ARGOS THERAPEUTICS INC

FORM 10-K
(Annual Report)

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  

FORM 10-K  

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

For the fiscal year ended December 31, 2014  

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

Commission File Number 001-35443  

ARGOS THERAPEUTICS, INC.  
(Exact name of registrant as specified in its charter)  

State or other jurisdiction of incorporation or organization Delaware  
(I.R.S. Employer Identification No.) 56-2110007  

4233 Technology Drive  
Durham, North Carolina  
(Address of principal executive offices)  

Registrant’s telephone number, including area code: (919) 287-6300  

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

Common Stock, par value $0.001 per share  

Name of Each Exchange on Which Registered  

NASDAQ Global Market  

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐  

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 ☒ No ☐  

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 ☒  

Accelerated filer ☐  

Non-accelerated filer ☒ (Do not check if a smaller reporting company)  

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 ☒ No ☐  

As of June 30, 2014 (the last business day of the registrant’s most recently completed second fiscal quarter), the aggregate market value of the registrant’s common stock held by non-affiliates was approximately $59.6 million based upon the closing price for shares of the registrant’s common stock of $8.03 as reported by the NASDAQ Global Market on that date. For purposes of this calculation, the registrant has assumed that its directors, executive officers and holders of 5% or more of the outstanding common stock are affiliates.  

As of March 23, 2015, there were 19,688,802 shares outstanding of the registrant’s common stock, par value $0.001 per share.
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Argos Therapeutics®, Argos® and Arcelis™, the Argos Therapeutics logo and other trademarks or service marks of Argos appearing in this Annual Report on Form 10-K are the property of Argos Therapeutics, Inc. The other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.
This Annual Report on Form 10-K, including “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including 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,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar 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 about:

- the progress and timing of our development and commercialization activities;
- the timing and conduct of our phase 3 clinical trial of AGS-003 for the treatment of metastatic renal cell carcinoma, or mRCC, and phase 2 clinical trials of AGS-003, including the timing of enrollment and completion of the trials and the period in which the results of the trials are anticipated to become available;
- the timing and conduct of our two phase 2 clinical trials of AGS-004 for the treatment of HIV, one for HIV eradication and one for long-term viral control in pediatric patients, including the timing of enrollment and the completion of the trials and the period in which results of the trials are anticipated to become available;
- our ability to obtain U.S. and foreign marketing approval for AGS-003 for the treatment of mRCC and for AGS-004 for the treatment of HIV, and the ability of these product candidates to meet existing or future regulatory standards;
- the potential benefits of our Arcelis platform and our Arcelis-based product candidates;
- our ability to build out and equip a new North American commercial manufacturing facility and supply on a commercial scale our Arcelis-based products;
- our intellectual property position and strategy;
- our expectations related to the sufficiency of our cash, cash equivalents and short-term investments;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We have based these forward-looking statements largely on our current plans, intentions, expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in “Item 1A. Risk Factors,” that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report on Form 10-K with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of filing of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements, except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Annual Report on Form 10-K also includes data based on our own internal estimates. While we believe these industry publications and third party research, surveys and studies are reliable, we have not independently verified such data.

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PART I

Item 1. Business

Overview

We are a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer based on our proprietary technology platform called Arcelis.

Our most advanced product candidate is AGS-003, which we are developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. We are currently conducting a pivotal phase 3 clinical trial of AGS-003 plus sunitinib and other targeted therapies for the treatment of newly diagnosed mRCC under a special protocol assessment, or SPA, with the Food and Drug Administration, or FDA. Patients in the trial will initially be treated with sunitinib. However, under the trial protocol, if sunitinib is discontinued due to disease progression or toxicity, it can be replaced with another approved targeted therapy. We refer to this trial as the ADAPT trial. We initiated the ADAPT trial in January 2013 and dosed the first patient in May 2013. We expect to complete enrollment by the end of second quarter 2015 and that the first interim analysis by the trial's independent data monitoring committee will be conducted in second quarter 2015. We also expect to have data from this trial in the second half of 2016 when we anticipate the required number of events to permit the primary analysis and assessment of overall survival to have occurred.

We believe that AGS-003 may be capable of treating a wide range of cancers and are planning to evaluate AGS-003 in clinical trials in additional cancer indications.

We are developing AGS-004, our second most advanced Arcelis-based product candidate, for the treatment of HIV. We have completed three clinical trials of AGS-004. These include phase 1 and phase 2a trials funded by government grants and a phase 2b trial that was funded in full by the National Institutes of Health, or NIH, and the National Institute of Allergy and Infectious Diseases, or NIAID, under a $39.8 million agreement. In addition, we are supporting an investigator-initiated phase 2 clinical trial of AGS-004 in adult HIV patients that is being conducted to evaluate the use of AGS-004 in combination with a latency reversing drug for HIV eradication, and we plan to support a second investigator-initiated phase 2 clinical trial of AGS-004 in 2015, to evaluate AGS-004 for long-term viral control in pediatric patients.

Our Arcelis Platform

Our proprietary Arcelis technology platform utilizes biological components from a patient’s own cancer cells or virus to generate fully personalized immunotherapies. These immunotherapies employ specialized white blood cells called dendritic cells to activate an immune response specific to the patient’s own disease. Arcelis is based on the work of Dr. Ralph Steinman, winner of the 2011 Nobel Prize in medicine for the discovery of the role of dendritic cells in the immune system. We believe our Arcelis-based immunotherapies are applicable to a wide range of cancers and infectious diseases and have the following attributes that we consider critical to a successful immunotherapy:

• target a patient’s disease-specific antigens, including mutated antigens, to elicit a potent immune response that is specific to the patient’s own disease;
• overcome the immune suppression that exists in cancer and infectious disease patients;
• induce memory T-cells, a specialized type of immune cell that is known to correlate with improved clinical outcomes for cancer and HIV patients;
• have minimal toxicity; and
• can be produced using a automated centralized manufacturing process at a cost that will be comparable to biologics.

We believe that our immunotherapies combine the advantages of other approaches to immunotherapy, including antigen-based approaches and pathway-based approaches such as checkpoint inhibition, while addressing the limitations they present.

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Our Development Programs

The following table summarizes our development programs for AGS-003 and AGS-004.

<table>
<thead>
<tr>
<th>Product Candidate</th>
<th>Primary Indication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGS-003</td>
<td>mRCC (clear cell)</td>
<td>• Ongoing pivotal phase 3 clinical trial; completion of enrollment expected by the end of second quarter 2015; overall survival data expected in the second half of 2016</td>
</tr>
<tr>
<td></td>
<td>mRCC (non-clear cell)</td>
<td>• Phase 2 investigator-initiated clinical trial expected to begin in the second half of 2015</td>
</tr>
<tr>
<td></td>
<td>Early stage RCC (neoadjuvant)</td>
<td>• Ongoing investigator-initiated phase 2 clinical trial; initial data expected in 2016</td>
</tr>
<tr>
<td></td>
<td>Early stage RCC (adjuvant)</td>
<td>• Investigator-initiated phase 2 clinical trial expected to begin mid-2015; initial data expected in 2016</td>
</tr>
<tr>
<td></td>
<td>Advanced solid tumors</td>
<td>• Two investigator-initiated phase 2 clinical trials expected to begin in the second half of 2015</td>
</tr>
<tr>
<td>AGS-004</td>
<td>HIV</td>
<td>• Phase 2b clinical trial complete; data announced on January 9, 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ongoing first stage of investigator-initiated phase 2 clinical trial for HIV eradication; Second stage expected to begin in the second half of 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Investigator-initiated phase 2 clinical trial for long-term viral control in pediatric patients planned for the second half of 2015</td>
</tr>
</tbody>
</table>

We hold all commercial rights to AGS-003 and AGS-004 in all geographies other than rights to AGS-003 in Russia and the other states comprising the Commonwealth of Independent States, which we exclusively licensed to Pharmstandard International S.A., and rights to AGS-003 in South Korea, which we exclusively licensed to Green Cross Corp. We have granted MEDcell Co., Ltd., or Medinet, an exclusive license to manufacture in Japan AGS-003 for the treatment of mRCC and an option to acquire a non-exclusive license to sell in Japan AGS-003 for the treatment of mRCC.

**AGS-003**

We are developing AGS-003 for the treatment of mRCC and other cancers. We are currently conducting a pivotal phase 3 clinical trial of AGS-003 plus sunitinib / targeted therapy for the treatment of newly diagnosed mRCC under an SPA with the FDA. We refer to this trial as the ADAPT trial. We initiated the ADAPT trial in January 2013 and dosed the first patient in May 2013. We plan to enroll approximately 450 patients in the trial to generate 290 events for the primary endpoint of overall survival. We plan to enroll these patients at approximately 140 clinical sites in North America and Europe. Under the trial protocol, these patients will be randomized between the AGS-003 plus sunitinib / targeted therapy combination arm and the sunitinib / targeted therapy alone control arm on a two-to-one basis. As of February 28, 2015, we have enrolled and randomized approximately 340 patients in the trial. We expect to complete enrollment by the end of second quarter 2015 and to have data from this trial in the second half of 2016 when we anticipate the required number of events to permit the primary analysis and assessment of overall survival to have occurred.

We believe that AGS-003 may be capable of treating a wide range of cancers and are planning to evaluate AGS-003 in clinical trials in additional cancer indications. In the second half of 2015, we plan to support an investigator-initiated open label phase 2 clinical trial of AGS-003 in patients with mRCC and non-clear cell, or NCC, histology. In the trial, we plan to evaluate the safety, efficacy and immunologic effects of AGS-003 when combined with targeted therapy in approximately 30 to 40 NCC mRCC patients.

In addition, we are supporting or plan to support two investigator-initiated phase 2 clinical trials, which are designed to evaluate treatment with AGS-003 in patients with early stage RCC prior to and following nephrectomy. The initial trial, which is designed to evaluate AGS-003 prior to nephrectomy, opened for enrollment late 2014 (neoadjuvant study) and the second trial to evaluate AGS-003 after standard nephrectomy (adjuvant RCC study) is on track to begin mid-2015. We expect that a total of 40 to 50 patients will be enrolled these two trials and that initial data from these trials will be available in 2016.

We also plan to begin additional investigator-initiated clinical trials of AGS-003, potentially in combination with other therapies, in other advanced solid tumor types, including bladder cancer and non-small cell lung cancer, or NSCLC, in the second half of 2015.
AGS-004

We are developing AGS-004 for the treatment of HIV and plan to focus this program on the use of AGS-004 in combination with other therapies for the eradication of HIV. The current standard of care, antiretroviral drug therapy, or ART, can reduce levels of HIV in a patient’s blood, increase the patient’s life expectancy and improve the patient’s quality of life. However, ART cannot eliminate the virus, which persists in latently infected cells, remains undetectable by the immune system and can recur. In addition, ART requires daily, life-long treatment and can have significant side effects.

We believe that by combining AGS-004 with therapies that are being developed to expose the virus in latently infected cells to the immune system, we can potentially eradicate the virus. We are supporting an investigator-initiated Phase 2 clinical trial of AGS-004 in up to twelve adult HIV patients to evaluate the use of AGS-004 in combination with one of these latency reversing therapies for this purpose at the University of North Carolina. This trial is being conducted in two stages. Stage 1 of this trial is designed to study immune response kinetics to AGS-004 in patients on continuous ART. The purpose is to better define the optimal dosing strategy in combination with a latency-reversing therapy. We expect that patients in Stage 1 will rollover into Stage 2, a separate protocol that will study AGS-004 in combination with one of the latency-reversing drugs. In January 2014, Collaboratory of AIDS Researchers for Eradication, or CARE, agreed that it would fund all patient clinical costs for Stage 1 of this phase 2 clinical trial, except for the associated manufacturing costs for which we are responsible.

We are developing AGS-004 for the treatment of HIV and plan to focus this program on the use of AGS-004 in combination with other therapies for the eradication of HIV. The current standard of care, antiretroviral drug therapy, or ART, can reduce levels of HIV in a patient’s blood, increase the patient’s life expectancy and improve the patient’s quality of life. However, ART cannot eliminate the virus, which persists in latently infected cells, remains undetectable by the immune system and can recur. In addition, ART requires daily, life-long treatment and can have significant side effects.

We also plan to explore the use of AGS-004 monotherapy to provide long-term control of HIV viral load in otherwise immunologically healthy patients and eliminate their need for ART. Accordingly, if the protocol and government funding are approved, we plan to support in the second half of 2015, an investigator-initiated phase 2 clinical trial of AGS-004 monotherapy in pediatric patients infected with HIV who have otherwise healthy immune systems, have been treated with ART since birth or shortly thereafter and, as a result, are lacking the antiviral memory T-cells to combat the virus.

In September 2013, we completed patient enrollment in our NIH-funded phase 2b clinical trial of AGS-004 in 53 HIV-infected patients. The primary endpoint of this trial was a comparison of the median viral load in AGS-004-treated patients with the median viral load in patients receiving placebo after 12 weeks of ART treatment interruption. Secondary endpoints of this trial include comparisons between AGS-004-treated patients and patients receiving placebo with respect to viral measurement changes from immediately prior to the commencement of ART to the end of the planned treatment interruption, duration of treatment interruption, changes in CD4+ T-cell counts, an indicator of the health of the immune system, and assessment of increases in antiviral immunity between AGS-004 treated and placebo-treated patients. We designed this trial to confirm the data that we obtained from the phase 2a clinical trial that we conducted in HIV infected patients and provide proof of concept of the ability of AGS-004 to induce an immune response to eliminate the cells responsible for viral replication.

In January 2015, we announced top-line results from the trial. The primary endpoint of the trial, which required a 1.1 Log lower median viral load after 12 weeks of interruption of ART in the treatment group versus the placebo group, was not achieved. However, we believe that data from the trial provided evidence of the ability of AGS-004 to induce memory T-cell responses which may have directly impacted the latent viral reservoir. Of the evaluated 22 patients who received AGS-004 and completed the 12-week treatment interruption period, 15 patients or approximately 70 percent had positive antiviral memory T-cell responses prior to beginning the treatment interruption versus zero percent of placebo patients. Within the AGS-004 treatment group, those patients that had antiviral memory T-cell responses had significantly fewer CD4+ T-cells with integrated HIV DNA when compared to non-responders. These findings relate directly to the utilization of AGS-004 in our ongoing adult eradication study and a planned pediatric study, where one of the key objectives is to decrease the latent HIV reservoir.

In the phase 2b trial, 54 patients received four doses of AGS-004 or placebo every four weeks while on standard ART, and then began a 12-week ATI, during which dosing continued every four weeks. In total, 36 participants completed ATI, 23 of whom received AGS-004. The trial was fully funded by NIH and NIAID.

We believe that by demonstrating that AGS-004 induced memory T-cell responses in a majority of patients and that those immune responders had fewer CD4+ T-cells with integrated HIV DNA, these data suggest that induced anti-viral memory T-cell responses may contribute to lower persistent viral reservoirs. These data support our plans to continue testing AGS-004 in the studies aimed at decreasing or eliminating the latent HIV reservoir. In addition, based on these data we believe that more frequent dosing of AGS-004 during ART may provide further benefit, but also highlight the need to better understand the mechanisms of immune evasion employed by the HIV virus in the absence of ART.
We believe the results of the AGS-004 Phase 2b trial allow us to now ask if combining AGS-004 treatment with HDAC inhibitors, part of a new class of latent reservoir mobilizers, will lead to the elimination of HIV-infected cells.

Strategy

Our goal is to become a leading biopharmaceutical company focused on discovering, developing and commercializing personalized immunotherapies for the treatment of a wide range of cancers. Key elements of our strategy are:

- complete clinical development and seek marketing approvals of AGS-003 for the treatment of mRCC;
- expand clinical development of AGS-003 in other cancers, including non-clear cell mRCC, early stage RCC and other solid tumors;
- commercialize AGS-003 in North America independently and with third parties outside North America;
- establish automated manufacturing processes based on our existing functioning prototypes of automated devices and, prior to the filing of our BLA for AGS-003, build out and equip a new North American facility for the commercial manufacture of products based on our Arcelis platform; and
- continue clinical development of AGS-004 for the treatment of HIV, potentially through government funding or other third party funding, and collaborate with third parties for commercialization on a worldwide basis;
- pursue expansion of our broad intellectual property protection for our Arcelis technology platform, product candidates and proprietary manufacturing processes through U.S. and international patent filings and maintenance of trade secret confidentiality.

Immunotherapy to Treat Cancer and Infectious Diseases

Cancer cells occur frequently in the human body, yet are effectively controlled by T-cells in the immune system, which recognize proteins produced by the cancer cells, known as antigens, as abnormal and kill the associated cancer cells. Two specific types of T-cells are necessary for an effective anti-cancer immune response: CD8+ T-cells, which kill cancer cells, and CD4+ T-cells, which provide a “help” signal that activates and directs the CD8+ T-cell response.

Cancer cells utilize several strategies to escape detection by the immune system and T-cells. For example, cancer cells secrete factors that act systemically to prevent T-cells from responding to activation signals, resulting in the inability of T-cells to carry out their role of killing cancer cells. Chronic viral infections such as HIV or hepatitis C present the same challenges to the immune system as cancer because the immune system must overcome this disease-induced immune suppression to recognize and respond to virus-infected cells.

Immunotherapy is intended to stimulate and enhance the body’s natural mechanism for recognizing and killing cancer cells and virus-infected cells. Current immunotherapeutic approaches to treat cancer can generally be separated into two different mechanisms of action: antigen-based approaches that target one or more specific antigens and pathway-based approaches that target specific immunologic pathways.

Antigen-Based Approaches

Cancer immunotherapies that use an antigen-based approach are designed to stimulate an immune response against one or more tumor-associated antigens. In most cases, the tumor-associated antigens that are being targeted are non-mutated, or normal, antigens, which are usually well tolerated by the immune system. In the context of cancer, these normal antigens are either produced at abnormally high levels or predominantly in tumor cells, or both. The goal of antigen-based immunotherapies is to activate the patient’s own immune system to seek out and kill the cancer cells that carry the targeted antigen. Dendreon Corporation’s Provenge (sipuleucel-T) for metastatic castrate-resistant prostate cancer is the only antigen-based immunotherapy that has been approved by the FDA. Because these immunotherapies are designed to target specific antigens, they are less likely to have toxicity. However, antigen-based immunotherapies may have limited efficacy because they are only able to capture one or a limited number of antigens, which may or may not be present in the patient’s cancer cells, and do not capture mutated antigens.
Pathway-Based Approaches

Immunotherapies that rely on the pathway approach are designed to overcome immunosuppression in patients by blocking signaling pathways that prevent T-cell activation and function. A new class of monoclonal antibody-based immunotherapies known as checkpoint inhibitors are being developed on the basis of this approach. For example, Bristol-Myers Squibb’s immunotherapy Yervoy (ipilimumab), an FDA-approved treatment for patients with unresectable or metastatic melanoma, is designed to act by blocking the function of a protein expressed in activated T-cells called CTLA4, which acts as a T-cell “off” switch. By blocking the function of CTLA4, the patient’s T-cells can become activated, resulting in an immune response against tumors. Another pathway that immunotherapies are being developed to address is the PD-1/PD-L1 pathway. In this pathway, activated T-cells expressing the protein PD-1 are disabled when binding occurs between PD-1 and its ligand, PD-L1, which is expressed on tumor cells. Immunotherapies are being developed to interrupt this pathway by binding to the PD-1 protein or the PD-L1 ligand to prevent them from binding with each other. Immunotherapies that use a pathway approach have demonstrated the ability to effectively overcome immunosuppression and enable T-cells to function against tumor cells and potentially virus-infected cells. However, pathway-based immunotherapies are limited because they act systemically to enable T-cells to function and do not specifically target a patient’s tumor or the associated antigens. This lack of specificity can negatively impact healthy tissue and generate unwanted toxicity.

Designing Immunotherapies Using Our Arcelis Platform

We believe that our proprietary Arcelis platform enables us to produce fully personalized immunotherapies that combine the advantages of the antigen-based and pathway-based approaches to immunotherapy while addressing the limitations and disadvantages of these approaches. We have designed our Arcelis platform to create product candidates which have attributes that we believe are critical to a successful immunotherapy:

- **Target disease-specific antigens, including mutated antigens.** The immunotherapy should target antigens, including mutated antigens, associated with the patient’s disease. We believe that immunotherapies that target only non-mutated, or normal, tumor-associated antigens will be limited in terms of efficacy as non-mutated antigens are generally poor at stimulating immune responses. Our Arcelis platform uses messenger RNA, or mRNA, from the patient’s own cancer or virus to yield a fully personalized immunotherapy that contains the patient’s disease-specific antigens, including mutated antigens, and is designed to elicit a potent immune response specific to the patient’s own disease.

- **Overcome disease-induced immune suppression.** The immunotherapy must be able to generate an effective immune response in patients whose immune systems are compromised by their disease. Both tumors and HIV are known to impair the functionality of CD4+ T helper cells, which aid their escape from CD8+ T-cell attack. Our Arcelis-based immunotherapies do not require CD4+ helper T-cells to mount an immune response with effective anti-tumor or anti-viral activity as we add the protein known as CD40 ligand, or CD40L, to provide the signaling that the CD4+ helper T-cells would otherwise provide.

- **Induce memory T-cells.** The immunotherapy should be able to induce specific T-cells, such as CD8+CD28+ memory T-cells, that are known to correlate with improved clinical outcomes for cancer and HIV patients. These memory T-cells are long lived and necessary for a durable immune response. Our Arcelis process produces dendritic cells that secrete IL-12, which is necessary to induce and expand patient-specific CD8+CD28+ memory T-cells. These memory T-cells are able to seek out and kill cancer or virus-infected cells that express the antigens identical to those displayed on the surface of the dendritic cells. In addition, because these newly generated memory T-cells do not express PD-1, they are not subject to inhibition by the PD-1/PD-L1 pathway.

- **Have minimal toxicity.** The immunotherapy should have minimal toxicity, which would potentially enable it to be combined with other therapies for cancer and infectious diseases. The mechanism of action of Arcelis-based products induces patient- and disease-specific memory T-cells. This target customization and specificity is less likely to impact healthy tissue and cause toxicity. Our Arcelis-based product candidates have been well tolerated in clinical trials in more than 170 patients with no serious adverse events attributed to our immunotherapies.

Our Arcelis platform is focused on dendritic cells which present antigens to the attention of the human immune system, including, in particular, T-cells, and are critical to the immune system’s recognition of proteins derived from cancer cells or virus-infected cells. Dendritic cells are capable of internalizing cancer or virus protein antigens and displaying fragments of these protein antigens on their surface as small peptides. The dendritic cells then present these peptide antigens to T-cells. This allows the T-cells to bind to these peptide antigens and, in the case of cancer, kill cancer cells and, in the case of infectious disease, kill virus-infected cells to control the spread of infectious pathogens.
At the clinical site. As shown in the graphic above, the manufacture of our Arcelis-based immunotherapies requires two components derived from the patient:

- A disease sample: In the case of cancer, the sample consists of tumor cells, and in the case of infectious disease, the sample consists of blood containing the virus. The disease sample is generally collected at the time of diagnosis or initial treatment.
- Monocytes: Monocytes are a type of white blood cell, which are obtained through a laboratory procedure called leukapheresis that occurs after diagnosis and at least three weeks prior to initiating treatment with our immunotherapy.

At our centralized manufacturing facility. The tumor cells or the blood sample and the leukapheresis product are shipped to our centralized manufacturing facility following collection at the clinical site. After receipt of these components at our facility, we take the following steps:

- We isolate the patient’s disease mRNA, which carries the genetic information to recreate the patient’s disease antigens, from the disease sample and amplify the mRNA so that only a small disease sample is required to manufacture the immunotherapy.
- Separately, we extract the monocytes from the leukapheresis product and culture them using a proprietary process to produce matured dendritic cells.
- We then culture the matured dendritic cells in a solution of the patient’s isolated mRNA and a proprietary synthetic CD40L RNA. We apply a brief electric pulse to the solution in a process referred to as electroporation, which enables the patient’s mRNA and the CD40L RNA to pass into, or load, the dendritic cells. The dendritic cells process the CD40L RNA into CD40L protein, enabling the dendritic cells to secrete IL-12, a cytokine required to induce and expand CD8+CD28+ memory T-cells.
- We then further culture the mRNA-loaded dendritic cells so that these cells allow for antigen expression from the patient’s mRNA and presentation in the form of peptides on the surface of the dendritic cells. These mature, loaded dendritic cells are formulated into the patient’s plasma that was collected during the leukapheresis to become the Arcelis-based product.
- After verifying the quality of the product, we then vial, freeze and ship the product to the clinic, which thaws the product and administers it to the patient by intradermal injection.

Patient treatment. Upon injection into the skin of the patient, the mature, loaded dendritic cells migrate to the lymph nodes near the site of the injection. It is at these lymph nodes that the dendritic cells come into contact with T-cells. This interaction with the loaded dendritic cells is intended to cause a measurable increase in patient- and disease-specific memory T-cells.

We believe that our Arcelis platform allows us to create fully personalized immunotherapies capable of treating a wide range of cancers and infectious diseases using an automated manufacturing process at a cost that will be comparable to other biologics. Specifically, our Arcelis platform allows us to:

- produce several years of customized therapy for a patient from a small disease sample and a single leukapheresis from that patient;
AGS-003 for the Treatment of Metastatic Renal Cell Carcinoma and Other Cancers

We are initially developing AGS-003 for use in combination with sunitinib and other targeted therapies for the treatment of mRCC. Sunitinib is an oral small molecule drug sold under the trade name Sutent and is the current standard of care for initial treatment, or first-line treatment, of mRCC following diagnosis.

We are currently conducting our pivotal phase 3 ADAPT clinical trial of AGS-003 plus sunitinib / targeted therapy compared to sunitinib / targeted therapy monotherapy for the treatment of newly diagnosed mRCC under an SPA with the FDA. We plan to enroll in the trial approximately 450 intermediate and poor risk patients with mRCC that pathologists have classified as predominately clear cell. The primary endpoint of the trial is overall survival. As of February 28, 2015, we had enrolled and randomized approximately 340 patients in the trial. We expect to complete enrollment by the end of second quarter 2015 and to have data from the trial in the second half of 2016. We have established an independent data monitoring committee that will conduct interim analyses of the trial data at such times as when approximately 25%, 50% and 75% of the required events for subjects randomized to the treatment phase of the trial have occurred.

In April 2012, the FDA notified us that we have obtained fast track designation for AGS-003 for the treatment of mRCC. We are also planning to explore the use of AGS-003 in non-clear cell mRCC, early stage RCC prior to and following nephrectomy and other advanced solid tumors, such as bladder cancer and non-small cell lung cancer, or NSCLC. We have or plan to support investigator-initiated clinical trials of AGS-003 for the treatment of these indications which began in late 2014 or will begin in 2015.

Renal Cell Carcinoma

RCC is the most common type of kidney cancer. The ACS estimates that there were 63,920 new cases of kidney cancer and 13,860 deaths from this disease in the United States in 2014. The NCCN estimates that 90% of kidney cancer cases are RCC. For patients with RCC that had metastasized by the time RCC was first diagnosed, a condition referred to as newly diagnosed mRCC, the five-year survival rate has historically been approximately 12%.

ACS statistics indicate that approximately 25% of newly diagnosed RCC patients present with mRCC annually in the United States. Additional patients who were initially diagnosed with earlier stage RCC may also progress to mRCC as these patients suffer relapses. The NCCN estimates between 20% to 30% of patients with early stage RCC will relapse within three years of surgical excision of the primary tumor. Although the NCI does not provide prevalence of RCC by stage, based on the NCCN’s three-year relapse rate, we estimate that there may be up to an additional 10,000 to 15,000 cases of mRCC identified annually in the United States. Combining newly diagnosed mRCC patients with patients who relapse, we estimate that there may be between 20,000 to 25,000 new cases of mRCC in the United States each year. We estimate, based on publicly available information, including 2013 quarterly and annual reports of companies that market targeted therapies approved for mRCC, that the current worldwide mRCC market for these targeted therapies exceeds $2 billion.

Physicians generally diagnose mRCC by examining a tumor biopsy under a microscope. Upon evaluation of the visual appearance of the tumor cells, a pathologist will classify the mRCC into clear cell or non-clear cell types. According to the NCCN, approximately 85% of all RCC diagnoses are clear cell RCC. Because clear cell types are the most common type of tumor cell, most of the more recently approved therapies for mRCC have limited their clinical trials to patients with the clear cell type of tumor cell. However, the FDA has not limited the approval of these therapies to clear cell types of mRCC, so they may be used for both clear cell and non-clear cell types.

mRCC Patient Classification

Upon diagnosis, the prognosis for patients with mRCC is classified into three overall disease risk profiles — favorable, intermediate and poor — using objective prognostic risk factors. These risk factors were originally developed by researchers at Memorial Sloan Kettering Cancer Center and subsequently revised by Dr. Heng and contributors from the Consortium based on clinical data from patients treated with sunitinib and other targeted therapies. These risk factors, which we refer to as the Heng risk factors, have been correlated to adverse overall survival in mRCC and include:

- time from diagnosis to the initiation of systemic therapeutic treatment of less than one year, which is indicative of more aggressive disease. We refer to this risk factor as the less than one year to treatment risk factor;
Patients exhibiting zero risk factors at the time of treatment are included in the favorable risk group; patients exhibiting one or two risk factors are included in the intermediate risk group; and patients exhibiting three or more risk factors are included in the poor risk group. Even when treated with standard of care therapies such as sunitinib, patients in the intermediate risk group have an expected survival of less than two years, and patients in the poor risk group have an expected survival of less than one year. In January 2013, Dr. Heng published in *Lancet Oncology* the following data from the Consortium database regarding overall survival of mRCC patients in these three risk groups treated with sunitinib and other targeted therapies:

- in 157 favorable risk patients, the median overall survival was 43 months;
- in 440 intermediate risk patients, the median overall survival was 22.5 months; and
- in 252 poor risk patients, the median overall survival was 7.8 months.

### Current Treatment

The initial treatment for most mRCC patients when the primary tumor is intact is surgical removal of the tumor, usually requiring partial or complete removal of the affected kidney, referred to as nephrectomy. The NCCN generally recommends systemic treatment with approved therapies for mRCC patients following nephrectomy for patients whose tumors have metastasized or for patients who present with mRCC upon diagnosis or as a result of a relapse from an earlier stage of RCC.

Historically, mRCC has been treated with non-specific, cytokine-based immunotherapies such as interferon-α and IL-2, which have demonstrated a clinical benefit in a small number of mRCC patients. However, due to their lack of specificity, these therapies have been demonstrated to have severe toxicities, which can lead to cardiopulmonary, neuropsychiatric, dermatologic, renal, hepatic and hematologic side effects and limits their use. For example, although high-dose IL-2 is the only therapy to have demonstrated durable complete mRCC remissions, its toxicity restricts its use to a small minority of patients and for a short duration.

In the past few years, several targeted therapies, such as Sutent (sunitinib), Votrient (pazopanib), Torisel (temsirolimus), Nexavar (sorafenib), Avastin (bevacizumab) plus interferon-α, Afinitor (everolimus) and Inlyta (axitinib), have been approved for the treatment of mRCC. While most of these targeted therapies have been evaluated in first-line treatment of mRCC, Sutent demonstrated a higher rate of progression free survival and overall survival in its pivotal phase 3 clinical trial than that shown by the other targeted therapies in their pivotal phase 3 clinical trials. According to an independent market research survey conducted during the second half of 2014 of 87 US-based medical oncologists and new prescription data (IMS), Sutent is still the first-line drug of choice for approximately half of newly treated advanced RCC patients. In addition, the data showed that the use of Votrient has been increasing as initial therapy for advanced RCC.

Although most of these targeted therapies have demonstrated prolonged progression free survival as compared to interferon-α, they are rarely associated with durable remissions or enhanced long-term survival, particularly in patients who are classified as intermediate or poor risk at the time of treatment. In addition, each of these targeted therapies has shortcomings that limit their use in the treatment of mRCC, including significant toxicities, such as neutropenia and other hematologic toxicities, fatigue, diarrhea, hand-foot syndrome, hypertension and other cardiovascular effects. The overlapping and combined toxicities of the targeted therapies have prevented their use in combination therapies. For instance, researchers conducting a phase 1 clinical trial of the combination of sunitinib and temsirolimus discontinued the trial due to toxicities. We believe that the inability to date to combine these therapies without additive toxicity and the absence of durable remissions and prolonged survival in patients with intermediate and poor risk disease indicates there is an unmet need for novel therapeutic approaches for mRCC that can improve efficacy without adding any appreciable toxicity.
**AGS-003 Opportunity**

We believe, based on the clinical results of AGS-003, that the combination of AGS-003 with sunitinib or other targeted therapies has the potential to address this unmet need for the following reasons:

- We believe that because the mechanism of action of AGS-003 is unrelated to the mechanism of action of sunitinib or the other targeted therapies, combining AGS-003 with these therapies has the potential to have an additive efficacy benefit.
- We believe that if a combination therapy with AGS-003 shows improved efficacy, the combination could be used as the standard of care for first-line treatment of mRCC in our targeted patient population.
- We believe that the lack of significant toxicity of AGS-003 will enable it to be combined with sunitinib and the other targeted therapies at a full dose for both therapies without added toxicity.
- We believe that, by following an initial cycle of sunitinib with AGS-003 in combination therapy, patients are likely to have a lower metastatic tumor burden, or at least a slowing of tumor progression, at the time of initiation of AGS-003 therapy, making it more likely that AGS-003 would have the opportunity to elicit immune responses and demonstrate an effect on the tumor.
- We believe that continued dosing of sunitinib, as well as certain of the other targeted therapies, decreases regulatory T-cells and myeloid-derived suppressor cells, both of which are immunosuppressive cells known to expand during cancer and suppress T-cell responses. As a result, by combining with these therapies, we believe that AGS-003 may be able to generate more potent T-cell responses.

