole License Agreement executed May 4, 2010 by and between Public Health Agency of Canada in Right of Canada and BioProtection Systems Corporation	S-1/A	11/8/2011	10.67
10.15		Amendment dated July 31, 2014 to the Sole License Agreement by and between BioProtection Systems Corporation and Public Health Agency of Canada in Right of Canada as Represented by the Minister of Health dated May 4, 2010	10-Q	11/10/2014	10.5
10.16	*	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
10.16.1		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
10.16.2		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
10.16.3		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
10.16.4		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
10.16.5		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
10.16.6		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
10.16.7		Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and	S-1/A	10/4/2011	10.45

	National Cancer Institute			
10.16.8	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
10.17	Lease dated September 1, 2000 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.46
10.18	Sublease Agreement effective February 1, 2001 by and between the Registrant and Iowa State Innovation System	S-1	12/21/2010	10.47
10.19	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
10.20	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
10.21	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
10.22	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
10.23	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
10.24	Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53

Table of Contents

10.25		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
10.26		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
10.27		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
10.28		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
10.29		Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54
10.30		Forgivable Loan Agreement dated March 10, 2010 by and between the Registrant and City of Ames, Iowa	S-1	12/21/2010	10.55
10.31		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
10.32		Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58
10.33		Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.59
10.34		Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57
10.35		Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.60
10.36		Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77
10.37		Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78
10.38		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
10.38.1		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
10.39	*	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
10.39.1		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
10.40		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
10.40.1		Amendment to Contract No. W911NF-09-C-0072 dated April 21, 2010 by and between BioProtection Systems	S-1/A	2/28/2011	10.72

	Corporation and the United States Department of Defense			
10.41	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
10.42	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
10.43	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
10.44	NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2
10.45	NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3
10.46	Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4
10.47	Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2013	8-K	3/28/2012	10.1

Table of Contents

10.48	*	Cooperative Research and Development Agreement between the Company and the National Cancer Institute, effective as of March 27, 2012	10-Q	5/10/2012	10.6	
10.49		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	
10.50		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	
10.51		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	
10.52		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	
10.53		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation Dated March 1, 2010	10-Q	8/8/2013	10.2	
10.54		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	
10.55		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	
10.56		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	
10.57	*	Amendment to License Agreement dated December 30, 2013, by and between Registrant and Central Iowa health System	10-K	3/12/2014	10.94	
10.58	*	Development and Process Transfer Program Leading to Commercial Manufacturing for algenpantucel-L HyperAcute Pancreas by and between the Company and WuXi AppTec, Inc. dated June 19, 2014	10-Q	8/5/2014	10.2	
10.59		Amendment dated September 30, 2014 to the Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec. Inc. dated June 19, 2014	10-Q	11/10/2014	10.2	
10.60	*	License and Collaboration Agreement dated October 16, 2014 by and among the Company, NewLink Global, Genentech, Inc. and F. Hoffmann-LaRoche Ltd.	10-Q	11/10/2014	10.1	
10.61	*	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	
10.62		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	
10.62.1		Memorandum of Agreement dated July 9, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005				X

10.63		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	
10.63.1		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	
10.63.2		Memorandum of Agreement dated September 21, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010				X
10.64	†	2014 Bonus Awards	8-K	1/6/2015	10.1	
10.65	†	2015 Salaries, Bonus Targets and Equity Awards	8-K	1/6/2015	10.2	
10.66		First Amendment dated March 31, 2015 to the License and Collaboration Agreement by and between the Company, NewLink Global, Genentech, Inc. and F. Hoffmann-La Roche Ltd. dated as of October 16, 2014	10-Q	5/11/2014	10.1	
10.67	†	Separation and Release Agreement between the Company and W. Jay Ramsey, dated as of May 22, 2015	10-Q	8/6/2015	10.3	
10.68	*	Amended and Restated Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec, Inc. dated January 4, 2016				X
21.1		Subsidiary Information				X

Table of Contents

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

---

† 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.