**Development Status**

We are conducting an ongoing pivotal phase 3 clinical trial of AGS-003. We have conducted three clinical trials of AGS-003 and its predecessor product, MB-002, which include:

- a phase 2 combination therapy clinical trial of AGS-003 in combination with sunitinib;
- a phase 1/2 monotherapy clinical trial of AGS-003; and
- a phase 1/2 monotherapy clinical trial of MB-002.

We submitted to the FDA an investigational new drug application, or IND, for AGS-003 in March 2003.

**Phase 2 Combination Therapy Clinical Trial**. From July 2008 to October 2009, we enrolled 21 newly diagnosed mRCC patients in a single arm, multicenter, open label phase 2 clinical trial of AGS-003 in combination with sunitinib. We conducted this clinical trial at nine clinical sites in the United States and Canada. Our design for the trial required adult patients with previously untreated mRCC, no prior nephrectomy or at least one accessible lesion for biopsy, a histologically confirmed predominantly clear cell tumor, and suitability for sunitinib therapy. The primary endpoint of the trial was complete response rate. Secondary endpoints included progression free survival, overall survival, safety, clinical benefit rate and immune response.

Patients in the trial generally received one initial six-week cycle of sunitinib, consisting of four weeks on drug and two weeks on drug holiday, prior to initiating the combined treatment with AGS-003. Patients then received a dose of AGS-003 every three weeks for a total of five doses, while also continuing three additional six-week cycles of sunitinib. This 24-week induction phase was followed by a booster phase during which patients received a dose of AGS-003 once every three months and continued to receive sunitinib in six-week cycles until disease progression.
The following table summarizes certain key data from the 11 intermediate risk and 10 poor risk patients enrolled in the phase 2 combination therapy clinical trial.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>(N=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS (1)</td>
<td>30.2 months</td>
</tr>
<tr>
<td>Median PFS (2)</td>
<td>11.2 months</td>
</tr>
<tr>
<td>Complete response (3)</td>
<td>0 patients</td>
</tr>
<tr>
<td>Partial response (4)</td>
<td>9 patients</td>
</tr>
<tr>
<td>Stable disease (5)</td>
<td>4 patients</td>
</tr>
<tr>
<td>Immune response</td>
<td>CD8+ CD28+ memory T-cells correlated with OS, PFS and reduced metastatic tumor burden; IL-2 and interferon-γ (IFN-γ) recovery</td>
</tr>
</tbody>
</table>

(1) Overall survival, or OS, is the length of time from the initiation of treatment to the patient’s death.
(2) Progression free survival, or PFS, is the length of time from treatment initiation to the worsening of the patient’s disease or the patient’s death.
(3) Complete response is the disappearance of all measurable target lesions and non-target lesions.
(4) Partial response is the overall tumor regression based on a decrease of at least 30% in the overall amount of measurable tumor mass in the body and improvement or no change in non-target lesions.
(5) Stable disease is neither sufficient decrease in tumor size to qualify as a partial response nor sufficient increase in tumor size to qualify as disease progression.
Particular observations from these data and the trial, which have informed our further clinical development of AGS-003, include:

**Efficacy Analysis**

- Seven patients survived for more than 4.5 years following enrollment in this trial. As of December 31, 2014, three of these seven patients remained alive and continued to be monitored for overall survival. Two of these patients have not progressed and continue to be dosed.

- Five poor risk patients did not receive five doses of AGS-003 due to early disease progression. Median overall survival in the 16 patients who received at least five doses of AGS-003 was 36.0 months.

- Median overall survival in the 11 intermediate risk patients was 61.9 months. Median overall survival in the 10 poor risk patients was 9.1 months.

- The following graphic shows data and follow-up as of December 31, 2014, the number of months that each patient in the phase 2 clinical trial survived from the time of enrollment in the trial. The three patients who remained alive as of December 31, 2014 are indicated by the arrows at the end of the bar. Two of these patients have continued AGS-003 for nearly six years. The five poor risk patients who did not receive five doses of AGS-003 are indicated with an “x” at the end of the bar.

- Of the nine patients who exhibited a partial response, four patients exhibited partial responses during the 24-week induction phase, including two patients who exhibited partial responses prior to initiation of treatment with AGS-003. The other three patients exhibited partial responses after prolonged dosing with AGS-003 during the booster phase. We do not believe that these late occurring partial responses have been observed in clinical trials of sunitinib alone. As a result, we believe that these late responses may relate to the immunologic effects of prolonged AGS-003 dosing and AGS-003’s effect on CD8+ CD28+ memory T-cells.
• We observed a statistically significant correlation between increased progression free survival and prolonged survival (p<0.001). Statistical significance is determined by methods that establish the p-value of the results. Typically, results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-twenty likelihood that the observed results occurred by chance.

**Immune Response Analysis**

• In the 14 patients in the trial who received at least five doses of AGS-003 and could be evaluated for memory T-cell response, we observed a statistically significant correlation between the increase in the number of CD8+ CD28+ memory T-cells over the initial five doses of AGS-003 and survival (p<0.002), progression free survival (p<0.031) and reduced metastatic tumor burden (p<0.045). We presented at the 2013 Annual Meeting of ASCO, Genitourinary Cancers Symposium results, as of May 14, 2012, showing the correlation with survival. The following graphics show, for each of these 14 patients, the increase in their tumor-specific memory T-cells that they exhibited as measured immediately prior to their first dose of AGS-003 and immediately following the patient’s fifth dose of AGS-003, or the absence of such increase, as compared to such patient’s survival.

**Phase 2 Combination Therapy Clinical Trial of AGS-003: Correlation of Immune Response and Overall Survival**

[Diagram showing increase in tumor-specific memory T-cells: Immediately Prior to First Dose Compared to Following Fifth Dose]

[Diagram showing overall survival from initiation of treatment as of May 14, 2012]

• AGS-003 was found to have positive impact on immune cell function and restoration of cellular immunity in a majority of patients, including an increase in levels of IL-2 and IFN-γ.
Safety

- The adverse events in this trial associated with AGS-003 were generally only mild injection site reactions, while the toxicities associated with sunitinib were consistent with those expected from treatment with sunitinib alone.

The original design for the phase 2 clinical trial called for the recruitment of 50 patients to generate 38 fully evaluable patients. However, in October 2009, we terminated enrollment in this trial early due to a lack of funding. As a result, only 21 patients were enrolled and received at least one dose of AGS-003. In addition, the trial was originally designed to enroll patients with favorable and intermediate risk disease profiles. Instead, the actual population enrolled consisted entirely of patients with intermediate or poor risk disease profiles who had the less than one year to treatment risk factor. Because the patient population had poorer prognoses when they entered the trial than we expected and we did not have a sufficient number of evaluable patients, we did not perform the statistical analysis to determine whether the primary endpoint of complete response rate was achieved. As a result, we expect the data from this trial to be considered by the FDA for the purpose of evaluating the safety and feasibility of AGS-003, but that it will only have a limited impact on the FDA’s ultimate assessment of the efficacy of AGS-003.

Based on our experience with the phase 2 clinical trial, we concluded that the secondary endpoints in the trial, progression free survival and overall survival, along with immune response, were the appropriate endpoints to consider for measuring the efficacy of AGS-003 in combination with sunitinib in patients with mRCC in our pivotal phase 3 clinical trial.

AGS-003 Phase 2 Combination Therapy Clinical Trial, as Compared to Independent Third Party mRCC Data. At ASCO in June 2013, Dr. Heng presented data from the Consortium database regarding overall survival and progression free survival for intermediate and poor risk patients treated with sunitinib and other targeted therapies, including data with respect to 1,189 intermediate and poor risk patients with the less than one year to treatment risk factor.

A summary comparison of the overall survival data from the Consortium database presented in June 2013 and our phase 2 clinical trial of AGS-003 in combination with sunitinib is set forth in the graphic below. This graphic compares the median overall survival data from the Consortium intermediate and poor risk patients with the less than one year to treatment risk factor with the median overall survival data from the 21 patients in our phase 2 clinical trial of AGS-003 in combination with sunitinib, all of whom had the less than one year to treatment risk factor. A majority of the Consortium patients and the patients in our phase 2 clinical trial had one or more additional risk factors.

Phase 2 Combination Therapy Clinical Trial of AGS-003:

Comparison of Median Overall Survival Data
Progression free survival for intermediate and poor risk patients in the Consortium database with the less than one year to treatment risk factor was 5.6 months, as compared to the 11.2 months of median progression free survival that we observed in the 21 patients in our phase 2 clinical trial of AGS-003 in combination with sunitinib.

In addition, data published in the British Journal of Cancer in 2013 reported on the long-term survival of 1,059 mRCC patients treated with sunitinib as first-line or second-line therapy in six prior clinical trials of sunitinib, including the pivotal phase 3 clinical trial of sunitinib. The graphic below sets forth, with respect to the approximately 455 patients characterized as intermediate or poor risk patients in the sunitinib trial data published by the British Journal of Cancer, the percentage of patients who survived for more than 30 months from initiation of treatment and, with respect to patients in our phase 2 clinical trial of AGS-003 in combination with sunitinib, the percentage of patients who survived for more than 30 months from enrollment in the trial:

Phase 2 Combination Therapy Clinical Trial of AGS-003:
Comparison of Survival > 30 Months

* The data that was presented in the British Journal of Cancer included data categorized by risk profile group. The number of patients in each risk profile group was presented as a percentage of a total population of 1,059 mRCC patients. Accordingly, the 455 intermediate risk and poor risk patients referenced in this table and elsewhere in this Annual Report on Form 10-K represent an approximation based on those percentages.

Furthermore, in a recent presentation by Dr. Sella during the 2014 ASCO Genitourinary Cancers Symposium, an analysis of median survival for 548 mRCC patients treated with Sutent as first-line (74%) or second-line (26%) therapy, the median survival for patients with 1-2 risk factors was 20.5 months. Notably, for 41% of these subjects who presented with 2 risk factors, their median survival was reduced to 14.1 months. In our phase 2 combination trial, median overall survival for the 11 intermediate risk patients was 61.7 months.

Although we believe comparisons between our data and these collections of data are useful in evaluating the overall results of our phase 2 clinical trial, the treatment of the Consortium patients and the sunitinib patients was conducted at different sites, at different times and in different patient populations than the treatment in our phase 2 combination therapy trial. The treatment also differed because certain of the Consortium patients received therapies other than sunitinib and certain of the patients in the sunitinib trials received sunitinib as a second-line treatment. All of the patients in our phase 2 clinical trial received sunitinib as first-line treatment.

Our ongoing pivotal phase 3 combination therapy clinical trial of AGS-003 is the first trial that we have conducted that directly compares sunitinib and AGS-003 as a combination therapy against sunitinib as monotherapy. Results of this head-to-head comparison may differ significantly from the comparisons presented above and elsewhere in this Annual Report on Form 10-K.

Phase 1/2 Monotherapy Clinical Trial. From April 2006 through October 2008, we enrolled 22 newly diagnosed mRCC patients in a single arm, multicenter, open label phase 1/2 clinical trial of AGS-003 as monotherapy. These patients were enrolled at six sites in the United States and Canada. The trial was designed as a two-stage trial. In stage 1, we would recruit 24 patients to generate at least 18 evaluable patients, and in stage 2, we would recruit an additional 22 patients to generate at least a total of 35 evaluable patients. In order to advance to stage 2 of the trial, we were required to achieve the primary endpoint for stage 1, which was three patients with a complete or partial response. Secondary endpoints included progression free survival, overall survival, safety and immunogenicity.

Our design for the trial required patients to be adults with mRCC with no prior nephrectomy, no history of prior RCC therapy and sufficient renal function in the remaining kidney. The trial was designed to enroll patients with favorable and intermediate risk disease profiles.

In the trial, patients were to be administered a dose of AGS-003 every two weeks for a total of five doses, followed by a dose of AGS-003 every month for an additional four doses during the 24-week induction phase of the trial. These doses were to be followed by booster doses every three months until disease progression. However, due to the approval of sunitinib and sorafenib at the time we were beginning to enroll patients in the trial and the resulting change in the standard of care for mRCC, we experienced delays in enrolling patients in the trial. As a result, we discontinued the trial after enrolling 22 patients and shifted our development focus for subsequent trials to AGS-003 as a combination therapy.
The following table summarizes certain key data from the nine intermediate risk and 13 poor risk patients enrolled in the phase 1/2 monotherapy clinical trial:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>(N=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS</td>
<td>15.6 months</td>
</tr>
<tr>
<td>Median PFS</td>
<td>5.6 months</td>
</tr>
<tr>
<td>Complete response</td>
<td>0 patients</td>
</tr>
<tr>
<td>Partial response</td>
<td>1 patient</td>
</tr>
<tr>
<td>Stable disease</td>
<td>7 patients</td>
</tr>
<tr>
<td>Immune response</td>
<td>IL-2 and IFN-γ recovery</td>
</tr>
</tbody>
</table>

Particular observations from these data and the trial, which have informed our further clinical development of AGS-003, include:

- As of November 30, 2013, one patient, who subsequently was treated with AGS-003 in combination with sunitinib, was still alive nearly seven years after initiation of AGS-003. Four other patients survived for more than 40 months following enrollment in the trial.

- The following graphic shows, as of December 31, 2013, the number of months that each patient in the phase 1/2 monotherapy clinical trial survived following enrollment in the trial. All patients were deceased as of December 31, 2013, except for one patient who was subsequently treated with AGS-003 in combination with sunitinib. This subject was still alive for approximately seven years after initiation of AGS-003, as of follow-up for this subject through late 2013.

- Only three patients received a targeted therapy following treatment with AGS-003, which we believe indicates that the clinical benefit demonstrated in this trial was a result of AGS-003 treatment.

- Despite the intermediate and poor risk population, eight of the evaluable patients experienced some degree of tumor regression at one point during the induction phase of treatment with AGS-003.
AGS-003 was found to have a positive impact on immune cell function and restoration of cellular immunity in a majority of patients, including an increase in levels of IL-2 and IFN-\(\gamma\). We did not measure CD8+CD28+ memory T-cells in this trial as, at the time this trial was conducted, the technology for monitoring CD8+CD28+ memory T-cells had not yet been developed.

AGS-003 was well-tolerated, with adverse events limited to mild injection site reactions, transient flu-like symptoms and tenderness in the lymph nodes.

The graphic below compares the median overall survival data for the Consortium intermediate and poor risk patients with the less than one year to treatment risk factor with the median overall survival data from the 22 patients in our phase 1/2 clinical trial of AGS-003, all of whom had the less than one year to treatment risk factor and a majority of whom had one or more additional risk factors. A majority of the intermediate and poor risk Consortium patients also had one or more additional risk factors.

Phase 1/2 Monotherapy Clinical Trial of AGS-003: Comparison of Median Overall Survival Data

![Phase 1/2 Monotherapy Clinical Trial of AGS-003: Comparison of Median Overall Survival Data](image1)

The graphic below shows the percentage of intermediate and poor risk patients in our phase 1/2 clinical trial who survived for more than 30 months from enrollment in the trial as compared to the percentage of sunitinib-treated intermediate and poor risk mRCC patients who survived for more than 30 months from initiation of treatment as set forth in the British Journal of Cancer report.

Phase 1/2 Monotherapy Clinical Trial of AGS-003: Comparison of Survival > 30 Months

![Phase 1/2 Monotherapy Clinical Trial of AGS-003: Comparison of Survival > 30 Months](image2)
Ongoing and Planned Clinical Development

Pivotal Phase 3 Combination Therapy Clinical Trial. We are currently conducting a pivotal phase 3 clinical trial of AGS-003 plus sunitinib / targeted therapies for the treatment of newly diagnosed mRCC under an SPA with the FDA. We refer to this trial as the ADAPT trial. We initiated the ADAPT trial in January 2013 and dosed the first patient in May 2013.

We have designed this trial to be a randomized, multicenter, open label trial of AGS-003 in combination with sunitinib / targeted therapy compared to sunitinib / targeted therapy monotherapy. We plan to enroll approximately 450 patients in the trial to generate 290 events for the primary endpoint of overall survival. We plan to enroll these patients at approximately 140 clinical sites in North America and Europe. Under the trial protocol, these patients will be randomized between the AGS-003 plus sunitinib / targeted therapy combination arm and the sunitinib / targeted monotherapy control arm on a two-to-one basis. As of February 28, 2015, we had collected tumor from approximately 880 patients for eligibility and had enrolled and randomized approximately 340 patients in the trial. We expect to complete enrollment of the trial by the end of second quarter 2015 and to have data from this trial in the second half of 2016 when we anticipate the required number of events to permit the primary analysis and assessment of overall survival to have occurred. We have established an independent data monitoring committee that will conduct interim analyses of the data from the trial at such times as when approximately 25%, 50% and 75% of the required events in the trial have occurred.

We have designed this trial with a primary endpoint of overall survival. Secondary endpoints include progression free survival, overall response rate and safety. In order to achieve the primary endpoint, results from the trial must demonstrate an increase of approximately six months in median overall survival for the AGS-003 plus sunitinib arm compared to the sunitinib monotherapy arm. Such a result would be statistically significant ($p \leq 0.05$).

Our design for this trial requires adult patients who have been newly diagnosed with mRCC with primary tumor intact and metastatic disease following nephrectomy, who have predominantly clear cell RCC based upon the tumor collected at nephrectomy and who have not received any prior therapies for RCC. Participating patients must be suitable candidates for sunitinib therapy and possess poor risk or intermediate risk disease at presentation, with the less than one year to treatment risk factor and not more than four Heng risk factors in total. As part of the trial design, the two arms of the trial will be balanced based upon known prognostic risk factors. Patients who are randomized will be stratified by number of risk factors (1, 2, 3 or 4) as well as whether they have measurable versus non-measurable metastatic disease following nephrectomy. We expect the patient population in the pivotal phase 3 clinical trial to be generally comparable to the patient population treated in our phase 2 combination therapy clinical trial. However, due to the limit on risk factors provided for by the protocol for the phase 3 clinical trial, we expect that the proportion of patients in the phase 3 clinical trial who are characterized as poor risk will be lower in the phase 3 clinical trial than in the phase 2 clinical trial. As of February 28, 2015, approximately 73% of the patients we had enrolled in the trial were intermediate risk patients (1-2 risk factors) and 27% were poor risk (3-4 risk factors).

Under the trial protocol, patients in the AGS-003 plus sunitinib / targeted therapy arm are dosed with AGS-003 once every three weeks for five doses, followed by a booster dose every three months. In accordance with its label, sunitinib dosing is administered in six-week cycles, consisting of four weeks on drug and two weeks on drug holiday. AGS-003 dosing is initiated at the end of the initial six-week sunitinib cycle. The first dose of AGS-003 is administered prior to the start of sunitinib dosing in the second sunitinib cycle. This dosing regimen is identical to the dosing regimen used in our phase 2 combination therapy clinical trial of AGS-003 and sunitinib, except that the start of the sixth dose is scheduled for week 24 to better provide patients the opportunity to receive a total of eight doses across 48 weeks. Patients in the sunitinib monotherapy control arm receive sunitinib on the same dosing schedule as patients receive sunitinib in the AGS-003-sunitinib combination arm.

Under the trial protocol, AGS-003 is administered for at least 48 weeks so that patients receive at least eight doses of AGS-003. Dosing will cease prior to 48 weeks if two events of disease progression or unacceptable toxicity occur or upon the joint decision of the patient and the investigator. If after 48 weeks of dosing of AGS-003, a patient has stable disease or is responding to treatment, dosing will continue once every three months until disease progression. If an investigator determines to discontinue sunitinib, either due to disease progression or toxicity, the investigator can, at any time during the trial after the first six week cycle of sunitinib, initiate second-line therapy with one of the other approved targeted therapies, including pazopanib, axitinib, everolimus or temsirolimus. In the event of discontinuation of sunitinib for patients in the combination therapy arm, such patients would continue with AGS-003 dosing in combination with the second-line therapy. In our phase 2 combination therapy clinical trial, dosing ceased upon the first event of disease progression and second-line therapy was not permitted.
Other Development Activities. We believe that AGS-003 may be capable of treating a wide range of cancers and are planning to evaluate AGS-003 in clinical trials in additional cancer indications.

- We plan to support an investigator-initiated open label phase 2 clinical trial of AGS-003 in patients with mRCC and non-clear cell, or NCC, histology in the second half of 2015. In the trial, we plan to evaluate the safety, efficacy and immunologic effects of AGS-003 when combined with targeted therapy in approximately 30 to 40 NCC mRCC patients.

- We are supporting two investigator-initiated phase 2 clinical trials, which are designed to evaluate treatment with AGS-003 in patients with early stage RCC prior to and following nephrectomy. The initial study, which will evaluate AGS-003 prior to nephrectomy, (neoadjuvant study) is ongoing. We expect that the second trial, which will evaluate AGS-003 after standard nephrectomy (adjunct RCC study), will begin mid-2015. We expect that between 40 and 50 patients in total will be enrolled across these two trials and that we will have initial data by 2016.

- In addition, we plan to initiate additional investigator-initiated clinical trials of AGS-003 in other advanced solid tumor types, including bladder cancer and non-small cell lung cancer during the second half of 2015.

AGS-004 for the Treatment of Human Immunodeficiency Virus

We are developing AGS-004, our second Arcelis-based product candidate, for the treatment of HIV. We have completed three clinical trials of AGS-004. These include phase 1 and phase 2 clinical trials that were funded by government grants and a phase 2b trial that was funded in full by the NIH.

Based on the clinical data that we have generated to date, we have determined to focus our development program on the use of AGS-004 in combination with other therapies to achieve complete virus eradication and the use of AGS-004 monotherapy to provide long-term control of HIV viral load in immunologically healthy patients and eliminate the need for ART.

Human Immunodeficiency Virus

HIV is characterized by a chronic viral infection and an associated deterioration of immune function. Specifically, the virus disables and kills crucial human immune cells called CD4+ T-cells. CD4+ T-cells are necessary to generate and maintain antiviral T-cells, including the CD8+CD28+ memory T cells that kill virus-infected cells. Over time, this viral impact on an infected person’s immune system outpaces the body’s natural ability to replace CD4+ T-cells and immunodeficiency results. As a result, the longer a person has been infected with the virus, the more functionally impaired these cells become.

At the same time, HIV infection causes the immune cells in HIV patients, including CD4+ T-cells and CD8+ T-cells that are not killed by the virus to be in a chronic state of activation. The persistent state of immune activation in HIV patients results in chronic inflammation. We believe that this inflammation plays a role in the elevated rates of age-related comorbidities, including malignancies and cardiovascular disease observed in HIV patients. In addition, the activation of the CD4+ T-cells supports virus replication which leads to the production of new virus and increased viral load.
HIV is a persistent virus that can rapidly adapt to its environment by mutating and creating HIV variants that are drug resistant and can evade immune attack. As a result, there are a large number of mutated variants of HIV existing in any one infected individual and no two individuals have identical viral sequences.

According to the World Health Organization, the number of people living with HIV in the world was approximately 35 million in 2013. The Centers for Disease Control and Prevention estimates that more than 1.2 million people are currently living with HIV in the United States and the number of new cases of HIV infection in the United States is expected to remain constant at approximately 50,000 cases per year.

Current treatments for HIV. In 1996, a combination of oral medications known as ART was introduced to treat patients with HIV. Since then, the introduction of new drug classes of ART and combination drug treatment strategies has enhanced treatment for HIV.

ART in HIV-infected patients can decrease levels of HIV in the blood to below the limits of detection, increase life expectancy and improve quality of life. However, there continues to be an unmet need for HIV therapies for the following reasons:

- ART can have significant side effects. The most recent U.S. guidelines on ART treatment contain a number of tables of adverse effects of combination regimens and how to manage them. Some combinations present potentially life-threatening complications and other complications that are chronic, cumulative and overlapping, and sometimes irreversible.

- ART requires life-long daily treatment. The risks of long-term daily administration of ART remain unknown but are potentially significant. In addition, the requirement for life-long daily treatment has made strict adherence to the treatment regime difficult. Poor compliance has led to the development of drug resistant HIV variants that are ineffectively controlled by the available armamentarium of ART.

- ART cannot eradicate the virus and, therefore, does not cure HIV-infected patients. For example, up to 20% of patients receiving ART fail to achieve normal CD4+ T-cell counts, resulting in a continued weakened immune system. In addition, certain patients are not able to achieve effective control of the virus using current treatment regimens. ART cannot eradicate the virus because the virus persists in latently infected cells. These cells, which constitute the HIV latent reservoir, do not express HIV antigens and are therefore invisible to the immune system. Instead, these cells serve as the source for virus replication and viral rebound in the absence of ART. Following discontinuation of treatment with ART, HIV viral levels return to levels observed prior to treatment with ART within 12 weeks of treatment interruption.

AGS-004 Opportunity

We believe, based on the mechanism of action of AGS-004 and the clinical data that we have generated, that AGS-004 has the potential to address this unmet need for the following reasons:

- **Potential to Eradicate HIV in Combination with Latency Reversing Drugs**. A number of companies and academic groups are evaluating drugs that can potentially activate the latently infected cells to increase viral antigen expression and make the cells vulnerable to elimination by the immune system. We believe that treating HIV-infected patients, who are being successfully treated with ART, with a combination of AGS-004 and one of these latency reversing drugs could lead to activation of antigen expression from the latently infected cells along with a potent memory T-cell response that is specific to the patient’s own unique viral antigens. We believe that this approach could potentially result in complete eradication of the patient’s virus.

- **Long-Term Viral Load Control in Immunologically Healthy Patients**. We believe that AGS-004 may allow for long-term virus control and eliminate the need for life-long treatment with ART in infected patients who have minimal immune suppression but no T-cell response against their virus. We have designed AGS-004 to induce CD8+ CD28+ memory T-cells that are specific to the patient’s own unique viral antigens, do not require CD4+ T-cell help to kill viral cells and do not result in CD4+ T-cell activation which typically increases viral replication and viral load. As reported in *Clinical & Experimental Immunology*, researchers have demonstrated that elevated levels of CD8+CD28+ memory T-cells in the blood are a statistically significant predictor of long-term non-progression in HIV-infected patients not treated with ART drugs. As a result, we believe that inducing these memory T-cells may lead to viral control. Patients with minimal immune suppression and no T-cell response include pediatric patients who have been successfully treated with ART drugs since birth or shortly thereafter and have generally healthy immune systems.

- **Minimal Toxicity**. AGS-004 has been well tolerated in clinical trials with no serious adverse events being attributed to it. As a result, we believe we can combine AGS-004 with other HIV therapies without additional toxicities.
AGS-004 is a fully personalized immunotherapy based on our Arcelis platform. It is produced by electroporating dendritic cells with mRNA encoding for patient-specific HIV antigens that have been derived from a patient’s virus-infected blood and with RNA that encodes the CD40L protein. The process for producing AGS-004 is the same process as is used to produce AGS-003, with the one key difference being that AGS-003 contains all of the antigens from a patient’s tumor cells while AGS-004 contains all variants unique to each individual patient of four selected HIV antigens (Gag, Nef, Vpr and Rev). We designed AGS-004 to include these antigens because immunity to them has been observed in long-term non-progressors and elite controllers, two groups of rare patients able to control virus replication without ART. Because no two patients share identical HIV antigen sequences and there are a large number of mutated variants of HIV existing in each infected patient, by using mRNA that is specific to the patient’s virus and that captures all of the unique patient-specific variants of each antigen, we believe our immunotherapy maximizes the relevance of the immune responses induced in each patient.

We have conducted three clinical trials of AGS-004, which include:

- a phase 2b clinical trial of AGS-004;
- a phase 2a clinical trial of AGS-004; and
- a phase 1 clinical trial of AGS-004.

We submitted to the FDA an IND for AGS-004 in August 2008.

**Phase 2b Clinical Trial.** We have completed a randomized, placebo controlled, double blind phase 2b clinical trial of AGS-004 in chronically infected patients on ART that we initiated in July 2010. We designed this trial to confirm the data obtained in the phase 2a clinical trial. In September 2013, we completed patient enrollment in the phase 2b clinical trial. We initially planned to enroll 42 chronically infected patients in the trial at nine clinical sites in the United States and Canada with the intent to generate 36 events for the primary endpoint analysis. However, due to a higher than anticipated dropout rate by patients who were unable to complete the full 12 week treatment interruption period provided for by the trial, we needed to enroll 53 patients in the trial to generate 36 events for the primary endpoint analysis. These patients were randomized between AGS-004 treatment and a placebo control on a two-to-one basis.

HIV infection is classified as “chronic” or “acute” based on how long the patient has been infected prior to starting ART. Patients with chronic HIV infection are patients who have initiated ART after at least six months from the time of initial infection. Patients with acute HIV infection are patients who have initiated ART less than 45 days after initial infection. This trial enrolled adult patients with chronic HIV-1 infection and undetectable viral loads as a result of treatment with ART. Patients also had to have adequate CD4+ T-cell counts and a pre-ART plasma viral sample to be used to manufacture AGS-004.
In this trial, patients first received intradermal doses of AGS-004 or placebo every four weeks for a total of four doses, together with their ART. Following the fourth dose of AGS-004 or placebo, patients discontinued their ART but continued to receive AGS-004 or placebo every four weeks for 12 weeks. We refer to this period as the treatment interruption period. Patients who demonstrated control of viral replication under 10,000 copies/ml and maintained CD4+ T-cell counts above 350 cells/mm³ could remain off ART and continue their treatment interruption past 12 weeks. Following the end of treatment interruption, all patients were eligible for continued treatment with the combination of AGS-004 and ART. A schematic of the trial design is shown below.

**Phase 2b Study Design for the Chronically Infected Cohort**

The primary endpoint of the trial was a comparison of the median viral load in the AGS-004-treated patients with the median viral load in patients receiving placebo after 12 weeks of ART treatment interruption. Under this protocol, the primary endpoint required that there was a \( \geq 1.1 \log_{10} \) difference in median viral load between the AGS-004-treated cohort compared to the placebo-treated cohort. A \( 1.1 \log_{10} \) reduction means a 92% lower virus concentration in the AGS-004-treated cohort compared to the placebo-treated cohort. Secondary endpoints included comparisons between AGS-004-treated patients and the patients receiving placebo with respect to change in viral load from pre-ART to the end of 12 weeks of treatment interruption, duration of treatment interruption, changes in CD4+ T-cell counts and safety.

In September 2011, we modified the protocol of the phase 2b clinical trial to add to the trial a single arm, open-label, unblinded cohort of up to 12 patients with acute HIV-1 infection and undetectable viral loads as a result of treatment with ART. We evaluated AGS-004 in this patient population to assess AGS-004 in patients who initiated ART during the acute phase of infection and as a result may have sustained less immune damage. Patients in this cohort were dosed in the same manner as patients in the chronically infected arm of the clinical trial. However, in this cohort, patients had to demonstrate a positive CD8+ CD28+ anti-HIV memory T-cell response in order to become eligible to enter the 12 week treatment interruption period. The primary endpoints for this cohort included the time to detectable viral load during the ART interruption period and comparison of changes in CD4+ T-cell counts during the ART interruption period between the acute cohort and the chronic cohort. Six patients were enrolled in this cohort. All six patients demonstrated a positive CD8+ CD28+ memory T-cell response and initiated treatment interruption. For the five of six patients that re-initiated ART after treatment interruption, there were no significant declines in CD4+ T cells between the interruption date and the re-initiation date. All six patients experienced viral rebound during treatment interruption with the times to detectable viral load ranging from two to eight weeks and the duration of treatment interruption for those patients who reinitiated ART ranged from approximately one month to approximately nine months. In addition, three of six patients had a decrease in circulating CD4+ T cells containing HIV DNA of 25%, 47% and 63%, respectively, when measured after three doses of AGS-004 while on ART.

In the phase 2b trial, 54 patients received the full four doses of AGS-004 or placebo during the first four weeks together with their ART. Of these patients, 36 patients continued on AGS-004 or placebo for the full 12-week treatment interruption period, 23 of whom received AGS-004.

In January 2015, we announced top-line results from the trial. The primary endpoint of the trial was not achieved. However, we believe that data from the trial provided evidence of the ability of AGS-004 to induce memory T-cell responses which may have directly impacted the latent viral reservoir. Of the evaluated 22 patients who received AGS-004 and completed the 12-week treatment interruption period, 15 patients or approximately 70 percent, had positive antiviral memory T-cell responses prior to beginning the treatment interruption versus zero percent of placebo patients. Within the AGS-004 treatment group, those patients that had antiviral memory T-cell responses had significantly fewer CD4+ T-cells with integrated HIV DNA when compared to non-responders. These findings relate directly to the utilization of AGS-004 in our ongoing adult eradication study and our planned pediatric study, where one of the key objectives is to decrease the latent HIV reservoir.
Safety analysis

In this trial, AGS-004 was safe and well tolerated. No AGS-004-related serious adverse events were reported. The most common adverse event was mild injection site reactions. During the antiretroviral treatment interruption, no notable differences in incidence of adverse events occurred compared to when patients were receiving AGS-004 in combination with antiretroviral drug therapy.

Phase 2a Clinical Trial. From 2008 to 2009, we enrolled 29 patients in a single arm, multicenter, open label phase 2a clinical trial of AGS-004. These patients were enrolled at eight clinical sites in Canada. Eight of these 29 patients had previously participated in our phase 1 clinical trial of AGS-004. We refer to these patients as rollover patients.

Despite treatment with ART, HIV persists in latently infected cells, and following discontinuation of treatment, HIV viral levels return to levels observed prior to treatment with ART. We designed the trial in this context to assess the ability of AGS-004 to control viral load after interruption of ART and to prevent viral load levels from returning, following discontinuation of treatment, to pre-ART treatment levels. We believe that the data from the trial demonstrate that AGS-004 can lead to a reduction in virus replication by targeting and eliminating cells that produce new virus.

The primary endpoint of the phase 2a clinical trial was a measurement of the ability of AGS-004 to improve immune control of HIV as measured by the proportion of patients capable of maintaining a minimal HIV viral load of less than 1,000 copies/mL and CD4+ T-cell counts above 350 cells/mm$^3$ on at least three time points during a 12-week ART treatment interruption. FDA guidelines recommend initiation of ART for patients with a CD4+ T-cell count below 350 cells/mm$^3$.

Secondary endpoints included safety, change in viral load from pre-ART to the end of the ART treatment interruption and changes in CD4+ T-cell counts.

To be included in this trial, patients had to be adults with chronic HIV-1 infection and undetectable viral loads as a result of their ongoing treatment with ART. Patients must also have had adequate CD4+ T-cell counts and a pre-ART plasma viral sample to be used to manufacture AGS-004.

Patients initially received four monthly doses of AGS-004, together with their ART. After receiving those doses, ART was discontinued and patients entered into a planned 12-week ART treatment interruption period, which is referred to as a structured treatment interruption, or STI. During the 12-week treatment interruption period, two additional monthly doses of AGS-004 were administered. Patients who maintained plasma viral loads under 10,000 copies/mL and CD4+ T-cell counts above 350 cells/mm$^3$ were eligible to remain off of ART beyond the 12-week treatment interruption period and receive up to two additional booster doses of AGS-004 at eight weeks after the second monthly dose administered during STI and at 12 weeks after the first booster dose. A graphic of the trial design is shown below:

Phase 2a Clinical Trial Design

Outcomes regarding viral load control

In the trial, 24 patients entered into the ART treatment interruption period in accordance with the trial protocol. The trial protocol specified that only patients with CD4+ T-cell counts above 450 cells/mm$^3$ and undetectable viral loads were eligible to enter the ART treatment interruption period. The five patients who did not enter the treatment interruption period according to the trial protocol had CD4+ T-cell counts below 450 cells/mm$^3$.

AGS-004 achieved the primary endpoint of the trial as eight patients maintained HIV viral loads of less than 1,000 copies/ml and CD4+ T-cell counts greater than 350 cells/mm$^3$ during at least three time points measured two weeks apart during the ART treatment interruption period.
In addition, 17 of the 24 patients who entered into the treatment interruption period in accordance with the trial protocol maintained a reduction in their levels of viral load compared to their pre-ART therapy viral load levels. We believe that change in viral load from pre-ART to the end of ART treatment interruption was the most relevant endpoint in the trial to our plans to develop AGS-004 for the eradication of HIV.

The graphic below shows the change in viral load from immediately prior to the commencement of ART for all 24 patients who entered the 12-week treatment interruption phase of the trial. For patients who did not complete the 12-week treatment interruption phase, the last viral load measurement prior to the patient restarting ART was used for the calculation.

Phase 2a Clinical Trial:
Change in Viral Load at Antiretroviral Therapy Restart or Completion of 12-week Treatment Interruption for All Patients Entering Antiretroviral Treatment Interruption per Protocol

The patients who entered the treatment interruption period in accordance with the trial protocol had a mean reduction of 81% in viral load after completion of 12 weeks of ART drug interruption or prior to restart of ART compared to their viral loads measured before the initiation of ART. The mean reduction in the four rollover patients who entered the 12-week ART treatment interruption in accordance with the trial protocol was 97%. Based on the results in the rollover patient subgroup, we believe that administration of more than four doses of AGS-004 prior to ART treatment interruption may lead to better viral load control after cessation of ART treatment.

In addition, we measured CD4+ T-cell count as a secondary endpoint in the trial. Of the 24 patients entering the 12-week antiretroviral treatment interruption, 21 patients maintained CD4+ T-cell counts above 350 cells/mm$^3$ and completed 12 weeks of treatment interruption.

Safety analysis

In this trial, AGS-004 was safe and well tolerated. No AGS-004-related serious adverse events were reported. The most common adverse event was mild injection site reactions. During the antiretroviral treatment interruption, no notable differences in incidence of adverse events occurred compared to when patients were receiving AGS-004 in combination with antiretroviral drug therapy.

Retrospective analysis regarding impact on anti-HIV immunity and HIV latent reservoirs

Latently infected cells differ from other infected cells in that the HIV genome is permanently integrated into the chromosomal DNA of the latently infected cells. These latently infected cells persist long-term and constitute the HIV latent reservoir, which serves as a source for low level virus replication and viral rebound in the absence of antiretroviral therapy. As a result, demonstration that latently infected cells can be targeted by immune responses induced by AGS-004 is essential to our development strategy pertaining to virus eradication.
Following the phase 2a clinical trial, we conducted a retrospective analysis of the effect of AGS-004 on cells harboring chromosomally integrated HIV DNA. We conducted this analysis in the 20 patients from the trial who had blood cells available prior to AGS-004 treatment and after the first four monthly doses of AGS-004 during continuous antiretroviral therapy. In the analysis, we observed that although the impact of AGS-004 on CD4+ T-cells with integrated HIV DNA in the 20 patient population was not statistically reduced, in the five rollover patients we analyzed, there was an average of a 23.3% reduction in CD4+ T-cells with integrated HIV DNA from the first measurement to the final dose of AGS-004. We believe that these data may indicate that administering more doses of AGS-004 during antiretroviral drug therapy may result in more efficient targeting of latently infected cells, a desirable property for our development strategy regarding eradication.

In addition, we analyzed archived pre- and post-AGS-004 administration blood draws from a subset of patients in this trial for HIV-specific T cell responses (N=7) and for PD-1 expression on activated CD8+ T cells (N=6). Results from these blood draws showed that AGS-004 induced anti-HIV 1 memory stem cell-like immune responses (T_SCM) that were associated with a longer time to viral rebound after ART treatment interruption. Longer times to viral rebound were also associated with lower expression of the checkpoint inhibitor PD-1 on activated CD8+ T cells.

**Phase 1 Clinical Trial.** From 2006 to 2007, we enrolled ten patients in a first-in-man single arm, single center, open label phase 1 clinical trial of AGS-004. The primary endpoint of this trial was the ability of AGS-004 to generate anti-HIV CD8+ CD28+ memory T-cell responses. The secondary endpoint was the safety of AGS-004 in combination with antiretroviral therapy. The inclusion and exclusion criteria were substantially similar to those for the phase 2a clinical trial of AGS-004. In the trial, patients received four doses of AGS-004 one month apart. This trial met its predefined endpoint of demonstrating CD8+ CD28+ memory T-cell responses against multiple HIV antigens in four of the nine patients whose materials were available for testing. AGS-004 was well-tolerated, with adverse events limited to mild injection site reactions, transient flu-like symptoms and tenderness in the lymph nodes.

Following completion of the phase 1 clinical trial, we completed a retrospective analysis of the contribution of AGS-004 to chronic inflammation using archived blood samples collected from patients during this trial. In this analysis, we assessed changes in CD4+ T-cells and CD8+ T-cells and analyzed the levels of immune activation based on markers for proliferation and cell activation before and after AGS-004 administration. This analysis showed that AGS-004 did not induce changes in the proportion of CD4+ and CD8+ T-cells compared to levels of such T-cells measured prior to AGS-004 administration and did not cause any elevation in systemic T-cell immune activation. We believe that these data indicate that AGS-004 is capable of inducing antiviral immune responses without an associated increase in markers associated with chronic inflammation.

**Adult Eradication Trial.** We are supporting an investigator-initiated phase 2 clinical trial of AGS-004 in adult HIV patients who are being treated with ART to evaluate the use of AGS-004 to eradicate the virus. The trial is being conducted by Dr. David Margolis, Professor of Medicine at the University of North Carolina. Dr. Margolis is the leader of the Collaboratory of AIDS Researchers for Eradication, or CARE, and has been a pioneer in the research of HIV latent reservoirs reversing treatments. The trial is being conducted in two stages. In the first stage, which is currently ongoing, HIV-infected patients are receiving AGS-004 while remaining on ART and the kinetics of the anti-HIV CD8+ CD28+ memory T-cell responses are being evaluated. In the second stage, the use of AGS-004 in combination with the latency reversing drug Vorinostat will be evaluated. The Stage 2 clinical protocol has been submitted to the FDA and is currently under review. In addition a decision by the NIH to fund clinical costs for Stage 2 is expected in second quarter 2015. CARE is funding all patient clinical costs for the first stage of this phase 2 clinical trial, except for the associated manufacturing costs for which we are responsible.

**Planned Pediatric Functional Cure Trial.** We believe that a patient population that could benefit from AGS-004 monotherapy consists of 14+ year old, HIV-infected individuals who have been treated with antiretroviral therapy since birth or shortly thereafter. These individuals are characterized by having very small HIV latent reservoirs and otherwise healthy immune systems, while lacking antiviral CD8+ CD28+ memory T-cell responses. We believe that successfully inducing antiviral CD8+ CD28+ memory T-cell responses in these patients could allow for long-term viral load control and eliminate the need for life-long antiretroviral therapy. We plan to support an investigator-initiated phase 2 clinical trial of AGS-004 in pediatric HIV patients in the second half of 2016 to evaluate the use of AGS-004 monotherapy to allow for long-term control of viral load and eliminate the need for antiretroviral therapy. We are currently developing the clinical protocol for this trial in the second half of 2015 to immunize pediatric HIV patients who were infected at birth and treated with antiretroviral therapy at or near birth. We are developing this clinical protocol in collaboration with Drs. Katherine Luzuriaga, University of Massachusetts, and Deborah Persaud, John Hopkins Medical Center, both specializing in pediatric virology. We are discussing with the NIH the protocol for this trial and the potential funding by the NIH of the costs of this trial. We plan to initiate this trial in the second half of 2015 if the protocol and the funding are approved.

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Our development of AGS-004 has received significant funding from the U.S. federal government. In September 2006, we entered into a multi-year research contract with the NIH and the National Institute of Allergy and Infectious Diseases, or NIAID, to design, develop and clinically test an autologous HIV immunotherapy capable of eliciting therapeutic immune responses. We are using funds from this contract to develop AGS-004. Under this contract, as it has been amended, the NIH and the NIAID have committed to fund up to $39.8 million, including reimbursement of our direct expenses and allocated overhead and general and administrative expenses of up to $38.4 million and payment of specified amounts totaling up to $1.4 million upon our achievement of specified development milestones. We have recorded total revenue of $36.8 million through December 31, 2014 under the NIH agreement. As of December 31, 2014, there was up to $3.0 million of potential revenue remaining to be earned under the agreement. This commitment extends until July 2016.

We have agreed to a statement of work under the contract, and are obligated to furnish all the services, qualified personnel, material, equipment, and facilities, not otherwise provided by the U.S. government, needed to perform the statement of work. In accordance with the laws applicable to government intellectual property rights under federal contracts, we have a right under our contract with the NIH to elect to retain title to inventions conceived or first reduced to practice under the NIH contract, subject to the right of the U.S. government to a royalty-free license to practice or have practiced for or on behalf of the United States the subject invention throughout the world. The government also has special statutory “march-in” rights to license or to require us to license such inventions to third parties under limited circumstances. In addition, we may not grant to any person the exclusive right to use or sell any such inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.

Other Programs

In addition to our development of AGS-003 and AGS-004 and our Arcelis-based platform, we are also developing AGS-009, a humanized anti-Interferon-α monoclonal antibody, for the treatment of systemic lupus erythematosus, or lupus, a chronic and disabling autoimmune disorder, and AGS-010, a recombinant human soluble CD83 protein, for organ and tissue transplantation and the treatment of autoimmune and inflammatory diseases. We discovered AGS-009 through our dendritic cell biology research. AGS-010 is the result of our research efforts into how the ability to turn off specific undesirable immune responses can have a therapeutic effect on all immune mediated diseases, including transplant rejection and autoimmune and inflammatory diseases. We plan to seek third party funding to fund the further development of AGS-009 and AGS-010.

Manufacturing

We currently manufacture our Arcelis-based products, AGS-003 and AGS-004, for use in our clinical trials of those product candidates at our facility in Durham, North Carolina. Our facility includes manufacturing suites for the production of products using our Arcelis technology platform. We have designed these suites to comply with the FDA’s current good manufacturing practice, or cGMP, requirements. We have manufactured the product for our development and clinical trial activities associated with AGS-003 and AGS-004 to date, and are manufacturing the product for our ongoing pivotal phase 3 combination therapy trial of AGS-003 using our current processes at our current facility. In order to produce AGS-003 on a commercial scale, we will require a full scale manufacturing facility and updated processes. Accordingly, we plan to establish automated manufacturing processes based on existing functioning prototypes of automated devices and build out and equip a new commercial manufacturing facility currently under construction for manufacture of our Arcelis-based products. As part of our BLA for AGS-003, we will need to demonstrate analytical comparability between AGS-003 that we produce using our current manual processes in our current facility and AGS-003 produced using the automated processes in our new facility.

In August 2014, we entered into a lease agreement with a developer for an approximately 120,000 square-foot building to be constructed in Durham County, North Carolina. This facility will house our corporate headquarters and commercial manufacturing. The shell of the new facility is being constructed on a build-to-suit basis in accordance with agreed upon specifications and plans. We expect the shell of the facility will be completed by the end of June 2015 after which the interior of the facility will be built out and equipped. Under the lease agreement, in February 2015, we exercised our option to purchase the property and entered into a Purchase and Sale Agreement with the developer. The purchase price to be paid by us is $7.6 million plus the amount of any additional costs incurred by the developer as a result of changes requested by us and the amount of any improvement allowances advanced to us by the developer prior to the closing. We expect the purchase of the property to close in the second half of 2015. Upon the closing, the lease agreement will terminate. We have reached agreement with governmental authorities for financial support in connection with building the facility and are seeking to enter into additional arrangements that provide additional financial support. We expect such additional arrangements will likely involve the incurrence of material obligations and debt liabilities.
We plan to establish automated manufacturing processes based on existing functioning prototypes of automated devices for the production of commercial quantities of our Arcelis-based product. These devices can be used to perform substantially all steps required for the manufacture of our Arcelis-based product candidates.

We plan to implement the automated processing in a modular and scalable manufacturing system in the new commercial facility. The modular facility design allows for expansion of the commercial capacity in line with the market demand of our product candidates. We believe that this modular approach will require less capital investment at product launch as manufacturing capacity can be increased incrementally as product demand increases after commercialization. We believe the modular manufacturing approach is optimal for personalized immunotherapies and allows for scalable capacity, minimizes facility size and complexity at launch, and results in a lower cost of goods for the commercial product.

In the new facility, we plan to use the automated equipment to perform Arcelis product processing in closed, single-use disposable containers. A patient’s disease sample would only be in contact with these disposable sets or containers and not with any component of our manufacturing equipment. Because our equipment would never be in direct contact with patient material, we believe that the time required to prepare the equipment between batches would be minimal. We also believe that automated processing of material in disposable containers will reduce the complexity and size of the facility by reducing the amount of required labor. We expect that automation will help ensure consistency of the manufacturing processes and facilitate compliance with cGMP.

Prior to implementing automated manufacture of AGS-003, we will be required to demonstrate that the new facility and the automated equipment are constructed and operated in accordance with cGMP. We will also be required to show the comparability between AGS-003 that we produce using the manual processes in our current facility and AGS-003 produced using the automated processes in our new facility. We plan to complete the build out, equipping and validation of the new facility by the end of 2016 prior to filing a BLA and initiating commercial launch.

In addition to providing commercial scale manufacturing of AGS-003, we believe that this facility and automated process will provide us key advantages, including:

- centralized manufacturing capable of delivering products to clinical sites throughout North America;
- automated manufacturing platform that is scalable for large disease indications; and
- manufacturing with a cost of goods that we expect will be comparable to other biologics and methods that are scalable, consistent and broadly applicable across patients and indications.

We have granted exclusive manufacturing rights for AGS-003 to Pharmstandard in Russia and the other states comprising the Commonwealth of Independent States, to Green Cross in South Korea and to Medinet in Japan. We have also agreed to enter into an agreement with Pharmstandard for the manufacture of AGS-003 in the European market.

Sales and Marketing

We hold exclusive commercial rights to all of our product candidates in all geographies other than rights to AGS-003 in Russia and the other states comprising the Commonwealth of Independent States, which are held by Pharmstandard, and rights to AGS-003 in South Korea, which are held by Green Cross. We have granted to Medinet an exclusive license to manufacture in Japan AGS-003 for the treatment of mRCC and an option to acquire a non-exclusive license to sell in Japan AGS-003 for the treatment of mRCC. We currently intend to retain North American marketing rights for AGS-003 and any future oncology products that we may develop. To maximize the value of these rights, we would expect to build a commercial infrastructure for such products comprised of a medical, marketing and sales team as well as a specialty distribution team to manage the logistics associated with AGS-003 production and distribution. Our commercial infrastructure would also include personnel who manage reimbursement activities with third party payors, such as managed care organizations, group purchasing organizations, oncology group networks and government accounts. We plan to hire selected personnel to fill key positions in advance of the approval of AGS-003. We currently have no sales and marketing or distribution capabilities or in-house personnel specializing in these functions. Outside North America, we plan to seek to enter into collaboration agreements with other pharmaceutical or biotechnology firms to commercialize AGS-003.

For AGS-004, we plan to seek to enter into collaboration agreements with other pharmaceutical or biotechnology firms to commercialize this product candidate on a worldwide basis.
Competition

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to or competitive with our products. 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 indications as our product candidates. It is probable that the number of companies seeking to develop products and therapies for the treatment of unmet needs in these indications will increase. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approaches, and others are based on entirely different approaches.

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 product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. 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. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third party payors.

mRCC

Historically, mRCC was treated with chemotherapy, radiation and hormonal therapies, as well as cytokine-based therapies such as interferon-α and IL-2. More recently, the FDA has approved several targeted therapies as monotherapies for mRCC, including Nexavar, marketed by Bayer Healthcare Pharmaceuticals, Inc. and Onyx Pharmaceuticals, Inc., Sutent and Inlyta, marketed by Pfizer, Inc., Avastin, marketed by Genentech, Inc., a member of the Roche Group, and Votrient, marketed by GlaxoSmithKline. Other recently approved targeted therapies for the treatment of mRCC are Torisel, marketed by Pfizer, and Afinitor, marketed by Novartis Pharmaceuticals Corporation. We believe that each of these existing therapies has efficacy or safety limitations and, as a result, that there remains an unmet need for novel therapeutic approaches for mRCC that can improve efficacy without adding appreciable toxicity. We believe that the safety profile that AGS-003 has demonstrated to date, which may enable it to be used in combination with these therapies with little or no additional toxicities, gives AGS-003 the potential to address this unmet need. Accordingly, existing therapies with which AGS-003 would be used as part of a combination would not be competitive with AGS-003. However, a standalone therapy for mRCC that demonstrated improved efficacy over currently marketed therapies with a favorable safety profile and without the need for combination therapy might pose a significant competitive threat to AGS-003.

Immatics Biotechnologies GmbH is developing a therapeutic cancer vaccine, IMA-901, which is a mixture of defined tumor-associated peptides, for the treatment of RCC. Immatics is conducting a pivotal phase 3 clinical trial comparing IMA-901 in combination with sunitinib against sunitinib alone in a subset of favorable and intermediate risk patients. If this clinical trial is successful, IMA-901 and sunitinib combination therapy would be in direct competition with AGS-003 and sunitinib combination therapy. Immatics could have a competitive advantage if it is able to introduce its product to the market before the time, if any, at which we receive marketing approval for AGS-003.

We estimate that there are numerous other cancer immunotherapy products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. A number of these product candidates are in late-stage clinical development or have recently been approved in different cancer types including two recently approved checkpoint inhibitor-based immunotherapies, Nivolumab which is marketed by Bristol-Myers Squibb and Pembrolizumab which is marketed by Merck.

HIV

There are numerous FDA-approved treatments for HIV, primarily antiretroviral therapies, marketed by large pharmaceutical companies. In addition, generic competition has recently developed as patent exclusivity periods for older drugs have expired, with more than 15 generic bioequivalents currently on the market. The presence of these generic drugs is resulting in price pressure in the HIV therapeutics market. Currently, there are no approved therapies for the eradication of HIV. We expect that major pharmaceutical companies that currently market antiretroviral therapy products or other companies that are developing HIV product candidates may seek to develop products for the eradication of HIV.
**Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our products and product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We are seeking a range of patent and other protections for our product candidates and platform technology. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

**Patents**

We own or exclusively license 12 U.S. patents and eight U.S. patent applications, as well as approximately 60 foreign counterparts, covering our Arcelis technology platform and Arcelis-based product candidates.

We use our Arcelis technology platform to generate fully personalized mRNA-loaded dendritic cell immunotherapies. As described above, the process of obtaining a disease sample and dendritic cells from a patient, using those materials to manufacture a fully personalized drug product and shipping the drug product to the clinical site for use in the treatment of the patient involves many important steps. These steps include:

- amplifying mRNA from a disease sample obtained from the patient;
- differentiating dendritic cell precursors (monocytes) isolated from the patient into immature dendritic cells;
- maturing the immature dendritic cells in culture and loading the mature dendritic cells with the amplified mRNA and CD40L protein; and
- formulating the matured, loaded dendritic cells in the patient’s plasma with cryoprotectants to protect the cells in the resulting drug product when the drug product is frozen and thawed.

We have sought to protect these steps or the equipment related to carrying out one or more of these steps through patents or trade secrets. We have also sought to protect the resultant drug product through patents.

These patents and patent applications are directed to one or more aspects of our Arcelis technology platform or Arcelis-based products. Specifically, these patents and patent applications are collectively directed to:

- Arcelis-based compositions of matter and products;
- methods of manufacturing Arcelis-based products;
- methods of using Arcelis-based products for treatment of tumors;
- compositions that we use in the manufacture of Arcelis-based AGS-004 products; and
- equipment that we intend to use for assisting the automated manufacture of Arcelis-based products.

We believe that all of the above aspects of our Arcelis technology platform are required to successfully produce our Arcelis-based product candidates and are covered by a combination of our patents, patent applications, trade secrets and know-how. The U.S. patents expire between 2016 and 2028, and the U.S. patent applications, if issued, would expire between 2016 and 2029, the counterpart patents in Europe and Japan expire between 2017 and 2028, and the counterpart patent applications in Europe and Japan, if issued, would expire between 2017 and 2027. Included in these patents and patent applications are:

- five U.S. patents and one U.S. patent application that are collectively directed toward the composition of matter of Arcelis-based products (dendritic cells loaded with RNA from tumors or pathogens), methods of manufacture of these products and methods of using these products to treat tumors. Each of the five U.S. patents encompass the AGS-003 composition of matter. One of the five U.S. patents encompasses the AGS-004 composition of matter. The U.S. patents expire in 2016 and the U.S. patent application, if issued, would expire in 2016. Corresponding patents in Europe and Japan and a pending corresponding patent application in Europe, if issued, would expire in 2017.

- three U.S. patents, one U.S. patent application and corresponding patent application in Europe and patent in Japan collectively directed towards an automated apparatus for the manipulation of nucleic acids in a closed container, components thereof and related methods of use. The U.S. and Japanese patents expire in 2027, and the patent applications in the United States and Europe, if issued, would expire in 2027.

In addition, if the use of Arcelis-based products for the treatment of RCC and HIV are approved by the FDA, then, depending upon factors such as the timing and duration of FDA review and the timing and conditions of FDA approval, as well as factors such as patent claim scope, some of our issued U.S. patents (or patents that may issue from our pending U.S. patent applications) may be eligible for limited patent term extension under the Hatch-Waxman Act.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of the process by which we manufacture our Arcelis-based drug product candidates are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Key Licenses

We are party to a number of license agreements that are important to our business.

Duke University. Pursuant to a 2000 agreement with Duke University, we hold an exclusive worldwide license to specified patents, patent applications and know-how owned or otherwise controlled by Duke, including for use in the development, manufacture and commercialization of dendritic cells loaded with tumor or pathogen RNA. Under the agreement, we:

- must pay all costs of prosecution and maintenance of the licensed patent rights;
- must pay an annual minimum royalty to Duke beginning with the calendar year beginning the second January 1 after first approval of a licensed product approved by the FDA or a comparable regulatory authority in a foreign country or any sale of a licensed product that does not require regulatory approval; and
- must pay low single-digit percentage royalties, subject to reduction in specified circumstances, to Duke on net sales of licensed products, which are creditable against the annual minimum royalty.

We are required to use reasonable commercial diligence to research, develop and market licensed products, to develop manufacturing capabilities, and to sublicense those patent rights for applications which we are not pursuing. If we fail to satisfy these obligations and do not cure such failure after receiving written notice from Duke, Duke may terminate the agreement or convert it to a nonexclusive license.

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We may terminate our agreement with Duke at any time upon three months’ written notice. The agreement will terminate upon expiration of the last to expire of the patent rights licensed under the agreement. The U.S. patents licensed under the agreement expire in 2016 and the patents licensed under the agreement in Europe and Japan expire in 2017. Either party may terminate the agreement upon written notice for fraud, willful misconduct or illegal conduct of the other party that materially adversely affects the terminating party. If either party fails to fulfill any of its material obligations under the agreement, subject to a cure process specified in the agreement, the non-breaching party may terminate the agreement. A party’s ability to cure a breach will only apply to the first two breaches. In addition, the agreement will terminate if we become insolvent, bankrupt or placed in the hands of a receiver or trustee.

Celldex Therapeutics, Inc. In July 2011, we entered into an agreement with Celldex Therapeutics, Inc., or Celldex, pursuant to which Celldex granted us a non-exclusive license to specified patents and patent applications directed to compositions and methods for processing dendritic cells. Upon the execution of the agreement, we paid Celldex $50,000 of a $100,000 upfront license fee. We paid the balance of this fee on January 31, 2012. Under this agreement, we must pay:

- a $75,000 annual license fee;
- a specified milestone payment based on the achievement of a specified regulatory milestone; and
- a specified dollar amount per dose of AGS-003 we sell.

We may terminate our agreement with Celldex at any time upon notice to Celldex. We or Celldex may terminate the agreement, subject to a cure period specified in the agreement, upon a material breach of the other party by providing written notice and waiting a specified period. The agreement will terminate upon the expiration of the last to expire of the patent rights licensed under the agreement on country-by-country basis. The latest date of expiration of the licensed Celldex patents is 2016.

Development and Commercialization Agreements

An important part of our business strategy is to enter into arrangements with third parties for the development and commercialization of our product candidates.

Pharmstandard. In August 2013, in connection with the purchase of shares of our series E preferred stock by Pharmstandard International S.A., or Pharmstandard, we entered into an exclusive royalty-bearing license agreement with Pharmstandard. Under this license agreement, we granted Pharmstandard and its affiliates a license, with the right to sublicense, to develop, manufacture and commercialize AGS-003 and other products for the treatment of human diseases, which are developed by Pharmstandard using our personalized immunotherapy platform, in the Russian Federation, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, which we refer to as the Pharmstandard Territory. We also provided Pharmstandard with a right of first negotiation for development and commercialization rights in the Pharmstandard Territory to specified additional products we may develop.

Under the terms of the license agreement, Pharmstandard licensed us rights to clinical data generated by Pharmstandard under the agreement and granted us an option to obtain an exclusive license outside of the Pharmstandard Territory to develop and commercialize improvements to our Arcelis technology generated by Pharmstandard under the agreement, a non-exclusive worldwide royalty-free license to Pharmstandard improvements to manufacture products using our Arcelis technology and a license to specified follow-on licensed products generated by Pharmstandard outside of the Pharmstandard Territory, each on terms to be negotiated upon our request for a license. In addition, Pharmstandard agreed to pay us pass-through royalties on net sales of all licensed products in the low single digits until it has generated a specified amount of aggregate net sales. Once the net sales threshold is achieved, Pharmstandard will pay us royalties on net sales of specified licensed products, including AGS-003, in the low double digits below 20%. These royalty obligations last until the later of the expiration of specified licensed patent rights in a country or the twelfth anniversary of the first commercial sale in such country on a country by country basis and no further royalties on specified other licensed products. After the net sales threshold is achieved, Pharmstandard has the right to offset a portion of the royalties Pharmstandard pays to third parties for licenses to necessary third party intellectual property against the royalties that Pharmstandard pays to us.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid up perpetual exclusive licenses. Either party may terminate the agreement for the other party’s uncured material breach or if specified conditions occur relating to the other party’s insolvency or bankruptcy and we may terminate the agreement if Pharmstandard challenges or assists a third party in challenging specified patent rights of ours. If Pharmstandard terminates the agreement upon our material breach or bankruptcy, Pharmstandard is entitled to terminate our licenses to improvements generated by Pharmstandard, upon which we may come to rely for the development and commercialization of AGS-003 and other licensed products outside of the Pharmstandard Territory, and Pharmstandard is entitled to retain its licenses from us and to pay us substantially reduced royalty payments following such termination.
In November 2013, we entered into an agreement with Pharmstandard under which Pharmstandard purchased additional shares of our series E preferred stock. Under this agreement, we agreed to enter into a manufacturing rights agreement for the European market with Pharmstandard and that the manufacturing rights agreement would provide for the issuance of warrants to Pharmstandard to purchase 499,788 shares of our common stock at an exercise price of $5.82 per share. As of February 28, 2015, we had not entered into this manufacturing rights agreement or issued the warrants.

Green Cross. In July 2013, in connection with the purchase of our series E preferred stock by Green Cross Corp., or Green Cross, we entered into an exclusive royalty-bearing license agreement with Green Cross. Under this agreement we granted Green Cross a license to develop, manufacture and commercialize AGS-003 for mRCC in South Korea. We also provided Green Cross with a right of first negotiation for development and commercialization rights in South Korea to specified additional products we may develop.

Under the terms of the license, Green Cross has agreed to pay us $500,000 upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $500,000 upon the initial regulatory approval of a licensed product in South Korea and royalties ranging from the mid-single digits to low double digits below 20% on net sales until the fifteenth anniversary of the first commercial sale in South Korea. In addition, Green Cross has granted us an exclusive royalty-free license to develop and commercialize all Green Cross improvements to our licensed intellectual property in the rest of the world, excluding South Korea, except that, as to such improvements for which Green Cross makes a significant financial investment and that generate significant commercial benefit in the rest of the world, we are required to negotiate in good faith a reasonable royalty that we will be obligated to pay to Green Cross for such license. Under the terms of the agreement, we are required to continue to develop and to use commercially reasonable efforts to obtain regulatory approval for AGS-003 in the United States.

The agreement will terminate upon expiration of the royalty term, which is 15 years from the first commercial sale, upon which all licenses will become fully paid up perpetual non-exclusive licenses. Either party may terminate the agreement for the other party’s uncured material breach or if specified conditions occur relating to the other party’s insolvency or bankruptcy and we may terminate the agreement if Green Cross challenges or assists a third party in challenging specified patent rights of ours. If Green Cross terminates the agreement upon our material breach or bankruptcy, Green Cross is entitled to terminate our licenses to improvements and retain its licenses from us and to pay us substantially reduced milestone and royalty payments following such termination.

Medinet. In December 2013, we entered into a license agreement with Medinet Co., Ltd. which was novated, amended and restated between the Company, Medinet Co., Ltd. and MEDcell Co., Ltd. in October 2014. Pursuant to the novation, Medinet Co., Ltd. assigned and transferred all of its rights and obligations under the original license agreement to MEDcell Co., Ltd. without any substantive change in the underlying rights or obligations. References to Medinet in this Form 10-K refer to Medinet Co., Ltd. prior to the novation and MEDcell Co., Ltd. from after the novation. Under this agreement, we granted Medinet an exclusive, royalty-free license to manufacture in Japan AGS-003 and other products using our Arcelis technology solely for the purpose of the development and commercialization of AGS-003 and these other products for the treatment of mRCC. We refer to this license as the manufacturing license. In addition, under this agreement, we granted Medinet an option to acquire a nonexclusive, royalty-bearing license under our Arcelis technology to sell in Japan AGS-003 and other products for the treatment of mRCC.

We refer to the option as the sale option and the license as the sale license.

Under the manufacturing license, if Medinet does not exercise the sale option, Medinet may only manufacture AGS-003 and these other products for us or our designee. If Medinet does not exercise the sale option, we and Medinet have agreed to negotiate in good faith a supply agreement under which Medinet would supply us or our designee with AGS-003 and these other products for development and sale for the treatment of mRCC in Japan. If Medinet exercises the sale option, it may only manufacture AGS-003 and these other products for itself, its related parties and its sublicensees. During the term of the manufacturing license, we may not manufacture AGS-003 or these other products for us or any designee for development or sale for the treatment of mRCC in Japan.

Medinet may exercise the option at any time until the earlier of December 31, 2015 and the date 30 days after we have provided Medinet with an interim report on our phase 3 clinical trial of AGS-003 following such time as 50% of the required events in the trial have occurred.

In consideration for the manufacturing license, Medinet paid us $1.0 million. Medinet also loaned us $9.0 million in connection with us entering into the agreement. We have agreed to use these funds in the development and manufacturing of AGS-003 and the other products. Medinet also agreed to pay us milestone payments of up to a total of $9.0 million upon the achievement of developmental and regulatory milestones and $5.0 million upon the achievement of a sales milestone related to AGS-003 and these products. If Medinet exercises the sale option, it will pay us $1.0 million, as well as royalties on net sales at a rate to be negotiated until the later of the expiration of the licensed patent rights in Japan and the twelfth anniversary of the first commercial sale in Japan. If we cannot agree on the royalty rate, we have agreed to submit the matter to arbitration.
We borrowed the $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0 % per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. We have the right to prepay the loan at any time. If we have not repaid the loan by December 31, 2018, then we have agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 31, 2018 will constitute pre-paid royalties under the license and will not be otherwise due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If we cannot agree on the royalty rate, we have agreed to submit the matter to arbitration.

Under the agreement, we have the right to revoke both the manufacturing license and the sale license to be granted to Medinet or the sale license only. If we exercise this right, we will be obligated to make a one-time payment to Medinet calculated based on the nonroyalty payments made to us by Medinet under the agreement, repay the outstanding amount due under the loan and assume certain obligations of Medinet, and Medinet will be obligated to assist us in transitioning the relevant rights in Japan to us or a party that we designate. If we exercise our revocation right with respect to the sale license only, the one-time payment will equal the total amount of nonroyalty payments. If we exercise our revocation right with respect to the manufacturing license and the sale license, the one-time payment will equal 150% or 200% of the nonroyalty payments depending on the timing of the exercise of the revocation right.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid up, perpetual non-exclusive licenses. Either party may terminate the agreement for the other party’s uncured material breach or if specified conditions occur relating to the other party’s insolvency or bankruptcy, and we may terminate the agreement if Medinet challenges or assists a third party in challenging specified patent rights of ours. If Medinet terminates the agreement upon our material breach or bankruptcy, Medinet is entitled to terminate our licenses to improvements and retain its royalty-bearing licenses from us.

Invetech. On October, 29, 2014, we entered into a development agreement with Invetech Pty Ltd, or Invetech. The development agreement supersedes and replaces the development agreement entered into by the parties as of July 20, 2005. Under the development agreement, Invetech agreed to continue to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products, or the Production Systems. Development services will be performed on a proposal by proposal basis. Invetech has agreed to defer 30% of its fees, but such deferral may not exceed $5,000,000. Deferred fees (plus interest of 7% per annum) would become payable either, at our option, in a lump sum within 90 days of the “Sunset Date Trigger Event” or pursuant to an installment plan (either in four installments payable within the first year or eight installments payable within the first two years after the “Sunset Date Trigger Event”). The “Sunset Date Trigger Event” is December 31, 2016 or is June 30, 2016 if prior to such date our ongoing phase 3 ADAPT clinical trial is closed early following the interim review at 50% or 75% of events, due to a positive efficacy outcome in favor of the active treatment arm that contains AGS-003. Invetech is entitled to a 10% bonus payment if this clinical trial is closed early indicating positive efficacy and Invetech has timely completed all activities up to the time of such early closure.

The development agreement requires the parties to discuss in good faith Invetech’s supply of Production Systems for use in manufacturing commercial product. We have an obligation to purchase $25.0 million worth of Production Systems, components, subsystems and spare parts for commercial use. Once that obligation has been satisfied, we have the right to have a third party supply Production Systems for use in manufacturing commercial product, provided that Invetech has a right of first refusal with respect to any offer by a third party and we may not accept an offer from a third party unless that offer is at a price that is less than that offered by Invetech and otherwise substantially the same or better terms. We will own all intellectual property arising from the development services (with the exception of existing Invetech intellectual property incorporated therein-under which we will have a license). The term of the development agreement will continue until the completion of the development of the Production Systems. The development agreement can be terminated early by either party because of a technical failure or by us without cause.

Saint-Gobain. In January 2015, we entered into a development agreement with Saint-Gobain Performance Plastics Corporation, or Saint-Gobain. Under the agreement, Saint-Gobain will develop a range of disposables for use in our automated production systems to be used for the manufacture of our Arcelis-based products, which we refer to as the Disposables. We do not expect the fees and expenses incurred under the Saint-Gobain Agreement to exceed $6,000,000. We made a payment of $400,000, and Saint-Gobain has agreed to defer one half of the fees and expenses incurred until the earlier of (i) the date upon which we have raised an additional $60.0 million in capital, and (ii) September 30, 2016. The Saint-Gobain agreement requires the parties to begin negotiating a commercial supply agreement under which Saint-Gobain would become the exclusive supplier of Disposables for the manufacture of our products treating solid tumors for no less than fifteen years. The agreement will continue until December 31, 2016, but can be terminated earlier by written agreement of the parties because of a material default or a failure to achieve a performance milestone.
Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical and biological products such as those we are developing and may market. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug and Biological Product Approval Process

In the United States, the FDA regulates drugs and biological products under the federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of a new drug application, or NDA, or a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Preclinical Studies. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess its potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials. Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their ClinicalTrials.gov website.
Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- **Phase 1:** The drug or biological product is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- **Phase 2:** The drug or biological product is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- **Phase 3:** The drug or biological product is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, phase 2 and phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients.

**Special Protocol Assessment.** The SPA process is designed to facilitate the FDA’s review and approval of drug and biological products by allowing the FDA to evaluate the proposed design and size of phase 3 clinical trials that are intended to form the primary basis for determining a drug or biological product’s efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the trial protocol and respond to a sponsor’s questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the trial protocol design and planned analysis of the trial adequately address objectives in support of a regulatory submission. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under an SPA, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment;
- a sponsor fails to follow a protocol that was agreed upon with the FDA;
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change are found to be false statements or misstatements or are found to omit relevant facts; or
- the FDA and the sponsor agree in writing to modify the trial protocol and such modification is intended to improve the study.

**Marketing Approval.** Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, an NDA, BLA or supplement to an NDA or BLA for certain types of new drug or biological products must contain data that are adequate to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.
The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA and requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, or other clinical development programs.

The FDA also could require submission of a risk evaluation and mitigation strategy, or REMS, plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA or BLA to determine, among other things, whether the product is safe and effective (described as safe, pure and potent for BLAs) and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product’s continued safety, purity and potency. The FDA is required to refer an application for a novel drug or biological product to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

If the FDA’s evaluation of the NDA or BLA and inspection of the manufacturing facilities and clinical trial sites are favorable, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or BLA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. If and when those conditions have been met to the FDA’s satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess a drug’s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Expedited Review and Approval Programs. The FDA has various programs, including fast track designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drug and biological products that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.
To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious aspect of a serious or life-threatening disease or condition and will fill an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

In addition, the FDA may give a priority review designation to drugs or biological products that provide safe and effective therapy where no satisfactory alternative exists or a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. For products regulated by the Center for Biologics Evaluation and Research, or CBER, the product must be intended to treat a serious or life-threatening disease or condition. A priority review means that the targeted time for the FDA to review an application is six months, rather than ten months. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor also can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs or biological products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug or biologic.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs and biological products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

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

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

**Exclusivity and Approval of Competing Products**

**Non-Patent Exclusivity**. Under the Patient Protection and Affordable Care Act, or PPACA, newly-approved biological products may benefit from statutory periods of non-patent data and marketing exclusivity. The PPACA, among other things, permits the FDA to approve biosimilar or interchangeable versions of biological products through an abbreviated approval pathway following periods of data and marketing exclusivity. Biological products that are considered to be “reference products” are granted two overlapping periods of data and marketing exclusivity: a four-year period during which no abbreviated biologics license application, or abbreviated BLA, relying upon the reference product may be submitted to the FDA, and a twelve-year period during which no abbreviated BLA relying upon the reference product may be approved by FDA. For purposes of the PPACA, a reference product is defined as the single biological product licensed under a full BLA against which a biological product is evaluated in an application submitted under an abbreviated BLA.

We believe that our investigational products, if approved via full BLAs, will be considered “reference products” that are entitled to both four-year and twelve-year exclusivity under the PPACA. The FDA, however, has not issued any regulations or final guidance explaining how it will implement the PPACA, including the exclusivity provisions for reference products. Since February 2012, the FDA has issued six draft guidance documents that provide its preliminary thoughts on how to interpret and implement the abbreviated BLA provisions of the PPACA. The FDA has requested public comments on these draft guidance documents, including the proper interpretation of PPACA exclusivity provisions. It is thus possible that the FDA will decide to interpret the PPACA in such a way that our products are not considered to be reference products for purposes of the PPACA or be entitled to any period of data or marketing exclusivity. Even if our products are considered to be reference products and obtain exclusivity under the PPACA, another company nevertheless could also market a competing version of any of our biological products if such company can complete, and the FDA permits the submission of and approves, a full BLA. Although protection under PPACA will not prevent the submission or approval of another “full” BLA, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety, purity, and potency (i.e., effectiveness).

**Pediatric Exclusivity**. Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the four- and 12-year non-patent exclusivity periods described above. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study or studies in accordance with an FDA-issued “Written Request” for such a study or studies.

**Orphan Drug Designation and Exclusivity**. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug (including a biologic) intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.
If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA or full BLA, to market the same drug for the same indication for seven years. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the previously approved orphan drug. For purposes of large molecule drugs, the FDA defines “same drug” as a drug that contains the same principal molecular structural features, but not necessarily all of the same structural features, and is intended for the same use as the drug in question. Notwithstanding the above definitions, a drug that is clinically superior to an orphan drug will not be considered the “same drug” and thus will not be blocked by orphan drug exclusivity.

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

The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical trials to support the approval of drugs, biologics, medical devices, and medical foods for rare diseases and conditions. An application for an orphan grant should propose one discrete clinical trial to facilitate FDA approval of the product for a rare disease or condition. The study may address an unapproved new product or an unapproved new use for a product already on the market.

**Foreign Regulation**

Although we do not currently market any of our products outside the United States and have no current plans to engage in product commercialization outside the United States, we may decide to do so in the future. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods, and may be otherwise complicated by some of our products and product candidates being controlled substances. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

**Pharmaceutical Coverage, Pricing and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at an appropriate return on investment. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug product candidates that we are developing and could adversely affect our net revenue and results.
Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third party reimbursement rates and drug pricing regulation may change at any time. In particular, the PPACA and a related reconciliation bill, which we collectively refer to as the Affordable Care Act or ACA, contain provisions that may reduce the profitability of drug products, including, for example, increased rebates for covered outpatient drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. For example, the FDASIA and PPACA provisions discussed above were enacted in 2012 and 2010, respectively. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance, policies or interpretations changed or what the impact of such changes, if any, may be.

Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities from which it may earn revenues and incur expenses, for which discrete financial information is available and whose operating results are regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. We view our operations and manage our business in one operating segment and all of our operations are in North America.

Employees

As of February 28, 2015, we had 113 employees, including 19 in research and development, 10 in clinical development, 70 in manufacturing and 14 in general and administrative functions. None of our employees is subject to a collective bargaining agreement or represented by a labor or trade union. We believe that our relations with our employees are good.

Corporate Information

We were incorporated in the State of Delaware on May 8, 1997. Our principal executive offices are located at 4233 Technology Drive, Durham, North Carolina 27704, and our telephone number is (919) 287-6300.

Available Information

We file with the Securities and Exchange Commission, or SEC, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and information statements and amendments to reports filed or furnished pursuant to Sections 13(a), 14 and 15(d) of the Securities Exchange Act of 1934, as amended. The public may obtain these filings at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding Argos and other companies that file materials with the SEC electronically. As soon as practicable after filing with the SEC, copies of our reports on Form 10-K, Forms 10-Q and Forms 8-K may also be obtained, free of charge, electronically through the investor relations portion of our web site, www.argotherapeutics.com/investor-relations/sec-filings/default.aspx.
We webcast our earnings calls on our investor relations website. Additionally, we provide notifications of news or announcements regarding our financial performance, including SEC filings, investor events and press and earnings releases, on the investor relations portion of our website. Further corporate governance information, including our corporate governance guidelines, board committee charters, Code of Business Conduct and Ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, or persons performing similar functions, is also available on our investor relations website under the heading “Corporate Governance.” The contents of our website are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC.

**Item 1A. Risk Factors**

*We operate in a dynamic and rapidly changing business environment that involves multiple risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below and in other sections of this Annual Report on Form 10-K and in our subsequent filings with the SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment.*

**Risks Related to the Development and Regulatory Approval of Our Product Candidates**

*We depend heavily on the success of our two product candidates, AGS-003 and AGS-004, both of which are still in clinical development. Clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.*

We currently have no products approved for sale. We have invested a significant portion of our efforts and financial resources in the development of AGS-003 for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers and AGS-004 for the treatment of HIV. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates. The success of these product candidates will depend on several factors, including the following:

- successful completion of clinical trials, including clinical results that are statistically significant as well as clinically meaningful in the context of the indications for which we are developing our product candidates;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing commercial manufacturing capabilities by building out and equipping a commercial manufacturing facility for our Arcelis-based product candidates;
- maintaining patent and trade secret protection and regulatory exclusivity for our product candidates, both in the United States and internationally;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- commercial acceptance of our products, if and when approved, by patients, the medical community and third party payors;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- effectively competing with other therapies; and
- a continued acceptable safety profile of the products following any marketing approval.
If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

If clinical trials of our product candidates, such as our ongoing pivotal phase 3 clinical trial of AGS-003, fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For instance, we failed to achieve the primary endpoint of our phase 2b clinical trial of AGS-004. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In particular, to date, we have not completed a clinical trial of AGS-003 against a placebo or a comparator therapy. While we believe comparisons to results from other reported clinical trials or from analyses of data from the International Metastatic Renal Cell Carcinoma Database Consortium, or the Consortium, can assist in evaluating the potential efficacy of our AGS-003 product candidate, there are many factors that affect the outcome for patients, some of which are not apparent in published reports. As a result, results from two different trials or between a trial and an analysis of a treatment database often cannot be reliably compared. Our ongoing pivotal phase 3 clinical trial of AGS-003 is intended to compare directly the combination of AGS-003 and sunitinib to treatment with sunitinib monotherapy. Based on the design of the trial, the data from the trial will need to demonstrate an increase of approximately six months in median overall survival for the AGS-003 plus sunitinib / targeted therapy arm as compared to the sunitinib / targeted therapy monotherapy control arm in order to show statistical significance and achieve the primary endpoint of the trial. We will need to show this statistically significant benefit of the combined therapy as compared to treatment with the sunitinib / targeted therapy monotherapy as part of a submission for approval of AGS-003. However, demonstration of statistical significance and achievement of the primary endpoint of the trial do not assure approval by the FDA or similar regulatory authorities outside the United States.

Patients in our ongoing pivotal phase 3 clinical trial who receive treatment with sunitinib / targeted therapy monotherapy may not have results similar to patients studied in other clinical trials of sunitinib or to patients in the Consortium database who were treated with sunitinib. If the patients in our ongoing pivotal phase 3 clinical trial who receive sunitinib / targeted therapy plus placebo have results which are better than the results that occurred in those other clinical trials or the results described in the Consortium database, we may not demonstrate a sufficient benefit from AGS-003 in combination with sunitinib to allow the FDA to approve AGS-003 for marketing. In addition, only 21 patients received the combination of AGS-003 and sunitinib in our phase 2 clinical trial. If the patients in our ongoing pivotal phase 3 clinical trial who receive the combination of AGS-003 and sunitinib / targeted therapy have results which are worse than the results that occurred in our phase 2 clinical trial, we may not demonstrate a sufficient benefit from the combination therapy to allow the FDA to approve AGS-003 for marketing.

For drug and biological products, the FDA typically requires the successful completion of two adequate and well-controlled clinical trials to support marketing approval because a conclusion based on two such trials will be more reliable than a conclusion based on a single trial. In the case of AGS-003, which is intended for a life-threatening disease, we intend to seek approval based upon the results of a single pivotal phase 3 clinical trial. The FDA reviewed our plans to conduct a single pivotal phase 3 clinical trial under its SPA process. In February 2013, the FDA advised us in a letter that it had completed its review of our plans under the SPA process. The FDA informed us that in order for a single trial to support approval of an indication, the trial must be well conducted, and the results of the trial must be internally consistent, clinically meaningful and statistically very persuasive. If the results for the primary endpoint are not robust, are subject to confounding factors, or are not adequately supported by other trial endpoints, the FDA may refuse to approve our NDA based upon a single clinical trial. In addition, because only 21 patients received the combination of AGS-003 and sunitinib in our phase 2 clinical trial, and as a result, we did not have enough evaluable patients to perform the statistical analysis to determine whether the primary endpoint of complete response rate was achieved in that trial, we expect that the data from our phase 2 clinical trial will have only a limited impact on the FDA’s ultimate assessment of efficacy of AGS-003. Thus, there can be no guarantee that the FDA will not require additional pivotal clinical trials as a condition for approving AGS-003.

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

- be delayed in obtaining marketing approval for our product candidates;
If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. For example, in September 2011, the FDA placed the original protocol for our ongoing pivotal phase 3 clinical trial of AGS-003 in combination with sunitinib on partial clinical hold due to unresolved questions regarding the planned measurement of the secretion of the cytokine interleukin-12, or IL-12, as part of the specifications for the release of AGS-003. We subsequently reached an agreement with the FDA regarding the IL-12 release specifications and the FDA lifted the partial clinical hold. Unforeseen events that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates include:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; for example, in our phase 2b clinical trial of AGS-004, we experienced a higher dropout rate than we anticipated due to the higher than expected number of patients who did not complete the full 12 week antiretroviral treatment interruption required by the protocol for the trial;
- our third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or institutional review boards may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

In addition, the patients recruited for clinical trials of our product candidates may have a disease profile or other characteristics that are different than we expect and different than the clinical trials were designed for, which could adversely impact the results of the clinical trials. For instance, our phase 2 combination therapy clinical trial of AGS-003 in combination with sunitinib was originally designed to enroll patients with favorable disease risk profiles and intermediate disease risk profiles and with a primary endpoint of complete response rate. However, the actual trial population consisted entirely of patients with intermediate disease risk profiles and poor disease risk profiles. This is a population for which published research has shown that sunitinib alone, as well as other of the targeted therapies for mRCC, rarely if ever produce complete responses in mRCC, and in our phase 2 clinical trial in this population the combination therapy of AGS-003 and sunitinib did not show a complete response rate that met the endpoint of the trial.
Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. For example, in response to our submission of an investigational new drug application, or IND, for AGS-004, the FDA raised safety concerns regarding the analytical treatment interruption contemplated by our protocol for our phase 2 clinical trial of AGS-004, and required a one year safety follow-up after the final dose for each patient. This resulted in the need for an amendment to the trial protocol and a four month delay prior to initiating the phase 2 clinical trial in the United States. In addition to additional costs, significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates and may harm our business and results of operations.

The FDA has reviewed the protocol for our ongoing pivotal phase 3 clinical trial of AGS-003 in combination with sunitinib under the SPA process. However, agreement by the FDA with the protocol under the SPA process does not guarantee that the trial will be successful or that, if successful, AGS-003 will receive marketing approval.

The FDA has reviewed, under the SPA process, the protocol for our ongoing phase 3 clinical trial of AGS-003 in combination with sunitinib / targeted therapy. The SPA process is designed to facilitate the FDA’s review and approval of drug and biological products by allowing the FDA to evaluate the proposed design and size of phase 3 clinical trials that are intended to form the primary basis for determining a drug candidate’s efficacy. In February 2012, we received a letter from the FDA advising us that the FDA had completed its review of our protocol for the pivotal phase 3 clinical trial under the SPA process. In the letter, the FDA stated that it had determined that the protocol sufficiently addressed the trial’s objectives and that the trial was adequately designed to provide the necessary data to support a submission for marketing approval.

An SPA does not guarantee that AGS-003 will receive marketing approval. The FDA may raise issues related to safety, trial conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. In addition, the combination of AGS-003 and sunitinib may not achieve the primary endpoint of the trial. Even if the primary endpoint in our pivotal phase 3 clinical trial is achieved, AGS-003 may not be approved. Many companies which have been granted SPAs have ultimately failed to obtain final approval to market their products.

In its February 2012 letter, the FDA informed us that in order for a single trial to support approval of an indication, the trial must be well conducted, and the results of the trial must be internally consistent, clinically meaningful and statistically very persuasive. If the results for the primary endpoint are not robust, are subject to confounding factors, or are not adequately supported by other trial endpoints, the FDA may refuse to approve our BLA based upon a single clinical trial. There can be no guarantee that the FDA will not require additional pivotal clinical trials as a condition for approving AGS-003.

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

We may not be able to initiate or continue clinical trials for our product candidates, including our pivotal phase 3 clinical trial of AGS-003, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Our competitors may have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors’ product candidates. For example, during the phase 1/2 monotherapy clinical trial of AGS-003 that we conducted, our ability to enroll patients in the trial was adversely affected by the FDA’s approval of sorafenib and sunitinib, because patients did not want to receive, and physicians were reluctant to administer, AGS-003 as a monotherapy once new therapies that showed efficacy in clinical trials were introduced to the market and became widely available.

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
• efforts to facilitate timely enrollment in clinical trials;
• patient referral practices of physicians;
• the ability to monitor patients adequately during and after treatment; and
• proximity and availability of clinical trial sites for prospective patients.

Based on the rate of enrollment in our ongoing pivotal phase 3 clinical trial of AGS-003, we expect to complete tumor collection of patients and to complete enrollment and randomization by the end of second quarter 2015. However, the actual amount of time for full enrollment randomization could be longer than planned. Enrollment delays in this phase 3 clinical trial or any of our other clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for this ongoing phase 3 clinical trial or any of our other clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, any significant delays or increases in costs of our ongoing phase 3 clinical trial of AGS-003 could result in the need for us to obtain additional financing to complete the trial.

We are developing AGS-004 for use with latency reversing drugs to eradicate HIV. If latency reversing drugs are not successfully developed for HIV on a timely basis or at all, we will be unable to develop AGS-004 for this use or will be delayed in doing so. In addition, because there are currently no products approved for HIV eradication, we cannot be certain of the clinical trials that we will need to conduct or the regulatory requirements that we will need to satisfy in order to obtain marketing approval of AGS-004 for this purpose.

We are focusing our development program for AGS-004 on the use of AGS-004 in combination with latency reversing drugs, including Vorinostat, to eradicate HIV. We rely on these latency reversing drugs because we recognize that the ultimate objective of virus eradication is unlikely to be achieved with immunotherapy alone because the immune system is not able to recognize the HIV virus in latently infected cells with a low level or lack of expression of HIV antigens.

Several companies and academic groups are evaluating latency reversing drugs that can potentially activate latently infected cells to increase viral antigen expression and make the cells vulnerable to elimination by the immune system. We are not a party to any arrangements with these companies or academic groups. If these companies or academic groups determine not to develop latency reversing drugs for this purpose because the drugs do not sufficiently increase viral antigen expression or have unacceptable toxicities, or these companies or academic groups otherwise determine to collaborate with other developers of immunotherapies on a combination therapy for complete virus eradication, we will not be able to complete our AGS-004 development program. In addition, if these companies or academic groups do not proceed with such development on a timely basis, our AGS-004 program correspondingly would be delayed.

A number of the latency reversing drugs being evaluated for use in HIV patients are currently approved in the United States and elsewhere for use in the treatment of specified cancer indications. If these drugs are not approved by the FDA or equivalent foreign regulatory authorities for use in HIV, the FDA and these other regulatory authorities may not approve AGS-004 without the latency reversing drug having received marketing approval for HIV. If the FDA and these other regulatory authorities approve AGS-004 without the approval of the latency reversing drug for HIV, the use of AGS-004 in combination with the latency reversing drug for virus eradication would require sales of the latency reversing drug for off-label use. In such event, the success of the combination of AGS-004 and the latency reversing drug would be subject to the willingness of physicians, patients, healthcare payors and others in the medical community to use the latency reversing drug for off-label use and of government authorities and third party payors to pay for the combination therapy. In addition, we would be limited in our ability to market the combination for its intended use if the latency reversing drug were to be used off-label.

Currently, there are no products approved for the eradication of HIV. As a result, we cannot be certain as to the clinical trials we will need to conduct or the regulatory requirements that we will need to satisfy in order to obtain marketing approval of AGS-004 for the eradication of HIV.

If serious adverse or inappropriate side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

All of our product candidates are still in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, such effects or characteristics could cause an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates, require us to conduct additional clinical trials or other tests or studies, and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities.
Our Arcelis-based product candidates are immuno-therapies that are based on a novel technology utilizing a patient’s own tissue. This may raise development issues that we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may prevent us from further developing and commercializing our product candidates.

AGS-003 and AGS-004 are based on our novel Arcelis technology platform. In the course of developing this platform and these product candidates, we have encountered difficulties in the development process. For example, we terminated the development of MB-002, the predecessor to AGS-003, when the results from the initial clinical trial of MB-002 indicated that the product candidate only corrected defects in the production of one of two critical cytokines required for effective immune response. There can be no assurance that additional development problems will not arise in the future which we may not be able to resolve or which may cause significant delays in development.

In addition, regulatory approval of novel product candidates such as our Arcelis-based product candidates manufactured using novel manufacturing processes 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. The FDA has only approved one personalized immunotherapy product to date. This lack of experience may lengthen the regulatory review process, require us to conduct additional 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.

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.

Development of our Arcelis-based product candidates is subject to significant uncertainty because each product candidate is derived from source material that is inherently variable. This variability could reduce the effectiveness of our Arcelis-based product candidates, delay any FDA approval of our Arcelis-based product candidates, cause us to change our manufacturing methods and adversely affect the commercial success of any approved Arcelis-based products.

The inherent variability of the disease samples from the patients to be treated with our Arcelis-based products vary from patient to patient. This inherent variability may adversely affect our ability to manufacture our products because each tumor or virus sample that we receive and process will yield a different product. As a result, we may not be able to consistently produce a product for every patient and we may not be able to treat all patients effectively. Such inconsistency could delay FDA or other regulatory approval of our Arcelis-based product candidates or if approved, adversely affect market acceptance and use of our Arcelis-based products. If we have to change our manufacturing methods to address any inconsistency, we may have to perform additional clinical trials, which would delay FDA or other regulatory approval of our Arcelis-based product candidates and increase the costs of development of our Arcelis-based product candidates.

The inherent variability of the disease samples from the patients to be treated with our Arcelis-based products may further adversely affect our ability to manufacture our products because variability in the source material for our product candidates, such as tumor cells or viruses, may cause variability in the composition of other cells in our product candidates. Such variability in composition or purity could adversely affect our ability to establish acceptable release specifications and the development and regulatory approval processes for our product candidates may be delayed, which would increase the costs of development of our Arcelis-based product candidates.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Failure to obtain regulatory approval for either of our product candidates will prevent us from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.
The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. To date, the FDA has only approved one personalized immunotherapy product. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

**Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.**

We are a party to arrangements with third parties, and intend to enter into additional arrangements with third parties, under which they would market our products outside the United States. In order to market and sell our products in the European Union and many other jurisdictions, we or such third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

**A fast track designation by the FDA may not actually lead to a faster development, regulatory review or approval process.**

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA fast track designation. In April 2012, the FDA notified us that we obtained fast track designation for AGS-003 for the treatment of mRCC. Fast track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

**Risks Related to Our Financial Position and Need for Additional Capital**

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

Since inception, we have incurred significant operating losses. Our net loss, after attribution to the noncontrolling interest, was $10.5 million for the year ended December 31, 2012, $23.9 million for the year ended December 31, 2013 and $53.3 million for the year ended December 31, 2014. As of December 31, 2014, we had an accumulated deficit of $204.2 million. To date, we have financed our operations primarily through our initial public offering of common stock, private placements of our preferred stock, convertible debt financings, bank debt, government contracts, government and other third party grants and license and collaboration agreements. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of any product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- continue our ongoing phase 3 clinical trial of AGS-003 for the treatment of mRCC and initiate additional clinical trials of AGS-003 for the treatment of cancers;
• initiate and conduct additional clinical trials of AGS-004 for the treatment of HIV;
• seek regulatory approvals for our product candidates that successfully complete clinical trials;
• continue to build out and equip our new commercial facility for the manufacture of our Arcelis-based products;
• establish a sales, marketing and distribution infrastructure to commercialize products for which we may obtain regulatory approval;
• maintain, expand and protect our intellectual property portfolio;
• continue our other research and development efforts;
• hire additional clinical, quality control, scientific and management personnel; and
• add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This development and commercialization will require us to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates, building out and equipping a new commercial manufacturing facility and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

**We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs, including our phase 3 clinical trial of AGS-003, our plans to build out and equip our new commercial manufacturing facility or our commercialization efforts.**

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our phase 3 clinical trial of AGS-003, initiate additional clinical trials of AGS-003, seek regulatory approval for our product candidates and build out and equip our new commercial manufacturing facility. In addition, if we obtain regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, terminate or eliminate our product development programs, our plans to build out and equip a new commercial manufacturing facility or our commercialization efforts.

As of December 31, 2014, we had cash, cash equivalents and short-term investments of $56.2 million and working capital of $54.2 million. We expect that our existing cash, cash equivalents and short-term investments, together with the second tranche of $12.5 million under our Loan Agreement with Horizon Technology Finance Corporation and Fortress Credit Co LLC and the anticipated funding under our NIH contract, will enable us to fund our operating expenses into the second half of 2016, including funding our ongoing phase 3 clinical trial of AGS-003, our planned phase 2 clinical trials of AGS-003, our ongoing and planned phase 2 clinical trials of AGS-004 and our continuing build-out and equipping of our new commercial manufacturing facility.

We will need to obtain significant financing prior to the commercialization of AGS-003, including to complete the planned build-out and equipping of our new commercial manufacturing facility and to fund any commercialization efforts in advance of regulatory approval of AGS-003. Our preliminary estimate indicates that we will require approximately an additional $50.0 million prior to the commercialization of AGS-003 to build out and equip the new commercial manufacturing facility. In addition, we expect to spend approximately an additional $25.0 million on development, equipment and disposables, including costs incurred under the development agreements we entered into with Invotech and Saint-Gobain in October 2014 and January 2015, respectively. We have initiated expenditures for these purposes and construction of the facility began in October 2014. We are actively exploring additional financing arrangements in connection with the build out and equipping of the commercial manufacturing facility and are in discussions with developers, lenders and other potential financing sources regarding potential financial support. We expect to enter into such arrangements during 2015 and that such arrangements will likely involve material obligations and debt liabilities. If we are unable to obtain additional financing when needed, in the required amounts or at all, we may not be able to complete the planned build-out and equipping of the new commercial facility or may be delayed in doing so.
Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing pivotal phase 3 clinical trial of AGS-003 and other clinical trials of AGS-003 that we may conduct;
- the progress and results of our ongoing phase 2 clinical trial of AGS-004 for HIV eradication and other clinical trials of AGS-004 that we may conduct and our ability to obtain additional funding under our NIH contract for our AGS-004 program;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs and timing of our build-out and equipping of our new commercial manufacturing facility;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval;
- the potential need to repay the $9.0 million loan under our license agreement with Medinet;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or invest in other businesses, products and technologies;
- our ability to obtain government or other third party funding for the development of our product candidates; and
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute AGS-003 outside North America and arrangements for the development and commercialization of our non-oncology product candidates, including AGS-004.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, government contracts, government and other third party grants or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We will require substantial funding to complete the planned leasing, build-out and equipping of a new commercial manufacturing facility, fund our commercialization efforts and fund our operating expenses and other activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.
We currently intend to collaborate with third parties for the manufacturing, development or commercialization of AGS-003 outside of North America. We plan to seek government or other third party funding for the continued development of AGS-004 and to collaborate with third parties for the development and commercialization of AGS-004. If we raise additional funds through government or other third party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If the loan from Medinet becomes due and we do not repay it, we have agreed to grant Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer.

Risk Related to the Commercialization of our Product Candidates

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing our company, developing our technology and product candidates and establishing collaborations. We have not yet demonstrated an ability to successfully complete a pivotal clinical trial, obtain marketing approvals, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

Even if AGS-003 or AGS-004 receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

We have never commercialized a product candidate. Even if AGS-003 or AGS-004 receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Gaining market acceptance for our Arcelis-based products may be particularly difficult as, to date, the FDA has only approved one personalized immunotherapy and our Arcelis-based products are based on a novel technology. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of sales, marketing and distribution support;
- the approval of other new products for the same indications;
- availability and amount of reimbursement from government payors, managed care plans and other third party payors;
- adverse publicity about the product or favorable publicity about competitive products;
- clinical indications for which the product is approved; and
- the prevalence and severity of any side effects.
If any of our product candidates receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- additional restrictions may be imposed on the distribution or use of the product via a risk evaluation and mitigation strategy, or REMS;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We plan to market and sell AGS-003 in North America independently and to enter into collaborations or other arrangements with third parties for the distribution or marketing of AGS-003 in the rest of the world. We plan to enter into collaborations or other arrangements with third parties for the distribution or marketing of AGS-004 and any of our other product candidates should such candidates receive marketing approval.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit 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

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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 are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Many marketed therapies for the indications that we are currently pursuing, or indications that we may in the future seek to address using our Arcelis platform, are widely accepted by physicians, patients and payors, which may make it difficult for us to replace them with any products that we successfully develop and are permitted to market.

There are several FDA-approved therapies for mRCC marketed and sold by large pharmaceutical companies. Approved monotherapies for mRCC include Nexavar (sorafenib), marketed by Bayer Healthcare Pharmaceuticals, Inc. and Onyx Pharmaceuticals, Inc.; Sutent (sunitinib) and Inlyta (axitinib), marketed by Pfizer, Inc.; Avastin (bevacizumab), marketed by Genentech, Inc., a member of the Roche Group; Votrient (pazopanib), marketed by GlaxoSmithKline plc; Torisel (temsirolimus), marketed by Pfizer; and Afinitor (everolimus), marketed by Novartis Pharmaceuticals Corporation. In addition, we estimate that there are numerous cancer immunotherapy products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. A number of these are in late stage development. One biotechnology company, Immatics Biotechnologies GmbH, or Immatics, is developing a therapeutic cancer vaccine, which is a mixture of defined tumor-associated peptides, for the treatment of RCC. Immatics is conducting a pivotal phase 3 clinical trial comparing its vaccine in combination with sunitinib against treatment with sunitinib alone in a subset of favorable and intermediate risk patients. If this clinical trial is successful, this combination therapy would be in direct competition with our AGS-003 and sunitinib combination therapy. In addition, if a standalone therapy for mRCC were developed that demonstrated improved efficacy over currently marketed therapies with a favorable safety profile and without the need for combination therapy, such a therapy might pose a significant competitive threat to AGS-003.

We are currently conducting a pivotal phase 3 clinical trial of AGS-003 plus sunitinib / targeted therapy. We elected to study AGS-003 in clinical trials in combination with sunitinib due in part to sunitinib being the current standard of care for first-line treatment of mRCC. Although we do not expect to seek FDA approval of AGS-003 solely in combination with sunitinib and have provided that, under the protocol for the phase 3 clinical trial, investigators may discontinue sunitinib due to disease progression or toxicity and initiate second-line treatment with other targeted therapies, if we obtain approval by the FDA, such FDA approval may be limited to the combination of AGS-003 and sunitinib. In such event, the commercial success of AGS-003 would be linked to the commercial success of sunitinib. As a result, if sunitinib ceases to be the standard of care for first-line treatment of mRCC or another event occurs that adversely affects sales of sunitinib, the commercial success of AGS-003 may be adversely affected.

There are also numerous FDA-approved treatments for HIV, primarily antiretroviral therapies marketed by large pharmaceutical companies. Generic competition has developed in this market as patent exclusivity periods for older drugs have expired, with more than 15 generic bioequivalents currently on the market. The presence of these generic drugs is resulting in price pressure in the HIV therapeutics market and could affect the pricing of AGS-004. Currently, there are no approved therapies for the eradication of HIV. We expect that major pharmaceutical companies that currently market antiretroviral therapy products or other companies that are developing HIV product candidates may seek to develop products for the eradication of HIV.
Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and device industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. These risks may be even greater with respect to our Arcelis-based products which are manufactured using a novel technology. None of our product candidates has been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for manufacturing of our Arcelis-based product candidates from human cell sources, and therefore the manufacturing process and handling requirements are extensive and stringent, which increases the risk of quality failures and subsequent product liability claims.
If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We currently hold $10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when we begin commercializing our product candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

We have based our research and development efforts on our Arcelis platform. Notwithstanding our large investment to date and anticipated future expenditures in our Arcelis platform, we have not yet developed, and may never successfully develop, any marketed drugs using this approach. As a result of pursuing the development of product candidates using our Arcelis platform, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

Our long-term business plan is to develop Arcelis-based products for the treatment of various cancers and infectious diseases. We may not be successful in our efforts to identify or discover additional product candidates that may be manufactured using our Arcelis platform. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

**Risks Related to Our Dependence on Third Parties**

Our reliance on government funding adds uncertainty to our research and commercialization efforts and may impose requirements that increase the costs of commercialization and production of our government-funded product candidates.

Our phase 2b clinical trial for AGS-004 for HIV was funded entirely by the NIH. We are seeking further government funding for continued development of AGS-004. However, increased pressure on governmental budgets may reduce the availability of government funding for programs such as AGS-004. In addition, contracts and grants from the U.S. government and its agencies include provisions that give the government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
Government agreements normally contain additional terms and conditions that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These include, for example:

- reduce or modify the government’s obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government’s financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

Government agreements normally contain additional terms and conditions that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

**We expect to depend on collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.**

We currently intend to commercialize AGS-003 independently in North America. We intend to collaborate with other third parties to manufacture, develop or commercialize AGS-003 outside North America. We have entered into an exclusive license agreement with Pharmstandard International S.A., or Pharmstandard, for the development and commercialization of AGS-003 in Russia and the other states comprising the Commonwealth of Independent States and an exclusive license agreement with Green Cross Corp., or Green Cross, for the development and commercialization of AGS-003 in South Korea. We have also entered into a license agreement with Medinet under which we granted Medinet an exclusive license to manufacture in Japan AGS-003 for the purpose of development and commercialization for the treatment of mRCC and an option to acquire a non-exclusive license to sell in Japan AGS-003 for the treatment of mRCC. We also plan to seek government or other third party funding for continued development of AGS-004 and to collaborate with third parties to develop and commercialize AGS-004. Our likely collaborators for any development, distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

Under our existing arrangements we have limited control, and under any additional arrangements we may enter into with third parties we will likely have limited control, over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these arrangements.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
• collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator’s strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

• collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or, require a new formulation of a product candidate for clinical testing;

• collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

• a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

• collaborators may have the right to conduct clinical trials of our product candidates without our consent and could conduct trials with flawed designs that result in data that adversely affect our clinical trials, our ability to obtain marketing approval for our product candidates or market acceptance of our product candidates. Pharmstandard, Green Cross and Medinet each have this right under our license agreements with them;

• collaborators may hold rights that could preclude us from commercializing our products in certain territories. For example, we have granted Medinet an exclusive license to manufacture in Japan AGS-003 for the treatment of mRCC and an option to acquire a non-exclusive license to sell in Japan AGS-003 for the treatment of mRCC. Even if Medinet does not exercise the option to acquire the license to sell, we will not have the right to manufacture AGS-003 in Japan for the purposes of development and commercialization of AGS-003 for the treatment of mRCC. If we and Medinet are unable to agree to the terms of a supply agreement under these circumstances, we will not be able to sell AGS-003 in Japan unless we repurchase these rights from Medinet;

• collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

• disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

• collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, our collaboration with Kyowa Hakko Kirin Co., Ltd. with respect to AGS-003 and AGS-004 was terminated by our collaborator.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we intend to collaborate with pharmaceutical and biotechnology companies for the development and commercialization of those product candidates. For example, we have entered into license agreements with third parties to develop and commercialize AGS-003 in Russia and the other states comprising the Commonwealth of Independent States, South Korea and Japan, and we intend to collaborate with other third parties to develop and commercialize AGS-003 in other parts of the world and to collaborate with third parties to develop and commercialize AGS-004.
We face significant competition in seeking appropriate collaborators. 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 clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are not able to obtain such funding or enter into collaborations for our product candidate, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop these product candidates or bring these product candidates to market and generate product revenue.

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

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

Risks Related to the Manufacturing of Our Product Candidates

We have commenced the build out of a new facility to manufacture our Arcelis-based products on a commercial scale using automated processes. We do not have experience in manufacturing Arcelis-based products on a commercial scale or using automated processes. If, due to our lack of manufacturing experience, we cannot manufacture our Arcelis-based products on a commercial scale successfully or manufacture sufficient product to meet our expected commercial requirements, our business may be materially harmed.

We currently have manufacturing suites in our facility located at our corporate headquarters in Durham, North Carolina. We manufacture our Arcelis-based product candidates for research and development purposes and for clinical trials at this facility. In August 2014, we entered into a lease agreement with a developer for an approximately 120,000 square-foot building to be constructed in Durham County, North Carolina. This facility will house our corporate headquarters and commercial manufacturing. The shell of the new facility is being constructed on a build-to-suit basis in accordance with agreed upon specifications and plans. We expect the shell of the facility will be completed by the end of June 2015 after which the interior of the facility will be built out and equipped.
We plan to establish automated manufacturing processes based on existing functioning prototypes of automated devices for the production of commercial quantities of our Arcelis-based product. These devices can be used to perform substantially all steps required for the manufacture of our Arcelis-based product candidates.

We do not have experience in manufacturing products on a commercial scale or using automated processes. In addition, because we are aware of only one company that has manufactured a personalized immunotherapy product for commercial sale, there are limited precedents from which we can learn. We may encounter difficulties in the manufacture of our Arcelis-based products due to our limited manufacturing experience. These difficulties could delay the build-out and equipping of the new facility and regulatory approval of the manufacture of our Arcelis-based products using the new facility and the automated processes, increase our costs or cause production delays or result in us not manufacturing sufficient product to meet our expected commercial requirements, any of which could damage our reputation and hurt our profitability. If we are unable to successfully increase our manufacturing capacity to commercial scale, our business may be materially adversely affected.

We have commenced build out a new commercial manufacturing facility and plan to equip this facility based on automated manufacturing processes and augment our manufacturing personnel in advance of any regulatory submission for approval of AGS-003. If we fail to build out and equip a new commercial manufacturing facility in compliance with regulatory requirements, implement our automated processes or augment our manufacturing personnel, we may not be able to initiate commercial operations or produce sufficient product to meet our expected commercial requirements.

In order to meet our business plan, which contemplates our manufacturing product internally using automated processes for the commercial requirements of AGS-003 and any other Arcelis-based product candidates that might be approved, we will need to build out and equip a new commercial manufacturing facility and add manufacturing personnel in advance of any regulatory submission for approval of AGS-003. The build-out and equipping of our facilities will require substantial capital expenditures and additional regulatory approvals. In addition, it will be costly and time consuming to recruit necessary additional personnel.

Prior to implementing the automated manufacturing processes for Arcelis-based products and filing a BLA for approval of AGS-003, we will be required to:

- demonstrate that the disposable components and sterilization and packaging methods used in the manufacturing process are suitable for use in manufacturing in accordance with current good manufacturing practice, or cGMP, and current Good Tissue Practices, or cGTP;
- build and validate processing equipment that complies with cGMP and cGTP;
- build out and equip a suitable manufacturing facility to accommodate the automated manufacturing process;
- perform process testing with final equipment, disposable components and reagents to demonstrate that the methods are suitable for use in cGMP and cGTP manufacturing;
- demonstrate consistency and repeatability of the automated manufacturing processes in the production of AGS-003 in our new facility to fully validate the manufacturing and control process using the actual automated cGMP processing equipment; and
- demonstrate comparability between AGS-003 that we produce using existing processes in our current facility and AGS-003 produced using the automated processes in our new facility.

We expect to complete this implementation in the second half of 2016, but such implementation could take longer, particularly if we are unable to achieve any of the required tasks on a timely basis, or at all. We are collaborating with Invetech and Saint-Gobain to develop the equipment and disposables necessary to implement the automated manufacturing processes for Arcelis-based products. If Invetech or Saint-Gobain do not perform as expected under the agreements or the projects with Invetech or Saint-Gobain are unsuccessful for any other reason, our business could be adversely affected and our timelines for AGS-003 could be delayed.

If the FDA requires us to conduct a bridging study to demonstrate comparability between AGS-003 that we produce manually and AGS-003 produced using the automated processes, the implementation of the automated manufacturing processes and the filing of the BLA will likely be delayed.

If we are unable to successfully build out and equip our commercial manufacturing facility in compliance with regulatory requirements, implement the automated processes required, demonstrate comparability between the AGS-003 used in our pivotal trial and the AGS-003 produced using the automated processes in the new facility, or hire additional necessary manufacturing personnel appropriately, our filing for regulatory approval of AGS-003 may be delayed or denied and we may not be able to initiate commercial operations even if any of our product candidates are approved for marketing.
Lack of coordination internally among our employees and externally with physicians, hospitals and third-party suppliers and carriers, could cause manufacturing difficulties, disruptions or delays and cause us to not have sufficient product to meet our expected clinical trial requirements or potential commercial requirements.

Manufacturing our Arcelis-based product candidates requires coordination internally among our employees and externally with physicians, hospitals and third-party suppliers and carriers. For example, a patient’s physician or clinical site will need to coordinate with us for the shipping of a patient’s disease sample and leukapheresis product to our manufacturing facility, and we will need to coordinate with them for the shipping of the manufactured product to them. Such coordination involves a number of risks that may lead to failures or delays in manufacturing our Arcelis-based product candidates, including:

- failure to obtain a sufficient supply of key raw materials of suitable quality;
- difficulties in manufacturing our product candidates for multiple patients simultaneously;
- difficulties in obtaining adequate patient-specific material, such as tumor samples, virus samples or leukapheresis product, from physicians;
- difficulties in completing the development and validation of the specialized assays required to ensure the consistency of our product candidates;
- failure to ensure adequate quality control and assurances in the manufacturing process as we increase production quantities;
- difficulties in the timely shipping of patient-specific materials to us or in the shipping of our product candidates to the treating physicians due to errors by third-party carriers, transportation restrictions or other reasons;
- destruction of, or damage to, patient-specific materials or our product candidates during the shipping process due to improper handling by third-party carriers, hospitals, physicians or us;
- destruction of, or damage to, patient-specific materials or our product candidates during storage at our facilities; and
- destruction of, or damage to, patient-specific materials or our product candidates stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians.

If we are unable to coordinate appropriately, we may encounter delays or additional costs in achieving our clinical and commercialization objectives, including in obtaining regulatory approvals of our product candidates and supplying product, which could materially damage our business and financial position.

If our existing manufacturing facility or the new commercial manufacturing facility that we plan to build out and equip are damaged or destroyed, or production at one of these facilities is otherwise interrupted, our business and prospects would be negatively affected.

We currently have a single manufacturing facility and expect that the new commercial manufacturing facility that we plan to build out and equip will be our only commercial manufacturing facility in North America. If our existing manufacturing facility or the new commercial manufacturing facility that we plan to build out and equip, or the equipment in either of these facilities, is damaged or destroyed, we likely would not be able to quickly or inexpensively replace our manufacturing capacity and possibly would not be able to replace it at all. Any new facility needed to replace either our existing manufacturing facility or the planned new commercial manufacturing facility would need to comply with the necessary regulatory requirements, need to be tailored to our specialized automated manufacturing requirements and require specialized equipment. We would need FDA approval before selling any products manufactured at a new facility. Such an event could delay our clinical trials or, if any of our product candidates are approved by the FDA, reduce or eliminate our product sales.
We maintain insurance coverage to cover damage to our property and equipment and to cover business interruption and research and development restoration expenses. If we have underestimated our insurance needs with respect to an interruption in our clinical manufacturing of our product candidates, we may not be able to adequately cover our losses.

**Risks Related to Our Intellectual Property**

*If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.*

We are a party to a number of intellectual property license agreements with third parties, including with respect to each of AGS-003 and AGS-004, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, under our license agreement with Duke University which relates to patents and patent applications directed towards the composition of matter of Arcelis-based products, dendritic cells loaded with RNA from tumors or pathogens, methods of manufacture of these products and methods of using these products to treat tumors, we are required to use commercially reasonable efforts to research, develop and market license products and to satisfy other specified obligations. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or to convert the license to a non-exclusive license, which could materially adversely affect the value of the product candidate being developed under the license agreement.

Termination of these license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms.

*If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.*

Our success depends in large part on our and our licensors’ ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development efforts before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties and are reliant on our licensors. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors’ patent rights are highly uncertain. Our and our licensors’ pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Third parties could practice our inventions in territories where we do not have patent protection. Furthermore, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, we own or exclusively license patents relating to our process of manufacturing a personalized drug product. A U.S. patent may be infringed by anyone who, without authorization, practices the patented process in the United States or imports a product made by a process covered by the U.S. patent. In foreign countries, however, importation of a product made by a process patented in that country may not constitute an infringing activity, which would limit our ability to enforce our process patents against importers in that country. Furthermore, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. If competitors are able to use our technologies, our ability to compete effectively could be harmed.

Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.
Assuming the other requirements for patentability are met, in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act, or AIA, enacted in September 2011, the United States moved to a first inventor to file system in March 2013. The United States Patent and Trademark Office only recently finalized the rules relating to these changes and courts have yet to address the new provisions. These changes could increase the costs and uncertainties surrounding the prosecution of our patent applications and the enforcement or defense of our patent rights. Furthermore, we may become involved in interference proceedings, opposition proceedings, or other post-grant proceedings, such as reissue, reexamination or inter partes review proceedings, which may challenge our patent rights or the patent rights of others.

For example, we have filed an application for reissue of one of our U.S. patents directed to methods of manufacture of dendritic cells from monocytes stored for more than six hours and up to four days without freezing. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to or stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, certain of the U.S. patents we exclusively license from Duke University expire as early as 2016 and the European and Japanese patents exclusively licensed from Duke University expire in 2017. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter such infringement or unauthorized use, we may be required to file infringement claims against third parties, which can be expensive and time consuming. In addition, during an infringement proceeding, a court may decide that the patent rights we are asserting are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we are reliant on them.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot ensure that third parties do not have, or will not in the future obtain, intellectual property rights such as granted patents that could block our ability to operate as we would like. There may be patents in the United States or abroad owned by third parties that, if valid, may block our ability to make, use or sell our products in the United States or certain countries outside the United States, or block our ability to import our products into the United States or into certain countries outside the United States.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. For example, third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party’s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may be unable to obtain any required license on commercially reasonable terms or even obtain a license at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.
We have research licenses to certain reagents and their use in the development of our product candidates. We would need commercial licenses to these reagents for any of our product candidates that receive approval for sale in the United States. We believe that commercial licenses to these reagents will be available. However, if we are unable to obtain any such commercial licenses, we may be unable to commercialize our product candidates without infringing the patent rights of third parties. If we did seek to commercialize our product candidates without a license, these third parties could initiate legal proceedings against us.

**We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

**Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.**

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

**Risks Related to Legal Compliance Matters**

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, cGTP requirements, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA imposes stringent restrictions on manufacturers’ communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
• restrictions on the marketing of a product;
• restrictions on product distribution;
• requirements to conduct post-marketing clinical trials;
• warning or untitled letters;
• withdrawal of the products from the market;
• refusal to approve pending applications or supplements to approved applications that we submit;
• recall of products;
• fines, restitution or disgorgement of profits or revenue;
• suspension or withdrawal of regulatory approvals;
• refusal to permit the import or export of our products;
• product seizure; or
• injunctions or the imposition of civil or criminal penalties.

Our relationships with customers and third party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

• the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

• the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance information related to payments to physicians and other health care providers or marketing expenditures. If our operations are found to be in violation of any of these laws or any other governmental applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law on reimbursement that results from the Medicare Modernization Act or other more recent legislation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.
Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new 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. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The new law is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates were to be approved as biological products under a BLA, such approved products should qualify for the four-year and 12-year periods of exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten these exclusivity periods as proposed by President Obama, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

**If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.**

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

**Risks Related to Employee Matters and Managing Growth**

*Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.*

We are highly dependent on Jeffrey Abbey, our President and Chief Executive Officer, Charles Nicolette, our Vice President of Research and Development and Chief Scientific Officer, and Fred Miesowicz, our Vice President of Manufacturing and Chief Operating Officer, as well as the other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.
Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development, regulatory, manufacturing and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, manufacturing and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock maintain the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 76.8% of our common stock as of February 28, 2015. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Our largest stockholder, Pharmstandard, could exert significant influence over us and could limit your ability to influence the outcome of key transactions, including any change of control.

Our largest stockholder, Pharmstandard, owns, in the aggregate, approximately 30.4% of our outstanding common stock as of February 28, 2015. In addition, two members of our board of directors are affiliates of Pharmstandard. As a result, we expect that Pharmstandard will be able to exert significant influence over our business. Pharmstandard may have interests that differ from your interests, and it may vote in a way with which you disagree and that may be adverse to your interests. The concentration of ownership of our capital stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may adversely affect the market price of our common stock.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained.

Our common stock began trading on The NASDAQ Global Market on February 6, 2014. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. For example, our stock has traded in a range from a low of $5.61 and high of $13.74 during the period of February 7, 2014 through March 16, 2015. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

• results of clinical trials of our product candidates or those of our competitors;
• the success of competitive products or technologies;
• potential approvals of our product candidates for marketing by the FDA or equivalent foreign regulatory authorities or our failure to obtain such approvals;
• regulatory or legal developments in the United States and other countries;
• the results of our efforts to commercialize our product candidates;
• developments or disputes concerning patents or other proprietary rights;
• the recruitment or departure of key personnel;
• the level of expenses related to any of our product candidates or clinical development programs;
• the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish a report by our management on our internal control over financial reporting beginning with our filing of this Annual Report on Form 10-K with the Securities and Exchange Commission, or the SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act of 2002 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act of 2002. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.
We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In our 2013 Annual Report on Form 10-K, we did not include all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In September 2014, we entered into a venture loan and security agreement with Horizon Technology Finance Corporation and Fortress Credit Co LLC. The terms of this agreement preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us, or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock to be less favorable, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our only facility is located in Durham, North Carolina, where we occupy approximately 20,000 square feet of office, laboratory and manufacturing space. Our lease expires in November 2016.

On August 18, 2014, we entered into a Lease Agreement, or the Lease Agreement, with TKC LXXII, LLC, a North Carolina limited liability company, or TKC. Under the Lease Agreement, we will lease certain land and an approximately 120,000 square-foot building to be constructed on approximately 11 acres in Durham County, North Carolina. This facility will house our corporate headquarters and primary manufacturing facility. The Lease Agreement is intended to replace our existing lease. The shell of the new facility will be constructed on a build-to-suit basis by TKC, at its expense, in accordance with agreed upon specifications and plans as set forth in the Lease Agreement.

The term of the Lease Agreement will be 10 years from the commencement date for the initial term, currently estimated to be May 1, 2015, with us having the option to extend the Lease Agreement by six five-year renewal terms. Initial rent will be approximately $46,917 per month, subject to certain fixed increases over the course of the term as set forth in the Lease Agreement and to adjustment based on our use of certain amounts allocated for upfitting the interior of the facility.
On February 16, 2015, we entered into a Purchase and Sale Agreement (the “Purchase Agreement”) with TKC which represented our exercise of the purchase option under the Lease Agreement. The purchase price to be paid by us is $7.6 million plus the amount of any additional costs incurred by TKC as a result of changes requested by us and the amount of any improvement allowances advanced to us by TKC prior to the closing. The Purchase Agreement is expected to close in the second half of 2015. Upon the closing, the Lease Agreement will terminate.

**Item 3. Legal Proceedings**

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation.

**Item 4. Mine Safety Disclosures**

Not Applicable.

**PART II**

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

Our common stock is listed on the NASDAQ Global Market under the symbol “ARGS” and began trading on February 7, 2014. Prior to that, there was no public trading market for our common stock. As of March 23, 2015, there were 19,688,802 outstanding shares and 65 stockholders of record. This number does not include beneficial owners whose shares were held in street name. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

The following table sets forth for the periods indicated the high and low closing sale prices for our common stock as reported on the NASDAQ Global Market:

<table>
<thead>
<tr>
<th>Period</th>
<th>High</th>
<th>Low</th>
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</thead>
<tbody>
<tr>
<td>First quarter (February 7, 2014 to March 31, 2014)</td>
<td>$13.74</td>
<td>$7.97</td>
</tr>
<tr>
<td>Second quarter</td>
<td>$10.55</td>
<td>$6.21</td>
</tr>
<tr>
<td>Third quarter</td>
<td>$10.80</td>
<td>$5.61</td>
</tr>
<tr>
<td>Fourth quarter</td>
<td>$10.28</td>
<td>$7.80</td>
</tr>
</tbody>
</table>

**Stock Performance Graph**

The graph set forth below compares the cumulative total stockholder return on an initial investment of $100 in our common stock between February 7, 2014, the date on which our common stock began trading on the NASDAQ Global Market, and December 31, 2014, with the comparative cumulative total return of such amount on (i) the NASDAQ Composite Index and (ii) the NASDAQ Biotechnology Index over the same period. We have not paid any cash dividends and, therefore, the cumulative total return calculation for us is based solely upon our stock price appreciation or depreciation and does not include any reinvestment of cash dividends. The graph assumes our closing sales price on February 7, 2014 of $8.00 per share as the initial value of our common stock.
The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

![Comparison of Cumulative Total Return Through December 31, 2014](image_url)

The information presented above in the stock performance graph shall not be deemed to be “soliciting material” or to be “filed” with the SEC or subject to Regulation 14A or 14C, except to the extent that we subsequently specifically request that such information be treated as soliciting material or specifically incorporate it by reference into a filing under the Securities Act of 1933, as amended, or a filing under the Securities Exchange Act of 1934, as amended.

**Dividends**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In September 2014, we entered into a venture loan and security agreement with Horizon Technology Finance Corporation and Fortress Credit Co LLC. The terms of this agreement preclude us from paying dividends.

**Recent Sales of Unregistered Securities**

Set forth below is information regarding shares of our common stock, shares of our preferred stock, warrants to purchase shares of our common stock, warrants to purchase shares of our preferred stock and stock options granted, by us since January 1, 2014 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

During the three months ended March 31, 2014, we granted options to employees and non-employee directors to purchase 23,375 shares of our common stock at exercise prices ranging from $11.00 to $11.09 per share, which in each instance was the closing price of our common stock on the grant date. In connection with our Loan Agreement signed in September 2014, the Company issued warrants to purchase a total of 82,780 shares of common stock at a per share exercise price of $9.06.

The stock options and the common stock issuable upon the exercise of such options were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about the Registrant or had access, through employment or other relationships, to such information.

**Purchase of Equity Securities**

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.
Use of Proceeds from Initial Public Offering

In February 2014, we issued and sold 6,228,725 shares of our common stock, including 603,725 shares of common stock sold pursuant to the underwriters’ exercise of their option to purchase additional shares, in our initial public offering at a public offering price of $8.00 per share, for aggregate gross proceeds of $49.8 million. The net offering proceeds to us, after deducting underwriting discounts and commissions of approximately $3.5 million and offering expenses of approximately $2.9 million, were approximately $43.4 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-193137), which was declared effective by the SEC on February 6, 2014.

As of December 31, 2014, we had used approximately $41.0 million of the net offering proceeds to fund the costs of our ongoing pivotal phase 3 clinical trial of AGS-003 for the treatment of mRCC and for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on February 6, 2014 pursuant to Rule 424(b) of the Securities Act.
You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes in “Item 8. Financial Statements and Supplementary Data” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2012, 2013 and 2014, and the consolidated balance sheet data as of December 31, 2013 and 2014 from our audited consolidated financial statements included in “Item 8. Financial Statements and Supplementary Data.” The consolidated statements of operations data for the year ended December 31, 2011 and the consolidated balance sheet data as of December 31, 2011 and 2012 was derived from our audited financial statements which are not included in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period. The consolidated financial information reflects a one-for-six reverse stock split of our common stock effected on January 17, 2014, which has been retrospectively applied for all periods presented.

### Consolidated Statements of Operations Data:

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$7,642,695</td>
<td>$7,039,010</td>
<td>$4,421,689</td>
<td>$1,974,019</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>12,668,025</td>
<td>17,616,892</td>
<td>23,991,151</td>
<td>45,498,916</td>
</tr>
<tr>
<td>General and administrative</td>
<td>3,703,813</td>
<td>6,135,581</td>
<td>4,662,317</td>
<td>8,599,359</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(8,729,143)</td>
<td>(16,713,463)</td>
<td>(24,231,779)</td>
<td>(52,124,256)</td>
</tr>
<tr>
<td>Other income (expense):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest income</td>
<td>1,259</td>
<td>4,604</td>
<td>7,184</td>
<td>66,580</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(6,656,366)</td>
<td>(292,496)</td>
<td>(4,705)</td>
<td>(1,123,579)</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>(4,661,811)</td>
<td>4,916,785</td>
<td>355,352</td>
<td></td>
</tr>
<tr>
<td>Derivative (expense) income</td>
<td>(94,668)</td>
<td>1,036,403</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investment tax credits</td>
<td>—</td>
<td>694,331</td>
<td></td>
<td>140,556</td>
</tr>
<tr>
<td>Other expense</td>
<td>—</td>
<td>(117,494)</td>
<td>(47,615)</td>
<td>(265,239)</td>
</tr>
<tr>
<td>Other (expense) income, net</td>
<td>(11,411,586)</td>
<td>6,242,133</td>
<td>310,216</td>
<td>(1,181,682)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(20,140,729)</td>
<td>(10,471,330)</td>
<td>(23,921,563)</td>
<td>(53,305,938)</td>
</tr>
<tr>
<td>Net loss attributable to noncontrolling interest</td>
<td>(63,047)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net loss attributable to Argos Therapeutics, Inc.</td>
<td>(20,077,682)</td>
<td>(10,471,330)</td>
<td>(23,921,563)</td>
<td>(53,305,938)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock</td>
<td>(926,542)</td>
<td>(351,371)</td>
<td>4,772,991</td>
<td>(863,226)</td>
</tr>
<tr>
<td>Less: Preferred stock dividend due to exchanges of preferred shares</td>
<td>—</td>
<td>—</td>
<td>(14,726,088)</td>
<td>—</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$(21,004,224)</td>
<td>$(10,822,701)</td>
<td>$(33,874,660)</td>
<td>$(54,169,164)</td>
</tr>
<tr>
<td>Basic and diluted net loss attributable to common stockholders per share</td>
<td>$ (197.29)</td>
<td>$(54.58)</td>
<td>$(147.37)</td>
<td>$(3.12)</td>
</tr>
<tr>
<td>Basic and diluted weighted average shares outstanding</td>
<td>106,466</td>
<td>198,306</td>
<td>229,865</td>
<td>17,367,665</td>
</tr>
</tbody>
</table>

### Consolidated Balance Sheet Data:

<table>
<thead>
<tr>
<th></th>
<th>As of December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2011</td>
</tr>
<tr>
<td>Cash, cash equivalents and short-term investments</td>
<td>$2,002,814</td>
</tr>
<tr>
<td>Working (deficit) capital</td>
<td>(19,541,194)</td>
</tr>
<tr>
<td>Total assets</td>
<td>5,973,958</td>
</tr>
<tr>
<td>Total long-term liabilities</td>
<td>—</td>
</tr>
<tr>
<td>Redeemable convertible preferred stock</td>
<td>77,722,306</td>
</tr>
<tr>
<td>Total stockholders’ (deficit) equity</td>
<td>(96,355,106)</td>
</tr>
</tbody>
</table>
You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, future financial performance, expense levels and liquidity sources, includes forward-looking statements that involve risks and uncertainties. You should read “Item 1A. Risk Factors” in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer and infectious diseases based on our proprietary technology platform called Arcelis.

Our most advanced product candidate is AGS-003, which we are developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. We are currently conducting a pivotal phase 3 clinical trial of AGS-003 plus sunitinib / targeted therapy for the treatment of newly diagnosed mRCC under a special protocol assessment, or SPA, with the Food and Drug Administration, or FDA. We refer to this trial as the ADAPT trial. We initiated the ADAPT trial in January 2013 and dosed the first patient in May 2013. We expect to complete enrollment by the end of second quarter 2015 and to have data from this trial in the second half of 2016 when we anticipate the required number of events to permit the primary analysis and assessment of overall survival to have occurred.

We are developing AGS-004, our second most advanced Arcelis-based product candidate, for the treatment of HIV. We have completed three clinical trials of AGS-004. These include phase 1 and phase 2a trials funded by government grants and a phase 2b trial that was funded in full by the National Institutes of Health, or NIH, and the National Institute of Allergy and Infectious Diseases, or NIAID, under a $39.8 million agreement. In addition, we are supporting an ongoing investigator-initiated phase 2 clinical trial of AGS-004 in adult HIV patients evaluating the use of AGS-004 in combination with a latency reversing drug for HIV eradication, and expect to support a second investigator-initiated phase 2 clinical trial of AGS-004 in the second half of 2015, to evaluate AGS-004 for long-term viral control in pediatric patients.

We have devoted substantially all of our resources to our drug development efforts, including advancing our Arcelis platform, conducting clinical trials of our product candidates, protecting our intellectual property and providing general and administrative support for these operations. We have not generated any revenue from product sales and, to date, have funded our operations primarily through our initial public offering, a venture loan, private placements of our preferred stock, convertible debt financings, government contracts, government and other third party grants and license and collaboration agreements. From inception in May 1997 through December 31, 2014, we have raised a total of $364.8 million in cash, including:

- $215.3 million from the sale of our common stock, convertible debt, warrants and preferred stock;
- $32.9 million from the licensing of our technology; and
- $104.1 million from government contracts, grants and license and collaboration agreements.
- $12.5 million from our venture loan and security agreement, or the Loan Agreement, with Horizon Technology Finance Corporation and Fortress Credit Co LLC, or the Lenders.

In February 2014, we issued and sold 6,228,725 shares of our common stock, including 603,725 shares of common stock sold pursuant to the underwriters’ exercise of their option to purchase additional shares, in our initial public offering, at a public offering price of $8.00 per share, for aggregate gross proceeds of $49.8 million. The net offering proceeds to us, after deducting underwriting discounts and commissions of approximately $3.5 million and offering expenses of approximately $2.9 million, were approximately $43.4 million.

On September 29, 2014, we entered into the Loan Agreement with the Lenders under which we may borrow up to $25.0 million in two tranches of $12.5 million each. We borrowed the first tranche of $12.5 million upon the closing of the transaction in September 2014.
Commercial Facility. In August 2014, we entered into a lease agreement, or the Lease Agreement, with TKC LXXII, LLC, a North Carolina limited liability company, or TKC. Under the Lease Agreement, we leased certain land and an approximately 120,000 square-foot building to be constructed on approximately 11 acres in Durham County, North Carolina. This facility will house our corporate headquarters and primary manufacturing facility. The Lease Agreement is intended to replace our existing lease, located at 4233 Technology Drive, Durham North Carolina, which currently expires in November 2016. The shell of the new facility will be constructed on a build-to-suit basis by TKC, at its expense, in accordance with agreed upon specifications and plans as set forth in the Lease Agreement.

The term of the Lease Agreement will be 10 years from the commencement date for the initial term, currently estimated to be May 1, 2015. We have an option to extend the Lease Agreement by six five-year renewal terms. Initial rent will be approximately $46,917 per month, subject to certain fixed increases over the course of the term as set forth in the Lease Agreement and to adjustment based on our use of certain amounts allocated for upfitting the interior of the facility.

Under the Lease Agreement, we were granted a purchase option under which we may exercise to acquire the facility.

In February 2015, we entered into a purchase and sale agreement with TKC exercising our purchase option under the Lease Agreement. The purchase price to be paid by us upon closing is $7.6 million plus the amount of any additional costs incurred by TKC as a result of changes requested by us and the amount of any improvement allowances advanced to us by TKC prior to the closing. We expect our exercise of the purchase option to close in the second half of 2015. Upon the closing, the Lease Agreement will terminate.

We have incurred losses in each year since our inception in May 1997. Our net loss was $10.5 million for the year ended December 31, 2012, $23.9 million for the year ended December 31, 2013 and $53.3 million for the year ended December 31, 2014. As of December 31, 2014, we had an accumulated deficit of $204.2 million. Substantially all of our operating losses have resulted from costs incurred in connection with our development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- continue our ongoing phase 3 clinical trial of AGS-003 for the treatment of mRCC and initiate additional clinical trials of AGS-003 for the treatment of other cancers;
- initiate and conduct additional clinical trials of AGS-004 for the treatment of HIV;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- continue to build out and equip a new commercial facility for the manufacture of our Arcelis-based products;
- establish a sales, marketing and distribution infrastructure to commercialize products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- hire additional clinical, quality control, scientific and management personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

We do not expect to generate significant funds or product revenue, unless and until we successfully complete development, obtain marketing approval and commercialize our product candidates, either alone or in collaboration with third parties, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization of AGS-003, AGS-004 or any of our other product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operating activities through a combination of equity offerings, debt financings, government contracts, government and other third party grants or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds through these means when needed, on favorable terms or at all.
**NIH Funding**

In September 2006, we entered into a multi-year research contract with the NIH and NIAID to design, develop and clinically test an autologous HIV immunotherapy capable of eliciting therapeutic immune responses. We have used funds from this contract to develop AGS-004, including to fund in full our phase 2b clinical trial of AGS-004. We have agreed to a statement of work under the contract, and are obligated to furnish all the services, qualified personnel, material, equipment, and facilities, not otherwise provided by the U.S. government, needed to perform the statement of work.

Under this contract, as amended, the NIH and NIAID have committed to fund up to a total of $39.8 million, including reimbursement of direct expenses and allocated overhead and general and administrative expenses of up to $38.4 million and payment of other specified amounts totaling up to $1.4 million upon our achievement of specified development milestones. This amount includes the September 2014 modification of the contract under which the NIH and NIAID agreed to fund up to an additional $500,000 to cover a portion of the manufacturing costs of the planned phase 2 clinical trial of AGS-004 for long-term viral control in pediatric patients. The NIH’s commitment under the contract extends to July 2016. Since September 2010, we have received reimbursement of our allocated overhead and general and administrative expenses at provisional indirect cost rates equal to negotiated provisional indirect cost rates agreed to with the NIH in September 2010. These provisional indirect cost rates are subject to adjustment based on our actual costs pursuant to the agreement with the NIH and may result in additional payments to us from the NIH and the NIAID to reflect our actual costs since September 2010.

We have recorded revenue of $36.8 million through December 31, 2014 under the NIH contract. This contract is the only arrangement under which we have generated substantial revenue. As of December 31, 2014, there was up to $3.0 million of potential revenue remaining to be earned under the agreement with the NIH.

**Collaborations**

**Pharmstandard**

In August 2013, in connection with the purchase of shares of our series E preferred stock by Pharmstandard International S.A., or Pharmstandard, we entered into an exclusive royalty-bearing license agreement with Pharmstandard. Under this license agreement, we granted Pharmstandard and its affiliates a license, with the right to sublicense, to develop, manufacture and commercialize AGS-003 and other products for the treatment of human diseases which are developed by Pharmstandard using our personalized immunotherapy platform in the Russian Federation, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, which we refer to as the Pharmstandard Territory. We also provided Pharmstandard with a right of first negotiation for development and commercialization rights in the Pharmstandard Territory to specified additional products we may develop.

Pharmstandard agreed to pay us royalties on net sales of all licensed products in the low single digits until it has generated a specified amount of aggregate net sales. Once the net sales threshold is achieved, Pharmstandard will pay us royalties on net sales of specified licensed products, including AGS-003, in the low double digits below 20%. After the net sales threshold is achieved, Pharmstandard has the right to offset a portion of the royalties Pharmstandard pays to third parties for licenses to necessary third party intellectual property against the royalties that Pharmstandard pays to us. For further information regarding this collaboration, see “Business — Development and Commercialization Agreements — Pharmstandard.”

In November 2013, we entered into an agreement with Pharmstandard under which Pharmstandard purchased additional shares of our series E preferred stock. Under this agreement, we agreed to enter into a manufacturing rights agreement for the European market with Pharmstandard and that the manufacturing rights agreement would provide for the issuance of warrants to Pharmstandard to purchase 499,788 shares of our common stock at an exercise price of $5.82 per share. As of February 28, 2015, we had not entered into this manufacturing rights agreement or issued the warrants. The shares of series E preferred stock converted to common stock on a 6-for-1 basis in connection with our initial public offering.

**Green Cross**

In July 2013, in connection with the purchase of shares of our series E preferred stock by Green Cross Corp., or Green Cross, we entered into an exclusive royalty-bearing license agreement with Green Cross. Under this agreement we granted Green Cross a license to develop, manufacture and commercialize AGS-003 for mRCC in South Korea. We also provided Green Cross with a right of first negotiation for development and commercialization rights in South Korea to specified additional products we may develop.
Under the terms of the license, Green Cross has agreed to pay us $0.5 million upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $0.5 million upon the initial regulatory approval of a licensed product in South Korea and royalties ranging from the mid-single digits to low double digits below 20% on net sales until the fifteenth anniversary of the first commercial sale in South Korea. For further information regarding this collaboration, see “Business—Development and Commercialization Agreements—Green Cross.” The shares of series E preferred stock converted to common stock on a 6-for-1 basis in connection with our initial public offering.

**Medinet**

In December 2013, we entered into a license agreement with Medinet Co., Ltd. which was novated, amended and restated between the Company, Medinet Co., Ltd. and MEDcell Co., Ltd. in October 2014. Pursuant to the novation, Medinet Co., Ltd. assigned and transferred all of its rights and obligations under the original license agreement to MEDcell Co., Ltd. without any substantive change in the underlying rights or obligations. References to Medinet in this Form 10-K refer to Medinet Co., Ltd. prior to the novation and MEDcell Co., Ltd. from after the novation. Under this agreement, we granted Medinet an exclusive, royalty-free license to manufacture in Japan AGS-003 and other products using our Arcelis technology solely for the purpose of the development and commercialization of AGS-003 and these other products for the treatment of mRCC. We refer to this license as the manufacturing license. In addition, under this agreement, we granted Medinet an option to acquire a nonexclusive, royalty-bearing license under our Arcelis technology to sell in Japan AGS-003 and other products for the treatment of mRCC. We refer to the option as the sale option and the license as the sale license.

In consideration for the manufacturing license, Medinet paid us $1.0 million. Medinet also loaned us $9.0 million in connection with us entering into the agreement. We have agreed to use these funds in the development and manufacturing of AGS-003 and the other products. Medinet also agreed to pay us milestone payments of up to a total of $9.0 million upon the achievement of developmental and regulatory milestones and $5.0 million upon the achievement of a sales milestone related to AGS-003 and these products. If Medinet exercises the sale option, it will pay us $1.0 million, as well as royalties on net sales at a rate to be negotiated until the later of the expiration of the licensed patent rights in Japan and the twelfth anniversary of the first commercial sale in Japan. If we cannot agree on the royalty rate, we have agreed to submit the matter to arbitration.

We borrowed the $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0% per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. We have the right to prepay the loan at any time. If we have not repaid the loan by December 31, 2018, then we have agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 31, 2018 will constitute pre-paid royalties under the license and will not be otherwise due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan and the twelfth anniversary of the first commercial sale in Japan. If we cannot agree on the royalty rate, we have agreed to submit the matter to arbitration.

We recorded the $1.0 million payment from Medinet as a deferred liability. In addition, because the $9.0 million promissory note was issued at a below market interest rate, we allocated the proceeds of the loan between the manufacturing license and the debt at the time of issuance. As a result, we recorded $6.9 million as notes payable, based upon an effective interest rate of 8%, and $2.1 million as a deferred liability. The total deferred liability recorded related to the manufacturing license was $3.1 million as of December 31, 2014. Interest expense of $0.7 million was recorded in the year ended December 31, 2014 based upon the effective interest rate of 8%. For further information regarding this collaboration, see “Business—Development and Commercialization Agreements—Medinet.”

**Financial Overview**

**Revenue**

To date, we have not generated revenue from the sale of any products. During the years ended December 31, 2012, 2013 and 2014, substantially all of our revenue has been derived from our NIH contract. We may generate revenue in the future from government contracts and grants, payments from future license or collaboration agreements and product sales. We expect that any revenue we generate will fluctuate from quarter to quarter.

**Research and Development Expenses**

Since our inception in 1997, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize our research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions;

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We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of AGS-003 and AGS-004. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, including in connection with our clinical trials, and related clinical trial fees. Commercial manufacturing development costs consist primarily of costs incurred under our development agreement with Invotech to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products. We have been developing AGS-003 and AGS-004, in parallel, and typically use our employee and infrastructure resources across multiple research and development programs. We do not allocate salaries, stock-based compensation, employee benefit or other indirect costs related to our research and development function to specific product candidates.

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, expense and results of our ongoing clinical trials;
- the scope, rate of progress, expense and results of additional clinical trials that we may conduct;
- the scope, rate of progress, expense and results of our commercial manufacturing development efforts;
- other research and development activities; and
- the timing of regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

AGS-003. Our most advanced product candidate is AGS-003, which we are developing for the treatment of mRCC and other cancers. We are currently conducting a pivotal phase 3 clinical trial of AGS-003 plus sunitinib / targeted therapy for the treatment of newly diagnosed mRCC under an SPA with the FDA. We refer to this trial as the ADAPT trial. We initiated the ADAPT trial in January 2013 and dosed the first patient in May 2013. We plan to enroll approximately 450 patients in the trial to generate 290 events for the primary endpoint of overall survival. As of February 28, 2015, we had collected tumor from approximately 880 patients for eligibility and had enrolled and randomized approximately 340 patients in the trial. We expect to complete enrollment by the end of second quarter 2015 and to have data from this trial in the second half of 2016 when we anticipate the required number of events to permit the primary analysis and assessment of overall survival to have occurred.
We estimate that the direct costs that we will incur in connection with conducting the planned pivotal phase 3 clinical trial will total approximately $50.0 million, of which $11.3 million was incurred in 2013 and $16.9 million in 2014. We are also exploring the use of AGS-003 in non-clear cell mRCC, early stage RCC prior to and following nephrectomy and other advanced solid tumors, including bladder cancer and non-small cell lung cancer (NSCLC). We have commenced support for or plan to support investigator-initiated clinical trials of AGS-003 for the treatment of these additional indications in 2015.

AGS-004. We are developing AGS-004, our second Arcelis-based product candidate, for the treatment of HIV. In 2014, we completed a randomized, placebo controlled, double blind phase 2b clinical trial of AGS-004 in chronically infected patients on ART that we initiated in July 2010. The phase 2 trial was funded under our $39.8 million NIH contract.

We are supporting an investigator-initiated Phase 2 clinical trial of AGS-004 in up to twelve adult HIV patients to evaluate the use of AGS-004 in combination with one of these latency reversing therapies for this purpose at the University of North Carolina. This trial is being conducted in two stages. Stage 1 of this trial is designed to study immune response kinetics to AGS-004 in patients on continuous ART. The purpose is to better define the optimal dosing strategy in combination with a latency-reversing therapy. We expect that patients in Stage 1 will rollover into Stage 2, a separate protocol that will study AGS-004 in combination with one of the latency-reversing drugs. In January 2014, Collaboratory of AIDS Researchers for Eradication, or CARE, agreed that it would fund all patient clinical costs of this phase 2 clinical trial, except for the associated manufacturing costs for which we will be responsible.

We also plan to explore the use of AGS-004 monotherapy to provide long-term control of HIV viral load in otherwise immunologically healthy patients and eliminate their need for ART. Accordingly, we plan to initiate in 2015 a phase 2 clinical trial of AGS-004 monotherapy in pediatric patients infected with HIV who have otherwise healthy immune systems, have been treated with antiretroviral therapy since birth or shortly thereafter and, as a result, are lacking the antiviral memory T-cells to combat the virus.

Commercial Manufacturing Development. Commercial manufacturing development costs consist primarily of costs incurred under our development agreement with Invotech to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products and our development agreement with Saint-Gobain to develop a range of disposables for use in the automated production system.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, operational and finance, information technology and human resources functions. Other significant general and administrative expenses include allocation of facilities costs, professional fees for accounting and legal services and expenses associated with obtaining and maintaining patents.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash, cash equivalents and short-term investments.

Interest expense consists primarily of cash and non-cash interest costs related to our debt. During the year ended December 31, 2014, interest expense primarily resulted from accrued interest on our note payable to Medinet, which was issued in December 2013 and interest from the Loan Agreement entered into in September 2014. During the year ended December 31, 2013, interest expense was not significant. During the year ended December 31, 2012, interest expense was incurred under various convertible notes outstanding until converted into redeemable preferred stock in April 2012.

Venture Loan and Security Agreement. In September 2014, we entered into the Loan Agreement with the Lenders under which we may borrow up to $25.0 million in two tranches of $12.5 million each. We borrowed the first tranche of $12.5 million upon the closing of the transaction on September 29, 2014. Subject to certain other funding conditions, the second tranche of $12.5 million will be available for drawdown at any time commencing on the date the we complete the enrollment and randomization of patients in the Company’s phase 3 clinical trial of AGS-003, which we expect to occur by the end of second quarter 2015 continuing until September 30, 2015. The per annum interest rate for each tranche is a floating rate equal to 9.25% plus the amount by which the one-month London Interbank Offered Rate exceeds 0.50% (effectively a floating rate equal to 8.75% plus the one-month LIBOR Rate). The total per annum interest rate shall not exceed 10.75%.

Medinet. In December 2013, in connection with the license agreement with Medinet, as described in Note 9, we borrowed $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0% per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. We have the right to prepay the loan at any time. If we have not repaid the loan by December 31, 2018, then we have agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 18, 2018 may constitute pre-paid royalties under the license or would be due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If we and Medinet cannot agree on the royalty rate, Medinet has agreed to submit the matter to arbitration. Because the $9.0 million promissory note was issued at a below market interest rate, we allocated the proceeds of the loan between the license agreement and the debt at the time of issuance. Accordingly, as of December 31, 2013, we recorded $6.9 million to notes payable, based upon an effective interest rate of 8.0%, and $2.1 million as a deferred liability. As of December 31, 2014, we recorded $7.6 million to notes payable, including $0.7 million accrued interest recorded during the year ended December 31, 2014. The total deferred liability was $3.1 million as of December 31, 2014 including the $1.0 million received by us for a manufacturing license.

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**Accretion of Preferred Stock**

Our preferred stock was reflected on our balance sheet at its cost, less associated issuance costs. The amount reflected on the balance sheet for our preferred stock was increased by periodic accretions of the issuance costs so that the original amount reflected on the balance sheet will equal the aggregate redemption price.

On February 12, 2014, all outstanding shares of our preferred stock converted into an aggregate of 13,188,251 shares of our common stock upon the closing of our initial public offering.

**Derivative Income (Expense)**

Prior to October 2012, we owned 49.94% of the capital of DC Bio. Under an amended and restated put agreement with the other shareholders of DC Bio, the other shareholders had the right to put the Common, Class A preferred and Class B preferred shares of DC Bio held by them to us in exchange for shares of our common stock, series B preferred stock and series C preferred stock at any time on or after March 31, 2011. We recorded a liability of $1.0 million on our balance sheet at December 31, 2011 reflecting the fair value of the put, which we calculated based on the estimated fair value of the shares of our common stock, series B preferred stock and series C preferred stock issuable in exchange for shares of DC Bio. In each reporting period, we recorded any change in the fair value of the shares underlying the put as expense, in the case of an increase in the fair value, and income, in the case of a decrease in fair value.

In October 2012 and December 2012, DC Bio repurchased the shares of DC Bio held by other entities. As of December 31, 2012, we owned 100.0% of the capital of DC Bio. We consolidate its results in our financial statements. The other shareholders’ previous ownership in DC Bio is reflected in our financial statements by reference to the equity attributable to noncontrolling interest.

**Critical Accounting Estimates**

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these 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. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing in “Item 8. Financial Statements and Supplementary Data,” we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

**Revenue Recognition**

We recognize revenue in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification 605, Revenue Recognition, or ASC 605. We recognize revenue when the following criteria are met: persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

We have previously entered into license agreements with collaborators. The terms of these agreements have included nonrefundable signing and licensing fees, as well as milestone payments and royalties on any future product sales developed by the collaborators under these licenses. We assess these multiple elements in accordance with ASC 605, in order to determine whether particular components of the arrangement represent separate units of accounting.
These collaboration agreements will be accounted for in accordance with Accounting Standards Update, or ASU, No. 2009-13, Topic 605—Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. This guidance requires the application of the “relative selling price” method when allocating revenue in a multiple deliverable arrangement. The selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists; otherwise, third-party evidence of selling price shall be used. If neither exists for a deliverable, the vendor shall use its best estimate of the selling price for that deliverable. We recognize upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations are accounted for separately as the obligations are fulfilled. If the license is considered to either not have stand-alone value or have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement is accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. If we cannot reasonably estimate the timing and the level of effort to complete our performance obligations under the arrangement, then we recognize revenue under the arrangement on a straight-line basis over the period that we expect to complete our performance obligations.

Our license agreements with Green Cross and Medinet provide for, and other agreements we may enter into may provide for, milestone payments. Revenues from milestones, if they are non-refundable and considered substantive, are recognized upon successful accomplishment of the milestones. If not considered substantive, milestones are initially deferred and recognized over the remaining performance obligation.

Our current license agreements with Pharmstandard, Green Cross and Medinet and any future license agreements we may enter into may provide for royalty payments. To date, we have not received any royalty payments and accordingly have not recognized any related revenue. We will recognize royalty revenue upon the sale of the related products, provided we have no remaining performance obligations under the arrangements.

We record deferred revenue when payments are received in advance of the culmination of the earnings process. This revenue is recognized in future periods when the applicable revenue recognition criteria have been met.

Under our NIH contract, we receive reimbursement of our direct expenses and allocated overhead and general and administrative expenses, as well as payment of other specified amounts totaling up to $1.4 million upon our achievement of specified development milestones. We recognize revenue from reimbursements earned in connection with the NIH contract as reimbursable costs are incurred. We recognize revenues from the achievement of milestones under the NIH contract upon the accomplishment of any such milestone.

**Accrued Expenses**

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

- fees paid to CROs in connection with clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- professional service fees; and
- unpaid salaries, wages and benefits.

We accrue our expenses related to clinical trials based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs 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 service fees, 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 will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.
Stock-Based Compensation

In accordance with ASC 718, Stock Compensation, we record the fair value of stock options, restricted stock awards and other stock-based compensation issued to employees as of the grant date as compensation expense. We recognize expense over the requisite service period, which is typically the vesting period. For non-employees, we also record stock options, restricted stock awards and other stock-based compensation issued to these non-employees at their fair value as of the grant date. We then periodically remeasure the awards to reflect the current fair value at each reporting period and recognize expense over the related service period.

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including stock price volatility, the expected life of stock options, risk free interest rate and the fair value of the underlying common stock on the date of grant.

- We do not have sufficient history to estimate the volatility of our common stock price. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants.

- The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future.

- The expected term represents the period that the stock-based awards are expected to be outstanding. Our historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore we estimate the expected term by using the simplified method provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

- We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.

- We estimate forfeitures based on our historical analysis of actual stock option forfeitures.

The assumptions that we used in the Black-Scholes option-pricing model for the years ended December 31, 2012, 2013 and 2014, are set forth below:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>1.20%</td>
<td>2.12%</td>
<td>2.26%</td>
</tr>
<tr>
<td>Dividend yield</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Expected option term (in years)</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Volatility</td>
<td>94%</td>
<td>94%</td>
<td>96%</td>
</tr>
</tbody>
</table>

Prior to February 7, 2014, the effective date our Common Stock began trading upon our initial public offering, the fair value of our common stock for purposes of determining the exercise price for stock option grants was determined by our board of directors, with the assistance and upon the recommendation of management, in good faith based on a number of objective and subjective factors consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid. Since our initial public offering, the exercise price per share of all option grants has been set at the closing price of our common stock on The NASDAQ Global Market on the applicable date of grant, which our board of directors believes represents the fair value of our common stock.

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Warrant Liability

We accounted for our preferred stock warrants in accordance with ASC Topic 480-10, *Distinguishing Liabilities from Equity*, which requires that a financial instrument, other than an outstanding share, that, at inception, includes an obligation to repurchase the issuer’s equity shares regardless of the timing or likelihood of the redemption, shall be classified as a liability. We measured the fair value of the warrant liability based on the fair value of the warrants which we determine based on an allocation of our enterprise value to all classes of equity and preferred stock, including the warrants. We utilized the probability-weighted expected return method, or PWERM method, to determine these values. In each reporting period, we recorded any change in fair value of the warrants as expense in the case of an increase in fair value and income in the case of a decrease in fair value.

In July 2013, in connection with the series D-1 exchange, all of our outstanding warrants to purchase shares of our series C preferred stock and series D-1 preferred stock were cancelled. There were no warrants to purchase preferred stock outstanding as of December 31, 2013 or during the year ended December 31, 2014.
The following table summarizes the results of our operations for each of the years ended December 31, 2012, 2013 and 2014, together with the changes in those items in dollars and as a percentage:

<table>
<thead>
<tr>
<th></th>
<th>Year Ended December 31,</th>
<th>$</th>
<th>%</th>
<th>Year Ended December 31,</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2013</td>
<td>2014</td>
<td>Change (in thousands)</td>
<td>2012</td>
<td>2013</td>
<td>Change</td>
</tr>
<tr>
<td>Revenue</td>
<td>$4,422</td>
<td>$1,974</td>
<td>$2,448</td>
<td>(55.4)%</td>
<td>$7,039</td>
<td>$4,422</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>23,991</td>
<td>45,499</td>
<td>21,508</td>
<td>89.7%</td>
<td>17,617</td>
<td>23,991</td>
</tr>
<tr>
<td>General and administrative</td>
<td>4,662</td>
<td>8,599</td>
<td>3,937</td>
<td>84.4%</td>
<td>6,135</td>
<td>4,662</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>28,653</td>
<td>54,098</td>
<td>25,445</td>
<td>88.8%</td>
<td>23,752</td>
<td>28,653</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(24,231)</td>
<td>(52,124)</td>
<td>(27,893)</td>
<td>115.1%</td>
<td>(16,713)</td>
<td>(24,231)</td>
</tr>
<tr>
<td>Interest income</td>
<td>7</td>
<td>67</td>
<td>60</td>
<td>*</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(5)</td>
<td>(1,124)</td>
<td>(1,119)</td>
<td>*</td>
<td>(293)</td>
<td>(5)</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>355</td>
<td>—</td>
<td>(355)</td>
<td>*</td>
<td>4,917</td>
<td>355</td>
</tr>
<tr>
<td>Derivative income</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>*</td>
<td>1,036</td>
<td>—</td>
</tr>
<tr>
<td>Investment tax credits</td>
<td>—</td>
<td>141</td>
<td>141</td>
<td>*</td>
<td>694</td>
<td>—</td>
</tr>
<tr>
<td>Other expense</td>
<td>(48)</td>
<td>(266)</td>
<td>(218)</td>
<td>*</td>
<td>(117)</td>
<td>(48)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(23,922)</td>
<td>$(53,306)</td>
<td>$(29,384)</td>
<td>122.8%</td>
<td>$(10,471)</td>
<td>$(23,922)</td>
</tr>
</tbody>
</table>

* Not meaningful

Revenue

To date, we have not generated revenue from the sale of any products. During the years ended December 31, 2012, 2013 and 2014, substantially all of our revenue was derived from our NIH contract. We may generate revenue in the future from government contracts and grants, payments from future license or collaboration agreements and product sales. We expect that any revenue we generate will fluctuate from quarter to quarter.

Revenue was $4.4 million for the year ended December 31, 2013, compared with $2.0 million for the year ended December 31, 2014, a decrease of $2.4 million, or 55.4%. The $2.4 million decrease for the year ended December 31, 2014 is due to a $2.2 million decline in reimbursement under our NIH contract associated with decreased activity in the year ended December 31, 2014 with respect to our phase 2b clinical trial of AGS-004 as the number of patients receiving treatment in the trial declined. This decrease in revenue was partially offset by $0.2 million in revenue recognized in connection with technology transfers with Medinet during the year ended December 31, 2014.

Revenue was $7.0 million for the year ended December 31, 2012, compared with $4.4 million for the year ended December 31, 2013, a decrease of approximately $2.6 million, or 37.2%. The $2.6 million decrease for the year ended December 31, 2013 is due to decreased reimbursement under our NIH contract associated with decreased activity with respect to our phase 2b clinical trial of AGS-004 as the number of patients receiving treatment in the trial declined.
Research and Development Expenses

The table below summarizes our direct research and development expenses by program for the years indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, including in connection with our clinical trials, and related clinical trial fees. Research and development expenses also include commercial manufacturing development costs consisting primarily of costs incurred under our development agreements with Invetech and Saint-Gobain to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products. We have been developing AGS-003 and AGS-004, in parallel, and typically use our employee and infrastructure resources across multiple research and development programs. We do not allocate salaries, stock-based compensation, employee benefit or other indirect costs related to our research and development function to specific product candidates. Those expenses are included in “Indirect research and development expense” in the table.

<table>
<thead>
<tr>
<th>Year Ended December 31,</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct research and development expense by program:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGS-003</td>
<td>$ 5,842</td>
<td>$ 11,301</td>
<td>$ 16,940</td>
</tr>
<tr>
<td>AGS-004</td>
<td>2,626</td>
<td>1,602</td>
<td>903</td>
</tr>
<tr>
<td>Other</td>
<td>403</td>
<td>52</td>
<td>131</td>
</tr>
<tr>
<td><strong>Total direct research and development program expense</strong></td>
<td>8,871</td>
<td>12,955</td>
<td>17,974</td>
</tr>
<tr>
<td>Commercial manufacturing development</td>
<td>—</td>
<td>—</td>
<td>11,588</td>
</tr>
<tr>
<td>Indirect research and development expense</td>
<td>8,746</td>
<td>11,036</td>
<td>15,937</td>
</tr>
<tr>
<td><strong>Total research and development expense</strong></td>
<td>$ 17,617</td>
<td>$ 23,991</td>
<td>$ 45,499</td>
</tr>
</tbody>
</table>

Research and development expenses were $24.0 million for the year ended December 31, 2013, compared with $45.5 million for the year ended December 31, 2014, an increase of $21.5 million, or 89.7%. The increase in research and development expense primarily reflects a $5.0 million increase in direct research and development expense, a $11.6 million increase in commercial manufacturing development expense and a $4.9 million increase in indirect research and development expense. The increase in direct research and development expenses resulted primarily from the following:

- Direct research and development expense for AGS-003 increased from $11.3 million for the year ended December 31, 2013 to $16.9 million in the year ended December 31, 2014. This increase primarily reflects increased patient enrollment in the ongoing pivotal phase 3 clinical trial of AGS-003 in combination with sunitinib in the year ended December 31, 2014 as compared with the year ended December 30, 2013; and
- Direct research and development expense with respect to AGS-004 decreased from $1.6 million in the year ended December 31, 2013 to $0.9 million in the year ended December 31, 2014 primarily due to the decreased activity in our phase 2b clinical trial of AGS-004 as the number of patients receiving treatment in the trial declined, which decrease was partially offset by $0.2 million in costs to support stage 1 of an investigator-initiated phase 2 clinical trial of AGS-004 in adult HIV patients aimed at eradication of the virus that began in May 2014.

We also incurred $11.6 million of research and development expense related to the initiation of our commercial manufacturing development efforts during the year ended December 31, 2014. The increase in indirect research and development expense was primarily due to higher personnel costs, as we had 80 employees engaged in research and development activities as of December 31, 2013 compared with 97 employees as of December 31, 2014.

We expect that our research and development expenses will increase for the foreseeable future as we seek to complete development of AGS-003 and AGS-004.

Research and development expenses were $17.6 million for the year ended December 31, 2012, compared with $24.0 million for the year ended December 31, 2013, an increase of approximately $6.4 million, or 36.2%. This increase in research and development expense primarily reflects a $4.1 million increase in direct research and development costs and an increase in indirect research and development expense of $2.3 million. The increase in direct research and development expenses resulted primarily from the following:

- Direct research and development expense for AGS-003 increased from $5.8 million for the year ended December 31, 2012 to $11.3 million in the year ended December 31, 2013. This increase primarily reflects increased activity in connection with the commencement in January 2013 of the pivotal phase 3 clinical trial of AGS-003 in combination with sunitinib; and
The increase in indirect research and development was primarily due to higher personnel costs as we had 56 employees engaged in research and development activities as of December 31, 2012 compared with 80 employees as of December 31, 2013.

**General and Administrative Expenses**

General and administrative expenses were $4.7 million for the year ended December 31, 2013, compared with $8.6 million for the year ended December 31, 2014, an increase of $3.9 million or 84.4%. This increase is primarily due to an additional $1.4 million in personnel costs, including salaries, benefits and stock-based compensation; an increase of $1.3 million in outside services including legal, patent, and other consulting services; and an increase of $1.2 million in expenses relating to our new status as a public company, including liability and directors’ and officers’ insurance, board of directors’ fees and expenses, franchise taxes and registration and service fees.

General and administrative expenses were $6.1 million for the year ended December 31, 2012, compared with $4.7 million for the year ended December 31, 2013, a decrease of $1.4 million or 24.0%. This decrease reflects a $0.5 million decrease in audit and tax consulting fees and a $1.6 million decrease in legal expenses reflecting our increased legal expenses in 2012 associated with the initial public offering that we withdrew in March 2012. These decreases were partially offset by an increase of $0.7 million primarily due to increased compensation and marketing expenses during the year ended December 31, 2013.

We expect that our general and administrative expenses will increase with the continued development and potential commercialization of our product candidates and as we adjust to operating as a public company. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to public companies.

**Interest Expense**

Interest expense was $5,000 for the year ended December 31, 2013, compared with $1.1 million for the year ended December 31, 2014. During the year ended December 31, 2014, interest expense primarily resulted from accrued interest on our note payable to Medinet, which was issued in December 2013, and interest from the Loan Agreement with the Lenders entered into in September 2014. We expect that interest expense will increase as a result of interest incurred under the Loan Agreement.

Interest expense was $0.3 million for the year ended December 31, 2012, compared with $5,000 for the year ended December 31, 2013. During the year ended December 31, 2012, interest expense primarily resulted from interest accrued on our outstanding 2010 convertible notes and July 2011 convertible notes. On April 10, 2012, the aggregate principal and interest on the 2010 convertible notes and the July 2011 convertible notes totaling $10.7 million converted into an aggregate of 3,023,661 shares of our series D preferred stock.

**Change in Fair Value of Warrant Liability**

Income from the change in fair value of the warrant liability was $0.4 million for the year ended December 31, 2013, compared with none for the year ended December 31, 2012. During the year ended December 31, 2014, income from the change in fair value of the warrant liability during the year ended December 31, 2013 increased to $4.9 million for the year ended December 31, 2012, compared with income of $0.4 million for the year ended December 31, 2013. These amounts represented the decrease in the fair value of the warrant liability during the respective periods.
Derivative (Expense) Income

Derivative income was $1.0 million for the year ended December 31, 2012, compared with zero for the years ended December 31, 2013 and 2014. Derivative income in 2012 reflected the termination of the put option held by the shareholders of DC Bio which resulted in the recognition of the derivative liability as income.

Investment Tax Credits

Other income of $140,556 was recognized during the year ended December 31, 2014 for scientific research and experimental development, or SR&ED, investment tax credits in Canada. Under Canadian and Ontario law, the Company’s Canadian subsidiary is entitled to SR&ED. Because these credits are subject to a claims review, the Company recognizes such credits when received. No such credits were received during the year ended December 31, 2013.

Investment tax credits were $0.7 million for the year ended December 31, 2012. We recorded no investment tax credits in the year ended December 31, 2013.

Other Expense

Other expense totaled $117,000, $48,000 and $266,000 for the years ended December 31, 2012, 2013 and 2014, respectively. Under a previous loan and security agreement to which we were a party, we had agreed to pay a success fee of $200,000 upon consummation of a liquidity event, including an initial public offering. Our initial public offering closed on February 12, 2014. Accordingly, this fee was paid in March 2014 and was recorded in Other expense on the consolidated statement of operations during the year ended December 31, 2014.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2014, we had cash, cash equivalents and short-term investments of $56.2 million.

Since our inception in May 1997 through December 31, 2014, we have funded our operations principally with $215.3 million from the sale of common stock, convertible debt, warrants and preferred stock, $32.9 million from the licensing of our technology, $104.1 million from government contracts, grants and collaboration agreements, and $12.5 million from the Loan Agreement.

As of December 31, 2014, the gross proceeds we have received from the issuance and sale of our preferred stock were as follows:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Year</th>
<th>Gross Proceeds (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Series A Preferred</td>
<td>2000</td>
<td>$1,594</td>
</tr>
<tr>
<td>Series B Preferred</td>
<td>2001</td>
<td>$39,382</td>
</tr>
<tr>
<td>Series B-1 Preferred</td>
<td>2004</td>
<td>$5,000</td>
</tr>
<tr>
<td>Series C Preferred</td>
<td>2008</td>
<td>$33,462</td>
</tr>
<tr>
<td>Series D Preferred</td>
<td>2012</td>
<td>$9,022</td>
</tr>
<tr>
<td>Series D-1 Preferred</td>
<td>2012</td>
<td>$15,978</td>
</tr>
<tr>
<td>Series E Preferred</td>
<td>2013</td>
<td>$48,000</td>
</tr>
</tbody>
</table>

Upon the closing of the initial public offering in February 2014, all of the then-outstanding shares of the Company’s redeemable convertible preferred stock automatically converted into 13,188,251 shares of common stock.

In February 2014, we issued and sold 6,228,725 shares of our common stock, including 603,725 shares of common stock sold pursuant to the underwriters’ exercise of their option to purchase additional shares, in our initial public offering at a public offering price of $8.00 per share, for aggregate gross proceeds of $49.8 million. The net offering proceeds to us, after deducting underwriting discounts and commissions of approximately $3.5 million and offering expenses of approximately $2.9 million, were approximately $43.4 million.

Venture Loan and Security Agreement. In September 2014, we entered into the Loan Agreement, with the Lenders, under which we may borrow up to $25.0 million in two tranches of $12.5 million each, or the Loan Facility.
We borrowed the first tranche of $12.5 million upon the closing of the transaction on September 29, 2014. Subject to certain other funding conditions, the second tranche of $12.5 million will be available for drawdown at any time commencing on the date we complete the enrollment and randomization of patients in our Phase 3 trial of AGS-003 and continuing until September 30, 2015. The per annum interest rate for each tranche will be a floating rate equal to 9.25% plus the amount by which the one-month LIBOR Rate exceeds 0.50% (effectively a floating rate equal to 8.75% plus the one-month LIBOR Rate). The total per annum interest rate shall not exceed 10.75%.

We have agreed to repay the first tranche of $12.5 million on an interest only basis monthly until September 30, 2016, followed by monthly payments of principal and accrued interest through the scheduled maturity date for the first tranche loan on September 30, 2018. In addition, a final payment for the first tranche loan equal to $625,000 will be due on September 30, 2018, or such earlier date specified in the Loan Agreement. We have agreed to repay any amounts advanced under the second tranche of $12.5 million in 18 monthly payments of interest only followed by 24 monthly payments of principal and accrued interest through the scheduled maturity date for the second tranche loan, which is 42 months following the date we draw down the second tranche loan. In addition, a final payment equal to 5.0% of the amount drawn under the second tranche loan will be due on the scheduled maturity date for such loan, or such earlier date specified in the Loan Agreement. In addition, if we repay all or a portion of the loan prior to the applicable maturity date, we will pay the Lenders a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs on or before 24 months after the funding date thereof, 2% if the prepayment occurs more than 24 months after, but on or before 36 months after, the funding date thereof, or 1% if the prepayment occurs more than 36 months after the funding date thereof.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets other than our intellectual property. We also have agreed not to pledge or otherwise encumber our intellectual property assets, subject to certain exceptions.

The Loan Agreement includes customary affirmative and restrictive covenants, but does not include any covenants to attain or maintain certain financial metrics, and also includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

In connection with the Loan Agreement, we issued to the Lenders and their affiliates warrants to purchase a total of 82,780 shares of our Common Stock at a per share exercise price of $9.06, or the Warrants. The Lenders may not exercise the Warrants for more than 41,390 of such shares of Common Stock until the earliest to occur of (i) a merger or consolidation of the Company, or a sale of all or substantially all of our assets, (ii) our satisfaction of the conditions precedent to the making of the second tranche loan, and (iii) the funding of the second tranche loan. The Warrants will terminate on the earlier of September 29, 2021 or such earlier date as specified in the Warrants.

Commercial Facility. On August 18, 2014, we entered into a Lease Agreement with TKC.

Under the Lease Agreement, we leased certain land and an approximately 120,000 square-foot building to be constructed on approximately 11 acres in Durham County, North Carolina. This facility will house our corporate headquarters and primary manufacturing facility. The Lease Agreement is intended to replace our existing lease, located at 4233 Technology Drive, Durham North Carolina, which currently expires in November 2016. The shell of the new facility is being constructed on a build-to-suit basis by TKC, at its expense, in accordance with agreed upon specifications and plans as set forth in the Lease Agreement.

The term of the Lease Agreement will be 10 years from the commencement date for the initial term, currently estimated to be May 1, 2015. We have the option to extend the Lease Agreement by six five-year renewal terms. Initial rent will be approximately $46,917 per month, subject to certain fixed increases over the course of the term as set forth in the Lease Agreement and to adjustment based on the Company’s use of certain amounts allocated for upfitting the interior of the facility. Under the lease agreement, we were granted a purchase option under which we may exercise to acquire the facility.

In February 2015, we entered into a purchase and sale agreement with TKC exercising our purchase option under the lease agreement. The purchase price to be paid by us upon closing is $7.6 million plus the amount of any additional costs incurred by TKC as a result of changes requested by us and the amount of any improvement allowances advanced to us by TKC prior to the closing. We expect our exercise of the purchase option to close in the second half of 2015. Upon the closing, the lease agreement will terminate.
Cash Flows

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

<table>
<thead>
<tr>
<th>Year Ended December 31,</th>
<th>2012 (in thousands)</th>
<th>2013 (in thousands)</th>
<th>2014 (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net cash (used in) provided by:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>$(13,198)</td>
<td>$(18,256)</td>
<td>$(45,241)</td>
</tr>
<tr>
<td>Investing activities</td>
<td>$(5,281)</td>
<td>$(10,057)</td>
<td>$(7,789)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>$24,871</td>
<td>$53,404</td>
<td>$56,966</td>
</tr>
<tr>
<td>Effect of exchange rate changes on cash</td>
<td>$(180)</td>
<td>$(8)</td>
<td>$(10)</td>
</tr>
<tr>
<td>Net increase (decrease) in cash and cash equivalents</td>
<td>$6,212</td>
<td>$25,083</td>
<td>$3,926</td>
</tr>
</tbody>
</table>

Operating Activities. Net cash used in operating activities of $13.2 million during the year ended December 31, 2012 was primarily a result of our $10.5 million net loss, changes in operating assets and liabilities of $0.4 million and non-cash items of $2.3 million. These non-cash items reflect the gain recorded due to the decrease in fair value of our warrant liability of $4.9 million and derivative income of $1.0 million, partially offset by the write-off of previously deferred financing costs of $1.8 million, non-cash interest costs related to our debt of $0.3 million, depreciation of $0.5 million and compensation expense related to stock options of $1.0 million.

Net cash used in operating activities of $18.3 million during the year ended December 31, 2013 was primarily a result of our $23.9 million net loss, partially offset by changes in operating assets and non-cash items of $1.3 million and liabilities of $4.3 million. These non-cash items primarily reflect the depreciation of $0.6 million and compensation expense related to stock options of $1.1 million, partially offset by the gain recorded due to the decrease in fair value of our warrant liability of $0.4 million.

Net cash used in operating activities of $45.2 million during the year ended December 31, 2014 was primarily a result of our $53.3 million net loss, partially offset by non-cash items of $4.4 million and changes in operating assets and liabilities of $3.7 million. These non-cash items primarily consisted of depreciation and amortization of $0.6 million, compensation expense related to stock options of $3.0 million and interest accrued on long-term debt of $0.7 million. The long-term portion of accrued manufacturing research and development expenses increased by $3.7 million.

Investing Activities. Net cash used in investing activities amounted to $5.3 million, $10.1 million and $7.8 million for the years ended December 31, 2012, 2013 and 2014, respectively. Cash used in investing activities during each of these periods primarily reflected our purchases of property and equipment or purchases of short-term investments. Purchases of property and equipment totaled $1.1 million, $0.6 million and $1.1 million during the years ended December 31, 2012, 2013 and 2014, respectively. Additionally, during the year ended December 31, 2014, we made a $1.3 million payment to a long-term restricted cash account to secure a letter of credit for the construction of our new facility under a build-to-suit lease agreement. Cash provided by investment activities during each of these periods was primarily due to sales and maturities of short-term investments.

Financing Activities. Net cash provided by financing activities amounted to $24.9 million, $53.4 million and $57.0 million for the years ended December 31, 2012, 2013 and 2014, respectively. Cash provided by financing activities for the year ended December 31, 2012 consisted primarily of the proceeds from the sale of our series D and D-1 preferred stock of $25.0 million and loan proceeds of $0.1 million, partially offset by stock issuance costs of $0.2 million. Cash provided by financing activities for the year ended December 31, 2013 primarily consisted of proceeds of $48.0 million from the sale of our series E preferred stock and attached common stock warrants and $6.9 million from the note payable to Medinet, partially offset by stock issuance costs of $1.5 million. Cash provided by financing activities for the year ended December 31, 2014 consisted primarily of proceeds of $49.8 million from the sale of common stock in our initial public offering, which closed on February 12, 2014, $12.5 million of loan proceeds from our Loan Agreement, which closed on September 29, 2014, partially offset by stock and debt issuance costs totaling $5.3 million, and payments on other notes payable of $51,481.

Significant Changes in Consolidated Balance Sheet as of December 31, 2014 Compared with December 31, 2013

Short-term investments increased by $5.4 million due to proceeds received from our initial public offering in February 2014. Property and equipment, net, increased by $3.9 million primarily due to the $3.4 million asset that we recognized related to a lease agreement signed in August 2014 for our new manufacturing facility and $0.5 million from construction in progress. Additionally, we recognized a $3.4 million facility lease obligation as of September 30, 2014 related to this lease agreement. Accounts payable increased by $0.5 million primarily due to the commencement of construction of the manufacturing facility. Long-term debt increased by $12.8 million primarily related to the borrowing of $12.5 million under the venture loan and security agreement on September 29, 2014 and accrued interest on the promissory note payable to Medinet. We also recognized a $3.5 million long-term liability under our manufacturing development agreement with Invetech as of December 31, 2014.
Funding Requirements

To date, we have not generated any product revenue from our development stage product candidates. We do not know when, or if, we will generate any product revenue. We do not expect to generate significant product revenue unless or until we obtain marketing approval of, and commercialize AGS-003 or AGS-004. At the same time, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue our phase 3 clinical trial of AGS-003, initiate additional clinical trials of AGS-003 and AGS-004, seek regulatory approval for our product candidates and lease, build out and equip a new commercial manufacturing facility. In addition, if we obtain regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. We will need substantial additional funding in connection with our continuing operations.

We expect that our existing cash, cash equivalents and short-term investments, including anticipated funding under our NIH contract, will enable us to fund our operating expenses into the second half of 2016. We intend to devote our cash, cash equivalents and short term investments to fund our pivotal phase 3 clinical trial of AGS-003 through data, to fund our planned phase 2 clinical trials of AGS-003 in non-clear cell mRCC, early stage RCC prior to and following nephrectomy and other solid tumors, to fund certain of the costs of the ongoing phase 2 clinical trial of AGS-004 for HIV eradication and the planned phase 2 clinical trial of AGS-004 for long-term viral control in pediatric patients, to initiate, but not complete, the planned build-out and equipping of our new commercial manufacturing facility, the exercise of our purchase and sale agreement for this new facility and for working capital and general corporate purposes.

We will need to obtain significant financing prior to the commercialization of AGS-003, including to complete the planned build-out and equipping of our new commercial manufacturing facility and to fund any commercialization efforts in advance of regulatory approval of AGS-003. We expect that we will need to spend approximately an additional $50.0 million to build out and equip the new commercial manufacturing facility that we plan to establish. In addition, we expect to spend approximately an additional $25.0 million on development, equipment and disposables, including costs incurred under the development agreements with Invetech and Saint-Gobain. We have initiated expenditures for these purposes and construction of the facility began in October 2014. We are actively exploring additional financing arrangements in connection with the build out and equipping of the commercial manufacturing facility and are in discussions with developers, lenders and other potential financing sources regarding potential financial support. We expect to enter into such arrangements during 2015 and that such arrangements will likely involve material obligations and debt liabilities. If we are unable to obtain additional financing when needed, in the required amounts or at all, we may not be able to complete the planned build-out and equipping of the new commercial facility or may be delayed in doing so.

We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing pivotal phase 3 clinical trial of AGS-003 and other clinical trials of AGS-003 that we may conduct;
- the progress and results of our ongoing phase 2 clinical trial for HIV eradication and other clinical trials of AGS-004 that we may conduct and our ability to obtain additional funding under our NIH contract for our AGS-004 program;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs and timing of our planned build-out and equipping of a new commercial manufacturing facility;
Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government contracts, government and other third party grants or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

We are seeking government or other third party funding for the continued development of AGS-004. In January 2014, CARE agreed that it would fund all patient clinical costs of Stage 1 of our phase 2 adult eradication clinical trial of AGS-004, except for the associated manufacturing costs for which we will be responsible. If we are unable to raise additional government or other third party funding when needed, we may be required to delay, limit, reduce or terminate our development of AGS-004 or to grant rights to develop and market AGS-004 that we would otherwise prefer to keep for ourselves.
Contractual Obligations and Commitments

The following table summarizes our significant contractual obligations and commercial commitments as of December 31, 2014 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

<table>
<thead>
<tr>
<th>Contractual Obligation Description</th>
<th>Total</th>
<th>Less Than 1 Year</th>
<th>1-3 Years</th>
<th>3-5 Years</th>
<th>More Than 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating leases for existing facilities and equipment</td>
<td>$909</td>
<td>$394</td>
<td>$515</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Facility lease obligation for new facility</td>
<td>$6,236</td>
<td>$375</td>
<td>$1,156</td>
<td>$1,208</td>
<td>$3,497</td>
</tr>
<tr>
<td>Notes payable to Horizon Technology and Fortress Credit</td>
<td>$12,500</td>
<td>—</td>
<td>$7,812</td>
<td>$4,688</td>
<td>—</td>
</tr>
<tr>
<td>Final payment to Horizon Technology and Fortress Credit</td>
<td>$625</td>
<td>—</td>
<td>—</td>
<td>$625</td>
<td>—</td>
</tr>
<tr>
<td>Note payable to Medinet</td>
<td>$9,000</td>
<td>—</td>
<td>—</td>
<td>$9,000</td>
<td>—</td>
</tr>
<tr>
<td>Other notes payable</td>
<td>$78</td>
<td>$31</td>
<td>$47</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Amount due under development agreement with Invetech</td>
<td>$3,476</td>
<td>—</td>
<td>$3,476</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Interest on long-term debt and development agreement with Invetech</td>
<td>$5,094</td>
<td>$1,177</td>
<td>$2,417</td>
<td>$1,500</td>
<td>—</td>
</tr>
<tr>
<td>Purchase obligation with Invetech</td>
<td>$25,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>$62,918</td>
<td>$1,977</td>
<td>$40,423</td>
<td>$17,021</td>
<td>$3,497</td>
</tr>
</tbody>
</table>

Under the Lease Agreement with TKC, we agreed to lease an approximately 120,000 square-foot building to be constructed on approximately 11 acres in Durham County, North Carolina. This facility will house our corporate headquarters and primary manufacturing facility. The Lease Agreement is intended to replace our existing lease, which currently expires in November 2016, located at 4233 Technology Drive, Durham North Carolina. The shell of the new facility will be constructed on a build-to-suit basis by TKC, at its expense, in accordance with agreed upon specifications and plans as set forth in the Lease Agreement.

The term of the Lease Agreement will be 10 years from the commencement date for the initial term, currently estimated to be May 1, 2015, with the Company having the option to extend the Lease Agreement by six five-year renewal terms. Initial rent will be approximately $46,917 per month, subject to certain fixed increases over the course of the term as set forth in the Lease Agreement and to adjustment based on our use of certain amounts allocated for upfitting the interior of the facility.

On February 16, 2015, we entered into a Purchase and Sale Agreement, or the Purchase Agreement, with TKC which represented our exercise of the purchase option under the Lease Agreement. The purchase price to be paid by us is $7.6 million plus the amount of any additional costs incurred by TKC as a result of changes requested by us and the amount of any improvement allowances advanced to us by TKC prior to the closing. The Purchase Agreement is expected to close in the second half of 2015. Upon the closing, the Lease Agreement will terminate. This commitment is not included in the above table of contractual obligations and commitments.

On September 29, 2014, we entered into the Loan Agreement with Horizon Technology Finance Corporation and Fortress Credit Co LLC under which we may borrow up to $25.0 million in two tranches of $12.5 million each. We borrowed the first tranche of $12.5 million upon the closing of the transaction on September 29, 2014. See Liquidity and Capital Resources – Sources of Liquidity for additional information regarding the Loan Agreement.

In October 2014, we entered into a development agreement with Invetech Pty Ltd, or Invetech. The development agreement supersedes and replaces the development agreement entered into by the parties as of July 20, 2005. Under the development agreement, Invetech agreed to continue to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products, or the Production Systems. Development services will be performed on a proposal by proposal basis. Invetech has agreed to defer 30% of its fees, but such deferral may not exceed $5,000,000. Deferred fees (plus interest of 7% per annum) would become payable either, at our option, in a lump sum within 90 days of the “Sunset Date Trigger Event” or pursuant to an installment plan (either in four installments payable within the first year or eight installments payable within the first two years after the “Sunset Date Trigger Event”). The “Sunset Date Trigger Event” is December 31, 2016 or is June 30, 2016 if, prior to such date, our ongoing phase 3 ADAPT clinical trial is closed early following the interim review at 50% or 75% of events, due to a positive efficacy outcome in favor of the active treatment arm that contains AGS-003. Invetech is entitled to a 10% bonus payment if this clinical trial is closed early indicating positive efficacy and Invetech has timely completed all activities up to the time of such early closure.
The development agreement requires the parties to discuss in good faith Invetech’s supply of Production Systems for use in manufacturing commercial product. We have an obligation to purchase $25.0 million worth of Production Systems, components, subsystems and spare parts for commercial use. Once that obligation has been satisfied, we have the right to have a third party supply Production Systems for use in manufacturing commercial product, provided that Invetech has a right of first refusal with respect to any offer by a third party and we may not accept an offer from a third party unless that offer is at a price that is less than that offered by Invetech and otherwise under substantially the same or better terms. We will own all intellectual property arising from the development services (with the exception of existing Invetech intellectual property incorporated therein-under which we will have a license). The term of the development agreement will continue until the completion of the development of the Production Systems. The development agreement can be terminated early by either party because of a technical failure or by us without cause.

In January 2015, we entered into a development agreement with Saint-Gobain. Under the agreement, Saint-Gobain will develop a range of disposables for use in our automated production systems to be used for the manufacture of our Arcelis-based products, which we refer to as the Disposables. We do not expect the fees and expenses incurred under the Saint-Gobain agreement to exceed $6,000,000. We made a payment of $400,000, and Saint-Gobain has agreed to defer one half of the fees and expenses incurred until the earlier of (i) the date upon which we have raised an additional $60.0 million in capital, and (ii) September 30, 2016. The Saint-Gobain agreement requires the parties to begin negotiating a commercial supply agreement under which Saint-Gobain would become the exclusive supplier of Disposables for the manufacture of our products treating solid tumors for no less than fifteen years. The agreement will continue until December 31, 2016, but can be terminated earlier by written agreement of the parties because of a material default or a failure to achieve a performance milestone.

We are a party to license agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-how. Under these agreements, we have agreed to pay the other parties milestone payments upon the achievement of specified clinical, regulatory and commercialization events and royalties based on future sales of products. We have not included these payments in the table as we cannot estimate if, when or in what amounts such payments will become due under these agreements.

**Net Operating Losses**

As of December 31, 2014, we had U.S. federal and state, and Canadian federal and provincial net operating loss carryforwards of approximately $158,406,400, $176,699,700, $6,579,600, and $6,579,600, respectively. These net operating loss carryforwards begin to expire in 2018, 2017, 2015 and 2015, respectively. As of December 31, 2014, we had U.S. federal and state tax credit carryforwards of approximately $5,028,400 and $340,400, respectively. These credit carryforwards begin to expire in 2020 and 2019, respectively. As of December 31, 2014, we had Canadian investment tax credit carryforwards of approximately $35,100 that begin to expire in 2024. The utilization of the net operating loss and tax credit carryforwards may be subject to limitation under the rules regarding a change in stock ownership as determined by the Internal Revenue Code, and state and foreign tax laws. Section 382 of the Internal Revenue Code of 1986, as amended, imposes annual limitations on the utilization of net operating loss carryforwards, other tax carryforwards, and certain built-in losses upon an ownership change as defined under that section. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain of our stockholders by more than 50 percentage points over a three year testing period. If we have undergone a Section 382 ownership change, an annual limitation would be imposed on certain of our tax attributes, including NOL and capital loss carryforwards, and certain other losses, credits, deductions or tax basis. As of December 31, 2014, we have not completed a formal study to determine whether there are 382 limitations that apply.

As of December 31, 2014, we have received $2.9 million in refunds through scientific research and experimental development tax credits through our consolidated subsidiary in Canada.

**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 Securities and Exchange Commission, or SEC, rules.

**Recent Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board (“FASB”) issued a new accounting standard update pertaining to disclosures for development stage entities. The new guidance eliminates the distinction of a development stage entity and certain related disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders’ equity. The new standard is effective prospectively for annual reporting beginning after December 15, 2014, and interim periods within those annual periods, but early adoption is permitted. The Company adopted this new accounting standard during the three months ended June 30, 2014.
In May 2014, the FASB issued a new accounting standard update pertaining to accounting for revenue from contracts with customers. The new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP. The standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2016, which is effective for the Company for the year ending December 31, 2017. The Company is currently evaluating the impact that the implementation of this standard will have on the Company’s consolidated financial statements.

In July 2013, the FASB issued a new accounting standard update on the financial statement presentation of unrecognized tax benefits. The new guidance provides that a liability related to an unrecognized tax benefit would be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The new guidance became effective for the Company on January 1, 2014 and it was applied prospectively to unrecognized tax benefits that existed as of the effective date with retrospective application permitted. This updated standard did not have a material impact on the Company’s condensed consolidated financial statements.

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

Our primary exposure to market risk is limited to our cash, cash equivalents and short-term investments, all of which have maturities of one year or less. The related interest income sensitivity is affected by changes in the general level of short-term U.S. interest rates. We primarily invest in high quality, short-term marketable debt securities issued by high quality financial and industrial companies.

Due to the short-term duration and low risk profile of our cash, cash equivalents and short-term investments, an immediate 10.0% change in interest rates would not have a material effect on the fair value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our cash, cash equivalents and short-term investments.

We do not believe that our cash, cash equivalents and short-term investments have significant risk of default or illiquidity. While we believe our cash, cash equivalents and short-term investments do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in fair value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

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

Our financial statements and the financial statement schedule required by this item, together with the report of our independent registered public accounting firm and the notes to our financial statements, appear on pages F-1 through F-33 of this Annual Report on Form 10-K and are incorporated herein by reference.

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

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices or financial disclosure required to be reported under this Item.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our vice president of finance, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2014, the end of the period covered by this Annual Report. The term “disclosure controls and procedures,” as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission (the “SEC”). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.
Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.


Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

MANAGEMENT

The following table sets forth the name, age and position of each of our executive officers and directors as of March 15, 2015.

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Abbey</td>
<td>53</td>
<td>President, Chief Executive Officer and Director</td>
</tr>
<tr>
<td>Charles A. Nicolette, Ph.D.</td>
<td>52</td>
<td>Chief Scientific Officer and Vice President of Research and Development</td>
</tr>
<tr>
<td>Frederick M. Miesowicz, Ph.D.</td>
<td>66</td>
<td>Chief Operating Officer and Vice President of Manufacturing</td>
</tr>
<tr>
<td>Douglas C. Plessinger</td>
<td>46</td>
<td>Vice President of Clinical and Medical Affairs</td>
</tr>
<tr>
<td>Lori R. Harrelson</td>
<td>45</td>
<td>Vice President of Finance</td>
</tr>
<tr>
<td>Joan Winterbottom</td>
<td>57</td>
<td>Chief Human Resources Officer</td>
</tr>
<tr>
<td>Hubert Birner, Ph.D. (1)(3)</td>
<td>48</td>
<td>Chairman of the Board of Directors</td>
</tr>
<tr>
<td>Jean Lamarre (1)</td>
<td>61</td>
<td>Director</td>
</tr>
<tr>
<td>Andrei Petrov (2)(3)</td>
<td>41</td>
<td>Director</td>
</tr>
<tr>
<td>Brian J. Underdown, Ph.D. (2)(3)</td>
<td>73</td>
<td>Director</td>
</tr>
<tr>
<td>Sander van Deventer M.D., Ph.D.</td>
<td>60</td>
<td>Director</td>
</tr>
<tr>
<td>Philippe Van Holle (1)(2)</td>
<td>60</td>
<td>Director</td>
</tr>
<tr>
<td>Alexey Vinogradov, Ph.D.</td>
<td>41</td>
<td>Director</td>
</tr>
</tbody>
</table>

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee
Jeffrey D. Abbey has served as our President and Chief Executive Officer and a member of our board of directors since February 2010. Mr. Abbey served in various other positions at our company from September 2002 to February 2010, including as our Vice President of Business Development from February 2004 to January 2009 and as our Chief Business Officer from January 2009 to February 2010. Prior to joining us, Mr. Abbey served as Vice President of Business Development and Finance at Internet Appliance Network, an information technology company, from 1999 to 2001. Mr. Abbey was a partner at Eilenberg and Krause, LLP, a corporate law firm, from 1994 to 1999. Mr. Abbey received an A.B. in mathematical economics from Brown University and an M.B.A. and J.D. from the University of Virginia. We believe that Mr. Abbey is qualified to serve on our board of directors due to his extensive knowledge of our company and our industry.

Charles A. Nicolette, Ph.D. has served as our Chief Scientific Officer since December 2007 and as our Vice President of Research and Development since December 2004. Dr. Nicolette served as our Vice President of Research from July 2003 to December 2004. Prior to joining us, Dr. Nicolette served in various positions at Genzyme Molecular Oncology, Inc., a biotechnology company, from 1997 to 2003, most recently as Director of Antigen Discovery. Dr. Nicolette received a B.S. from the State University of New York at Stony Brook and a Ph.D. in biochemistry and cellular and developmental biology from the State University of New York at Stony Brook, completing his doctoral dissertation and post-doctoral fellowship at Cold Spring Harbor Laboratory.

Hubert Birner, Ph.D. has served as the Chairman of our board of directors since 2005 and a member of our board of directors since 2001. Dr. Birner joined the Munich office of TVM Capital, a venture capital firm and affiliate of ours, as an investment manager in 2000 and currently serves as the Managing Partner of the firm. From 1998 to 2000, Dr. Birner served as head of European business development and director of marketing for Germany at Zeneca Agrochemicals, a biopharmaceutical company. Prior to joining Zeneca Agrochemicals, Dr. Birner served as a management consultant in McKinsey & Company’s European healthcare and pharmaceutical practice. Dr. Birner has served on the board of directors of Proton Therapeutics, Inc. since 2006 and of SpePharm Holdings BV since 2007. Dr. Birner previously served on the board of directors of Horizon Pharma, Inc., Bioxell SA, and Evotec AG. Dr. Birner received an M.B.A. from Harvard Business School and a doctorate in biochemistry from Ludwig-Maximilians University in Munich, Germany. His doctoral thesis was honored with the Hoffmann-La Roche prize for outstanding basic research in metabolic diseases. We believe that Dr. Birner is qualified to serve as the Chairman of our board of directors due to his extensive experience with biopharmaceutical companies and his years of experience providing strategic and advisory services to pharmaceutical and biotechnology companies as a lead director and investor.
Jean Lamarre has served as a member of our board of directors since February 2013. Mr. Lamarre is the President of 2856166 Canada Inc., a management consulting firm that he founded in 1992. Mr. Lamarre has been a lead director, the Chairman and from 2008 to 2015, Executive Chairman of Semaf Inc., a gold production company. From 1984 to 1991, Mr. Lamarre served as the Chief Financial Officer of the Lavali Group, one of the world’s leading design and construction firms. Mr. Lamarre is also a member of the Independent Review Committee of Investor Group Investment Management Ltd. He also serves as Chairman of D-Box Technologies Inc. and a number of private companies. Mr. Lamarre received a B.Comm. in applied economics from HEC Montreal. We believe that Mr. Lamarre is qualified to serve on our board of directors due to his valuable and relevant experience as a senior financial executive.

Andrei Petrov, Ph.D. has served as a member of our board of directors since August 2013. Dr. Petrov has been the Chief Scientific Officer of International Biotechnology at Center Generium, a private scientific research and drug development company, since 2011, and the Chief Executive Officer of CJSC ‘Kollektsiya,’ a venture investment company, since 2013. From 2008 to 2011, Dr. Petrov served as Senior Scientist at CJSC Masterclone, a drug discovery and development company. Dr. Petrov has also served as a member on the board of directors of Affitech A/S since 2010, and as a member on the board of directors of codon AG since 2012. We believe that Dr. Petrov is qualified to serve on our board of directors due to his extensive experience in drug discovery and development, international collaboration and co-development as well his business development skills in mergers, acquisitions and licensing deals.

Brian J. Underdown, Ph.D. has served as a member of our board of directors since 1999. Dr. Underdown joined Lumira Capital Corp. (formerly MDS Capital Corp.), a venture capital firm, in 1997, and currently serves as a Managing Director. Before joining Lumira, Dr. Underdown served as Assistant Vice President of Research at Pasteur Merieux Connaught from 1994 to 1997. Dr. Underdown has been a member of the board of directors of Vistagen Therapeutics, Inc. since 2009. Dr. Underdown received a Ph.D. from McGill University and undertook post-doctoral studies at Washington University School of Medicine. We believe that Dr. Underdown is qualified to serve on our board of directors due to his experience in the biopharmaceutical industry and his scientific background.

Sander van Deventer, M.D., Ph.D. has served as a member of our board of directors since 2001. Dr. van Deventer has been a General Partner of Forbion Capital Partners (formerly ABN AMRO Capital) since 2006. From 2008 to 2009, he served as the Chief Executive Officer of Amsterdam Molecular Therapeutics, or AMT, a gene therapy company that he co-founded in 1998. He has also served as a member of AMT’s board of directors since 2007. Dr. van Deventer has also served as a Professor of Translational Gastroenterology at Leiden University since 2008. He received an M.D. and Ph.D. from the University of Amsterdam. We believe that Dr. van Deventer is qualified to serve on our board of directors due to his experience as a founder of a biopharmaceutical company and his expertise in clinical development.

Philippe Van Holle has served as a member of our board of directors since November 2014. Mr. Van Holle held the position of Senior VP Global Human Resources at Celgene Corporate HQ in Summit, New Jersey from January 2013 until October 2014. From January 1, 2012 until December 2012, he held the position of Chairman International in Celgene. He was President EMEA from November 2008 to December 2011, after building the European organization as Head of Europe since January 2006. Mr. Van Holle served as Vice President Northern Europe for the Genzyme Corporation from September 2001 to December 2003. Previously, he had been Vice President Global Marketing at Baxter International, for the Renal Division, which he joined in 1998. He was Vice President Marketing, Amgen Europe from 1989 to 1997. Mr. Van Holle received his undergraduate degree in Econometrics at the Antwerp University St. Ignatius, Belgium in 1976 and a M.B.A from Cornell University. We believe that Mr. Van Holle is qualified to serve on our board of directors due to his experience in the biopharmaceutical industry and as a senior executive.

Alexey Vinogradov, Ph.D. has served as a member of our board of directors since February 2014. Dr. Vinogradov has served as a Managing Partner of CJSC Kollektiya, or Inbio Ventures, a management company for Pharmstandard International, S.A., since 2012. Prior to joining Inbio Ventures, from 2009 to 2012, Dr. Vinogradov served as Investment Manager at Bioprocess Capital Partners, Russia’s first venture capital fund, specializing in life sciences and drug discovery. From 2004 to 2009, Dr. Vinogradov was employed by the International Science and Technology Center, where he provided consulting and investment support to early-stage biotechnology companies. From 2002 to 2004, Dr. Vinogradov was employed by Core-Biotech, a private company specialized in industrial biotechnology. Dr. Vinogradov received a Ph.D. in biochemistry from Moscow State University and completed a post-doctoral fellowship at Wageningen University (the Netherlands). We believe that Dr. Vinogradov is qualified to serve on our board of directors due to his experience in the venture capital and biopharmaceutical industries and his scientific background.
Board Composition and Election of Directors

Our board of directors is currently authorized to have up to eight members. In accordance with the terms of our certificate of incorporation and bylaws, our board of directors is divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. The members of the classes are divided as follows:

- the class I directors are Brian J. Underdown, Ph.D., Sander van Deventer, M.D., Ph.D. and Alexey Vinogradov, Ph.D., and their term expires at our annual meeting of stockholders to be held in 2015;
- the class II directors are Hubert Birner, Ph.D. and Jean Lamarre, and their term expires at our annual meeting of stockholders to be held in 2016; and
- the class III directors are Jeffrey D. Abbey, Andrei Petrov and Philippe Van Holle, and their term expires at our annual meeting of stockholders to be held in 2017.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. In accordance with the terms of our certificate of incorporation and bylaws, our directors may only be removed for cause by the affirmative vote of the holders of 75% or more of our voting stock.

Under applicable NASDAQ rules, a director only qualifies as an “independent director” if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that all of our directors, other than Mr. Abbey, are independent directors as defined by applicable NASDAQ rules. In making such determinations, our board of directors considered the relationships that each such non-employee director and director nominee has with our company and all other facts and circumstances that our board of directors deems relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and director nominee.

There are no family relationships among any of our directors or executive officers.

Board Leadership Structure

The positions of chairman of the board of directors and chief executive officer are presently separated and have generally been separated at our company. The duties of the chairman of the board include the following:

- chairing meetings of our board and of the independent directors in executive session;
- meeting with any director who is not adequately performing his or her duties as a member of our board or any committees;
- facilitating communications between other members of our board and the chief executive officer;
- determining the frequency and length of board meetings and recommending when special meetings of our board should be held;
- preparing or approving the agenda for each board meeting; and
- reviewing and, if appropriate, recommending action to be taken with respect to written communications from stockholders submitted to our board.

Our board of directors decided to separate the roles of chairman and chief executive officer because it believes that a bifurcated leadership structure offers the following benefits:

- increasing the independent oversight of our company and enhancing our board’s objective evaluation of our chief executive officer;
- freeing the chief executive officer to focus on company operations instead of board administration;
- providing the chief executive officer with an experienced sounding board;
- providing greater opportunities for communication between stockholders and our board;
- enhancing the independent and objective assessment of risk by our board; and
- providing an independent spokesman for our company.
Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees operates under a charter that has been approved by our board.

Audit Committee

The current members of our audit committee are Hubert Birner, Ph.D., Jean Lamarre and Philippe Van Holle. Mr. Lamarre chairs our audit committee. Mr. Van Holle has served on the committee since February 2015. Mr. Van Holle replaced Brian Underdown, who served as a member of our audit committee from October 2014 until February 2015. In addition, David W. Gryska, a former member of our board of directors, served as a member of our audit committee until October 2014 at which time he ceased to serve as a member of our board of directors.

Our audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function, if any;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

All audit and non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Mr. Lamarre is an “audit committee financial expert” as defined in applicable SEC rules and qualifies as independent as defined under the applicable NASDAQ rules for audit committee members. We believe that the composition of our audit committee meets all applicable requirements with respect to audit committee composition under the current NASDAQ Global Market and SEC rules and regulations.

Compensation Committee

The current members of our compensation committee are Andrei Petrov, Brian J. Underdown, and Philippe Van Holle. Dr. Underdown chairs our compensation committee. Mr. Van Holle has served on the committee since he joined our board of directors in November 2014. Mr. Van Holle replaced David W. Gryska, a former member of our board of directors, who served as a member of our compensation committee until October 2014 at which time he ceased to serve as a member of our board of directors.

Our compensation committee’s responsibilities include:

- reviewing and approving, or making recommendations to our board with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board with respect to director compensation;
- reviewing and discussing annually with management our compensation disclosure required by SEC rules; and
- preparing the annual compensation committee report required by SEC rules.
The members of our nominating and corporate governance committee are Hubert Birner, Ph.D., Andrei Petrov and Brian J. Underdown, Ph.D. Dr. Birner chairs our nominating and corporate governance committee. Our nominating and corporate governance committee’s responsibilities include:

- identifying individuals qualified to become members of our board;
- recommending to our board the persons to be nominated for election as directors and to each of our board’s committees;
- reviewing and making recommendations to our board with respect to our board leadership structure;
- reviewing and making recommendations to our board with respect to management succession planning;
- developing and recommending to our board corporate governance principles; and
- overseeing a periodic evaluation of our board.

**Code of Ethics and Code of Conduct**

On December 20, 2013, we adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, or persons performing similar functions. The code became effective on February 6, 2014. We have posted a current copy of the code on our website, www.argostherapeutics.com. In addition, we intend to post on our website all disclosures that are required by law or NASDAQ stock market listing standards concerning any amendments to, or waivers from, any provision of the code.

**Item 11. Executive Compensation**

This section describes the material elements of compensation awarded to, earned by or paid to each of our named executive officers in 2014. This section also provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers and is intended to place into perspective the data presented in the tables and narrative that follow. Our “named executive officers” for 2014 were:

- Jeffrey D. Abbey, our president and chief executive officer;
- Charles A. Nicolette, Ph.D., our vice president of research and development and chief scientific officer; and
- Frederick M. Miesowicz, Ph.D., our vice president of manufacturing and chief operating officer.
Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to our named executive officers during 2014 and 2013.

<table>
<thead>
<tr>
<th>Name and Principal Position</th>
<th>Year</th>
<th>Salary ($)</th>
<th>Bonus ($)</th>
<th>Option Awards ($) (1)</th>
<th>All Other Compensation ($) (2)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Abbey (3)</td>
<td>2014</td>
<td>379,788</td>
<td>163,800</td>
<td>482,991</td>
<td>16,632</td>
<td>1,043,211</td>
</tr>
<tr>
<td>President and Chief Executive Officer</td>
<td>2013</td>
<td>300,000</td>
<td>136,800</td>
<td>2,112,044</td>
<td>3,136</td>
<td>2,551,980</td>
</tr>
<tr>
<td>Charles A Nicolette, Ph.D.</td>
<td>2014</td>
<td>294,327</td>
<td>88,200</td>
<td>202,618</td>
<td>8,117</td>
<td>593,262</td>
</tr>
<tr>
<td>Vice President of Research and Development and Chief Scientific Officer</td>
<td>2013</td>
<td>250,000</td>
<td>71,250</td>
<td>891,946</td>
<td>3,033</td>
<td>593,262</td>
</tr>
<tr>
<td>Frederick M. Miesowicz, Ph.D.</td>
<td>2014</td>
<td>284,552</td>
<td>72,455</td>
<td>104,357</td>
<td>13,623</td>
<td>474,987</td>
</tr>
<tr>
<td>Vice President of Manufacturing and Chief Operating Officer</td>
<td>2013</td>
<td>261,380</td>
<td>74,493</td>
<td>504,879</td>
<td>3,112</td>
<td>843,864</td>
</tr>
</tbody>
</table>

(1) The amounts reported in the “Option Awards” column reflect the aggregate fair value of share-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standard Codification, or ASC, Topic 718. See Notes 2 and 12 to our consolidated financial statements appearing in “Item 8. Financial Statements and Supplementary Data” of this annual report regarding assumptions underlying the valuation of the option awards.

(2) The amounts reported in the “All Other Compensation” column reflect, for each named executive officer, the sum of the incremental cost to us of all perquisites and other personal benefits, which are comprised of post-tax insurance earnings.

(3) Mr. Abbey also serves as a member of our board of directors but does not receive any additional compensation for his service as a director.

Narrative Disclosure to Summary Compensation Table

The primary elements of our executive compensation program are:

- base salary;
- annual cash bonuses; and
- equity incentive awards

We strive to achieve an appropriate mix between the various elements of our compensation program to meet our compensation objectives and philosophy; however, we have not adopted any formal policies or guidelines for allocating compensation among these elements.

Base Salary. We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary. Prior to the closing of our initial public offering, or IPO, the 2014 annual base salaries of Mr. Abbey, Dr. Nicolette and Dr. Miesowicz were $300,000, $250,000 and $261,380, respectively. Effectively, upon the closing of our IPO in February 2014, the 2014 annual base salaries of Mr. Abbey, Dr. Nicolette and Dr. Miesowicz were increased to $390,000, $300,000 and $287,518, respectively.

Annual Cash Bonus. In addition to base salaries, our executive officers are eligible to receive annual discretionary cash bonuses based on the achievement of corporate objectives and individual performance. Bonuses are typically prorated on a monthly basis, as applicable, for executive officers who commence employment after the beginning of the year. Our executive officers’ annual bonus opportunities are generally set in their employment agreements as a specified percentage of annual base salary. The 2014 annual target bonus amount for Mr. Abbey was 50% of his base salary, for Dr. Nicolette was 35% of his base salary and for Dr. Miesowicz was 30% of his base salary. In determining annual bonuses, we have generally attributed 85% of the target bonus to the achievement of specified corporate objectives and 15% to the individual’s effectiveness in helping us achieve our corporate objectives or other individual performance criteria. The annual corporate objectives are recommended by our chief executive officer and approved by the compensation committee and the board of directors. Historically, annual bonuses have been determined by the compensation committee and ratified by the non-employee directors in December of each year and paid by the end of December of the year in which they were determined. For 2014, we paid cash bonuses of $163,800 to Mr. Abbey, $88,200 to Dr. Nicolette and $72,455 to Dr. Miesowicz.
Our equity award program is the primary vehicle for offering long-term incentives to our executives. We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have used stock option grants for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. The use of options also can provide tax and other advantages to our executive officers relative to other forms of equity compensation. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees.

We award stock options broadly to our employees, including to our non-executive employees. Grants to our executives and other employees are made at the discretion of our board of directors and are not made at any specific time period during a fiscal year. All of our named executive officers have received stock option grants under our 1999 stock option plan, our 2008 stock incentive plan, or our 2014 stock incentive plan, each of which is described below. The 1999 stock option plan has expired and no further options may be granted under that plan. Our board of directors and the Company’s stockholders adopted a new equity incentive plan described under “— Stock Option and Other Equity Compensation Plans” below, effective upon the closing of our IPO in February 2014, and has determined not to grant any additional awards under our 2008 stock incentive plan. Our 2014 plan affords our compensation committee continued flexibility in making a wide variety of equity awards.

Initial option grants to our executive officers are generally set forth in their employment agreements. These initial grants are the product of negotiation with the executive officer, but we generally seek to establish equity ownership levels that we believe are commensurate with the equity stakes held by executive officers serving in similar roles at comparable biopharmaceutical companies. In addition, from time to time in connection with corporate finance transactions and at other times as our compensation committee and board of directors deem appropriate, we provide subsequent option grants to those executive officers determined to be performing well.

The majority of the stock option grants we have made to our executive officers vest over four years. However, from time to time, our board of directors has approved grants with different and sometimes shorter vesting provisions. Our historical practice has been to provide for 100% acceleration of vesting of outstanding stock options in the event of a change of control. Additional information regarding the effect of accelerated vesting upon a change in control with respect to our named executive officers is discussed below under “— Agreements with our Named Executive Officers.”

In July 2014 options were granted to each executive that vest upon the successful achievement within specified time parameters of specified performance milestones designed for such executive. The performance milestones for each executive include milestones related to two or more of the Company’s stock price, clinical and non-clinical development of AGS-003, regulatory approval of AGS-003, commercial supply of AGS-003, business development activities and the expansion of the Company’s program pipeline. The achievement of any milestone shall be determined by the compensation committee of our board. Each milestone is weighted and assigned a percentage such that the achievement of a particular milestone will result in the vesting of that portion of the option.

**Grants of Plan-Based Awards**

The following table sets forth, for each of our named executive officers, information regarding each grant of a plan-based award made during the fiscal year ended December 31, 2014. This information supplements the information about these awards set forth in the Summary Compensation Table.

<table>
<thead>
<tr>
<th>Name</th>
<th>Grant Date</th>
<th>All Option Awards: Number of Securities Underlying Options (#)</th>
<th>Exercise or Base Price of Option Awards ($/Sh)</th>
<th>Grant Date Fair Value of Option Awards ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Abbey</td>
<td>7/28/2014</td>
<td>58,400(1)</td>
<td>6.09</td>
<td>291,406</td>
</tr>
<tr>
<td></td>
<td>7/28/2014</td>
<td>87,600(2)</td>
<td>6.09</td>
<td>191,406</td>
</tr>
<tr>
<td>Charles A Nicolette, Ph.D.</td>
<td>7/28/2014</td>
<td>18,000(1)</td>
<td>6.09</td>
<td>89,872</td>
</tr>
<tr>
<td></td>
<td>7/28/2014</td>
<td>27,000(2)</td>
<td>6.09</td>
<td>71,030</td>
</tr>
<tr>
<td>Frederick M. Miesowicz, Ph.D.</td>
<td>7/28/2014</td>
<td>10,200(1)</td>
<td>6.09</td>
<td>50,928</td>
</tr>
<tr>
<td></td>
<td>7/28/2014</td>
<td>15,300(2)</td>
<td>6.09</td>
<td>53,429</td>
</tr>
</tbody>
</table>

(1) This option was granted on July 28, 2014 and vests as to 25% of the shares on July 1, 2015, with the remaining 75% of the shares vesting in equal amounts monthly over the three year period commencing on July 1, 2015, provided that the recipient continues to provide services to us over such period.

(2) This option was granted on July 28, 2014 and vests based on the achievement of various individual performance and market targets at various dates through December 31, 2017, provided that the recipient continues to provide services to us through the individual target measurement date.

(3) Amounts reported represent the grant date fair value of the stock options granted during 2014 over the entire term of the options, computed in accordance with ASC 718. The valuation assumptions used in calculating the fair value of the stock options are set forth in note 12 to our consolidated financial statements.
Outstanding Equity Awards at 2014 Fiscal Year End

The following table provides information about outstanding stock options held by each of our named executive officers at December 31, 2014. All of the listed options were granted under our 2014 and 2008 stock incentive plans.

<table>
<thead>
<tr>
<th>Name</th>
<th>Number of Securities Underlying Unexercised Options (#) Exercisable</th>
<th>Number of Securities Underlying Unexercised Options (#) Unexercisable</th>
<th>Option Exercise Price ($)</th>
<th>Option Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Abbey</td>
<td>14,175(1)</td>
<td>—</td>
<td>4.20(8)</td>
<td>7/2/18</td>
</tr>
<tr>
<td></td>
<td>5,706(2)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/10/20</td>
</tr>
<tr>
<td></td>
<td>50,425(3)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/10/20</td>
</tr>
<tr>
<td></td>
<td>58,751(4)</td>
<td>4,701(4)</td>
<td>4.20(8)</td>
<td>4/10/22</td>
</tr>
<tr>
<td></td>
<td>45,602(5)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/11/22</td>
</tr>
<tr>
<td></td>
<td>104,573(6)</td>
<td>281,545(6)</td>
<td>5.82</td>
<td>11/1/23</td>
</tr>
<tr>
<td></td>
<td>17,355(7)</td>
<td>58,400(9)</td>
<td>6.09</td>
<td>7/27/24</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>87,600(10)</td>
<td>6.09</td>
<td>7/27/24</td>
</tr>
<tr>
<td>Charles A. Nicolette, Ph.D.</td>
<td>14,640(1)</td>
<td>—</td>
<td>4.20(8)</td>
<td>7/2/18</td>
</tr>
<tr>
<td></td>
<td>5,893(2)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/10/20</td>
</tr>
<tr>
<td></td>
<td>14,619(3)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/10/20</td>
</tr>
<tr>
<td></td>
<td>29,376(4)</td>
<td>2,351(4)</td>
<td>4.20(8)</td>
<td>4/10/22</td>
</tr>
<tr>
<td></td>
<td>22,801(5)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/11/22</td>
</tr>
<tr>
<td></td>
<td>43,778(6)</td>
<td>117,865(6)</td>
<td>5.82</td>
<td>11/1/23</td>
</tr>
<tr>
<td></td>
<td>7,713(7)</td>
<td>20,768(7)</td>
<td>5.82</td>
<td>11/1/23</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>18,000(9)</td>
<td>6.09</td>
<td>7/27/24</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>27,000(10)</td>
<td>6.09</td>
<td>7/27/24</td>
</tr>
<tr>
<td>Frederick M. Miesowicz, Ph.D.</td>
<td>13,943(1)</td>
<td>—</td>
<td>4.20(8)</td>
<td>7/2/18</td>
</tr>
<tr>
<td></td>
<td>5,612(2)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/10/20</td>
</tr>
<tr>
<td></td>
<td>6,809(3)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/10/20</td>
</tr>
<tr>
<td></td>
<td>22,031(4)</td>
<td>1,763(4)</td>
<td>4.20(8)</td>
<td>4/10/22</td>
</tr>
<tr>
<td></td>
<td>17,102(5)</td>
<td>—</td>
<td>4.20(8)</td>
<td>12/11/22</td>
</tr>
<tr>
<td></td>
<td>24,324(6)</td>
<td>65,491(6)</td>
<td>5.82</td>
<td>11/1/23</td>
</tr>
<tr>
<td></td>
<td>4,820(7)</td>
<td>12,980(7)</td>
<td>5.82</td>
<td>11/1/23</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>10,200(9)</td>
<td>6.09</td>
<td>7/27/24</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>15,300(10)</td>
<td>6.09</td>
<td>7/27/24</td>
</tr>
</tbody>
</table>

(1) This option was granted on July 2, 2008 and vested as to 50% of the shares on the date of grant, with the remaining 50% of the shares vesting in equal amounts monthly over the two year period commencing on April 1, 2008.

(2) This option was granted on December 5, 2008 and vested in specified increments over a two-year period ending on April 1, 2010.

(3) This option was granted on December 10, 2010. This option vested in equal monthly installments over a four year period, with the first installment vesting on February 24, 2010, provided that recipient continued to provide services to us over such period.

(4) This option was granted on April 10, 2012 and vested as to 1/3 of the shares on the date of grant, with the remaining 2/3 of the shares vesting in equal amounts monthly over the three year period commencing on April 10, 2012, provided that the recipient continues to provide services to us over such period.
Agreements with our Named Executive Officers

We have entered into written employment agreements with each of our named executive officers. The agreements set forth the terms of the named executive officer’s compensation, including base salary, severance and an annual cash bonus opportunity. In addition, the agreements provide that the named executive officers are eligible to participate in company-sponsored benefit programs that are available generally to all of our employees. The agreements also subject our named executive officers to certain non-competition and non-solicitation restrictions. In connection with the commencement of their employment with us, our named executive officers executed our standard confidential information and invention assignment agreements.

Pursuant to the terms of their agreements, our named executive officers were initially entitled to receive the following annual base salaries: $300,000 for Mr. Abbey, $250,000 for Dr. Nicolette and $261,380 for Dr. Miesowicz. Effective upon the closing of our IPO on February 12, 2014, these annual base salaries were increased to: $390,000 for Mr. Abbey, $300,000 for Dr. Nicolette and $287,518 for Dr. Miesowicz. Effective January 1, 2015, these annual base salaries were increased to: $450,000 for Mr. Abbey, $325,000 for Dr. Nicolette and $296,000 for Dr. Miesowicz.

In addition, each named executive officer is eligible to receive an annual performance cash bonus under his employment agreement based on the achievement of corporate objectives and the named executive officer’s individual performance, which is determined by our board of directors in its sole discretion. The bonus opportunity is calculated as a percentage of the named executive officer’s then annual base salary. Prior to the close of our IPO, the target annual bonus percentage for each named executive officer was as follows: 40% for Mr. Abbey, 25% for Dr. Nicolette and 25% for Dr. Miesowicz. Following the close of our IPO on February 12, 2014, the target annual bonus percentage for each named executive officer was increased to: 50% for Mr. Abbey, 35% for Dr. Nicolette and 30% for Dr. Miesowicz and for the year ending December 31, 2015 was increased to 50% for Mr. Abbey, 35% for Dr. Nicolette and 30% for Dr. Miesowicz. Each named executive officer must be employed on the date the bonus is paid in order to be eligible for and receive his annual bonus.

Potential Payments upon Termination or Change in Control

Upon execution and effectiveness of a separation agreement and release of all claims, each named executive officer is entitled to severance payments if his employment is terminated under specified circumstances pursuant to the terms of his employment agreement.

If we terminate the named executive officer’s employment without cause or if the named executive officer terminates his employment with us for good reason in accordance with the terms of his employment agreement, the named executive officer is entitled to receive from us an amount equal to nine months of his then annual base salary, payable in nine equal monthly installments in accordance with our payroll practices, and standard health insurance coverage for a period of nine months, subject to such benefits being available to non-employees. If his standard health insurance coverage is not available to non-employees under our company sponsored plan, we will reimburse the named executive officer in an amount equal to the cost of the premium for coverage under a medical plan at the same level and on the same terms and conditions in place immediately before his termination.
If we terminate the named executive officer’s employment without cause or if the named executive officer terminates his employment with us for good reason in accordance with the terms of his employment agreement, in either case within 90 days before or six months after a “change in control event” as defined in our 2008 stock incentive plan, and such event also constitutes a “change in control event” within the meaning of the regulations promulgated under Section 409A of the Internal Revenue Code, as amended, or the Code, Mr. Abbey and Dr. Nicolette will be entitled to receive the payments and benefits specified above for a period of 15 months rather than nine months. Additionally, in such circumstances, Mr. Abbey and Dr. Nicolette will each be entitled to receive an amount equal to 15 months of his target bonus for the year in which his employment terminates, payable in 15 equal monthly installments in accordance with our payroll practices.

Dr. Miesowicz will be entitled to receive an amount equal to nine months of his target bonus for the year in which his employment terminates, payable in nine equal monthly installments in accordance with our payroll practices.

Under Mr. Abbey’s and Dr. Nicolette’s employment agreements, effective upon the close of our IPO on February 12, 2014 and for a period of four years from such date, to the extent that any payment, benefit or distribution, or combination thereof, by us or any of our affiliates to the executive officer pursuant to his employment agreement or any other agreement, plan or arrangement would constitute a “parachute payment” within the meaning of Section 280G of the Code and would be subject to the excise tax imposed under Section 4999 of the Code, Mr. Abbey and Dr. Nicolette, as applicable, will be entitled to receive a “gross-up” payment equal to the sum of such excise tax and related interest or penalties, plus the amount necessary to put him in the same after-tax position that he would have been in had he not incurred any tax liability under Section 4999 of the Code. After such four-year period, the applicable executive officer will not be entitled to any such “gross up” payment associated with any “parachute payment” or excise tax. Dr. Miesowicz is not entitled to any “gross up” payment associated with any “parachute payment” under his employment agreement.

If required by Section 409A of the Code, the payments we are required to make to each named executive officer in the first six months following the termination of such named executive officer’s employment under his respective employment agreement will be made as a lump sum on the date that is six months and one day following such termination.

Under the terms of the stock options granted to our named executive officers prior to 2013 under our 2008 stock incentive plan, upon a “change of control event” as defined in our 2008 stock incentive plan, all unvested portions of any outstanding options held by them will vest in full. Under the terms of the stock options granted to our named executive officers in 2013 under our 2008 stock incentive plan, upon a “change of control event”, all unvested portions of any outstanding options held by them will vest in full if we terminate the named executive officer’s employment without cause or if the named executive officer terminates his employment with us for good reason, in each case within ninety days before or six months after the “change in control event”.

**2014 Stock Incentive Plan**

In January 2014, our board of directors adopted and our stockholders approved the 2014 stock incentive plan, which became effective immediately prior to the closing of our IPO, which occurred in February 2014. The 2014 stock incentive plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Upon effectiveness of the plan, the number of shares of our common stock that were reserved for issuance under the 2014 stock incentive plan was the sum of 1,951,182 shares, plus such number of shares of our common stock (up to 357,841 shares) as was equal to the sum of the number of shares of common stock reserved for issuance under the 2008 stock incentive plan that remained available for grant under the 2008 stock incentive plan immediately prior to the closing of our IPO and the number of shares of common stock subject to outstanding awards under the 2008 stock incentive plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right, plus an annual increase, to be added on the first day of the 2015 fiscal year and each subsequent anniversary through January 1, 2024, equal to the lowest of 2,309,023 shares of our common stock, 4% of the number of our outstanding shares on the first day of each such fiscal year and an amount determined by our board of directors. On January 1, 2015, an additional 589,722 shares of common stock were authorized for issuance under the 2014 stock incentive plan.

As of February 28, 2015, options to purchase 1,067,053 shares of our common stock, at a weighted average exercise price per share of $6.90, were outstanding under the 2014 stock incentive plan and 1,831,692 shares remained available for issuance.

Our employees, officers, directors, consultants and advisors will be eligible to receive awards under the 2014 stock incentive plan. However, incentive stock options may only be granted to our employees.

Pursuant to the terms of the 2014 stock incentive plan, our board of directors will administer the plan and, subject to any limitations in the plan, select the recipients of awards and determines:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which may not be less than the fair market value of our common stock on the date of grant of the options; and

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Our board of directors has delegated authority to an executive officer to grant awards under the 2014 stock incentive plan to all of our employees, except employees at or above the director level. Our board of directors has fixed the terms of the awards to be granted by such executive officer, including the exercise price of such awards, and the maximum number of shares subject to awards that such executive officer may make.

Upon a merger or other reorganization event, our board of directors may, in its sole discretion, take any one or more of the following actions pursuant to the 2014 stock incentive plan as to some or all outstanding awards other than restricted stock:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant’s unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant;
- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (1) the number of shares of common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and
- provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted stock will continue for the benefit of the successor company and will, unless the board of directors may otherwise determine, apply to the cash, securities or other property into which shares of our common stock are converted or exchanged pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2014 stock incentive plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

No award may be granted under the 2014 stock incentive plan on or after January 17, 2024. Our board of directors may amend, suspend or terminate the 2014 stock incentive plan at any time, except that stockholder approval will be required to comply with applicable law or stock market requirements.

2008 Stock Incentive Plan

In February 2008, our board of directors adopted our 2008 stock incentive plan. Our stockholders approved our 2008 stock incentive plan in March 2008. Upon the completion of our IPO, our board of directors agreed not to grant any further awards under the 2008 stock incentive plan but all outstanding awards will continue to be governed by their existing terms.

Types of Awards. The 2008 stock incentive plan provides for the grant of incentive stock options within the meaning of Section 422 of the Internal Revenue Code, nonstatutory stock options, restricted stock awards, consisting of restricted stock and restricted stock units, and other forms of stock-based awards. Awards under the plan may be granted to our employees, directors and individual consultants and advisors. Only our employees are eligible to receive incentive stock options.
When initially adopted, an aggregate of 201,278 shares were reserved for issuance under the 2008 stock incentive plan. The 2008 stock incentive plan was subsequently amended to increase the total number of shares which were available for issuance under the plan to 2,325,898.

As of December 31, 2014, options to purchase 1,891,688 shares of our common stock, at a weighted average exercise price per share of $5.46, were outstanding under the 2008 stock incentive plan.

Our board of directors, or a duly authorized committee thereof, is authorized to administer our 2008 stock incentive plan. Our board of directors delegated certain authority to administer the 2008 stock incentive plan to our compensation committee; however, our general practice was that awards were approved by the board of directors. In addition, our compensation committee delegated to Mr. Abbey the authority to award stock options to purchase 251,324 shares of our common stock to non-executive employees. Our board of directors or its authorized committee has the authority under the plan to interpret and adopt rules and procedures relating to the 2008 stock incentive plan, as well as to determine the terms of any award or amend the terms of any award made under the plan. No amendment to any award made under the plan may materially and adversely affect the rights of a participant under any outstanding award without the participant’s consent.

Each stock option awarded under the 2008 stock incentive plan was granted pursuant to a notice of stock option and stock option agreement. The board of directors determined the exercise price for a stock option, within the terms and conditions of the 2008 stock incentive plan, provided that the exercise price of a stock option generally could not be less than 100% of the fair market value of our common stock on the date of grant. The vesting and other terms of each grant under the 2008 stock incentive plan were determined by the board of directors in its discretion; however, shares subject to stock options granted under the 2008 stock incentive plan generally vest in installments over a specified period of service, typically four years. The board of directors determined the term of stock options granted under the 2008 stock incentive plan, subject to limitations in the case of some incentive stock options, as described below. In general, if an optionee’s service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionee may generally exercise the vested portion of any option for a period of three months following the cessation of service. If an optionee’s service relationship with us, or any of our affiliates, ceases due to disability or death or if an optionee dies within a specified period following cessation of service, the optionee or a beneficiary generally may exercise the vested portion of any option for a period of 12 months following the death or disability. If an optionee’s services are terminated for cause, options generally terminate immediately upon such termination. In no event may an option be exercised beyond the expiration of its term.

Stock purchased upon the exercise of a stock option may, depending on the terms of the particular option agreement, be paid for using any of the following: (1) cash or check, (2) a broker-assisted cashless exercise, (3) so long as our common stock is registered under the Securities Exchange Act of 1934, the tender of common stock previously owned by the optionee, (4) delivery of a promissory note, (5) payment of other lawful consideration as determined by the plan administrator, or (6) any combination of the above.

Incentive stock options are subject to certain restrictions contained in the Internal Revenue Code. Among such restrictions, incentive stock options may be granted only to our employees. The maximum term of an incentive stock option is ten years from the date of grant. Any incentive stock option granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates must have an exercise price equal at least to 110% of the fair market value of the stock subject to the option on the date of grant, and the term of the incentive stock option may not exceed five years from the date of grant. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year under all of our stock plans may not exceed $100,000.

Each restricted stock award granted under the 2008 stock incentive plan was granted pursuant to a summary of restricted stock purchase and a restricted stock purchase agreement. An award of restricted stock entitles a participant to acquire shares of our common stock that are subject to specified restrictions, which may include a repurchase right or forfeiture right, if the shares are issued at no cost, in our favor that lapses in accordance with a vesting schedule or as conditions specified in the award are satisfied. The board of directors determined the terms and conditions of restricted stock awards, including the conditions for repurchase or forfeiture and the purchase price, if any. Unless the board of directors determined otherwise, participants holding shares of restricted stock are entitled to all ordinary cash dividends paid with respect to such shares.

The board of directors may amend, suspend or terminate the plan at any time, subject to approval of the stockholders in certain circumstances if required by the Internal Revenue Code to ensure that incentive stock options are tax-qualified and to a participant’s consent to the extent that any amendment to the plan may materially and adversely affect the rights of a participant under any outstanding award.
Effect of Certain Corporate Transactions. Unless otherwise provided in an individual award document, in the event of specified changes of control of our company, our board of directors may take any one or more actions as to any outstanding equity award, or as to a portion of any outstanding equity award, including:

- providing that such awards will be assumed, or substantially equivalent awards substituted, by the acquiring or succeeding corporation or an affiliate thereof;
- providing, upon notice to the participant, that all unexercised awards will terminate immediately prior to the consummation of such transaction unless exercised within a specified period of time;
- providing that all or any outstanding awards will become vested or exercisable, or restrictions applicable to such awards will lapse, in full or in part, at or immediately prior to such event;
- in the event of a consolidation, merger, combination, reorganization or similar transaction under the terms of which holders of our common stock will receive a cash payment per share surrendered in the transaction, making or providing for an equivalent cash payment in exchange for the termination of such equity awards; or
- providing that in the event of a liquidation or dissolution awards will convert into the right to receive liquidation proceeds.
- The majority of the awards granted under the 2008 stock incentive plan provide that the unvested portion of such award would become fully vested upon specified changes of control of our company.

Transferability. Awards made under the 2008 stock incentive plan are not transferable except by will or by the laws of descent or distribution or, other than in the case of an incentive stock option, pursuant to a domestic relations order.

1999 Stock Option Plan

In December 1999, our board of directors adopted and our stockholders approved the 1999 stock option plan. In 2008, our employees who then held options under the 1999 stock option plan agreed to the cancellation and termination of all of their options previously granted under the 1999 stock option plan in exchange for the grant of new options under our 2008 stock incentive plan described above, and the board of directors determined at that time to discontinue making awards under the 1999 stock option plan. As of December 31, 2013, options to purchase 11 shares of our common stock at a weighted average exercise price per share of $3,221.29 were outstanding under the 1999 stock option plan. The 1999 stock option plan has expired and no shares of our common stock are available for issuance under that plan other than shares that may be issued upon exercise of the outstanding options to purchase up to six shares of our common stock.

Administration. Our board of directors administered the 1999 stock option plan and had the authority to interpret the terms of the 1999 stock option plan and the options granted under it.

Eligibility. The 1999 stock option plan provided for the grant of incentive stock options within the meaning of Section 422 of the Code and nonstatutory stock options. Our employees, including officers, non-employee directors, advisors and independent consultants, were eligible to receive options under the 1999 stock option plan, provided that incentive stock options could be granted only to employees.

Effect of Certain Corporate Transactions. The 1999 stock option plan provided that, unless otherwise determined by our board of directors at the time of grant, in the event of a merger, consolidation, corporate reorganization or any transaction in which all or substantially all of our assets or stock were sold, leased, transferred or otherwise disposed of, unless otherwise provided in an individual’s option agreement, any unvested portion of a stock option granted under the 1999 stock option plan would become fully vested unless the surviving or acquiring corporation assumed or substituted comparable options for the outstanding options granted under the plan or replaced the options with a cash incentive program that preserved the intrinsic value of the options at the time of the transaction and provided for subsequent payout over the same vesting schedules as the options being replaced.

2014 Employee Stock Purchase Plan

In January 2014, our board of directors adopted and our stockholders approved the 2014 Employee Stock Purchase Plan, or the 2014 ESPP, which became effective immediately prior to the closing of our IPO. Our compensation committee administers the 2014 ESPP.
The 2014 ESPP provides for six month offering periods during which eligible employees may elect to have wages or salary withheld through payroll deductions for the purpose of purchasing shares at the end of the period. All of our employees or employees of any designated subsidiary, as defined in the 2014 ESPP, are eligible to participate in the 2014 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- such person has been employed by us or a designated subsidiary for at least three months prior to enrolling in the 2014 ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2014 ESPP.

No employee is eligible to receive an option to purchase shares of our common stock that would result in the employee owning 5% or more of the total combined voting power or value of our stock immediately after the grant of such option.

We intend to make multiple offerings to our employees to purchase stock under the 2014 ESPP. Purchase plan periods under the 2014 ESPP will commence at such times or times as our board of directors determines. The first purchase plan period commenced on September 1, 2014 and ended on February 28, 2015. Our board of directors has currently authorized additional offering periods of six months each, beginning on March 1 and September 1 of each year until amended, suspended or terminated by the board. Payroll deductions made during each purchase plan period will be held for the purchase of our common stock at the end of each purchase plan period.

On the offering commencement date of each purchase plan period, we will grant to each eligible employee who is then a participant in the 2014 ESPP an option to purchase shares of our common stock. The employee may authorize up to a maximum of 10% of his or her base pay to be deducted by us during the purchase plan period. Each employee who continues to be a participant in the 2014 ESPP on the last business day of each purchase plan period is deemed to have exercised the option, to the extent of accumulated payroll deductions within the 2014 ESPP ownership limits. Under the terms of the 2014 ESPP, the option exercise price shall be determined by our board of directors for each purchase plan period and the option exercise price will be at least 85% of the applicable closing price. If our board of directors does not make a determination of the option exercise price, the option exercise price will be 85% of the lesser of the closing price of our common stock on either the first business day of the purchase plan period or the last business day of the purchase plan period. In no event may an employee purchase in any one purchase plan period a number of shares that exceeds the number of shares determined by dividing (1) the product of $2,083 and the number of full months in the purchase plan period by (2) the closing price of a share of our common stock on the commencement date of the purchase plan period. Our board of directors may, in its discretion, choose a different purchase plan period of twelve months or less for each offering.

An employee who is not a participant on the last day of the offering period is not entitled to exercise any option, and the employee’s accumulated payroll deductions will be refunded. An employee’s rights under the purchase plan terminate upon voluntary withdrawal from the purchase plan at any time, or when the employee ceases employment for any reason.

We will be required to make equitable adjustments in connection with the 2014 ESPP and any outstanding awards to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combination of shares, reclassification of shares, spin-offs and other similar changes in capitalization.

Upon the occurrence of a reorganization event, as defined in the 2014 ESPP, our board of directors is authorized to take any one or more of the following actions as to outstanding options under the 2014 ESPP:

- provide that options will be assumed, or substantially equivalent options will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- upon the occurrence of a reorganization event in which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event, change the last day of the purchase plan period to be the date of the consummation of the reorganization event and provide that participants will receive a cash payment equal to the acquisition price times the number of shares of common stock that the participant’s accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the option price minus the result of multiplying such number of shares by such option price; and
Our board of directors may at any time, and from time to time, amend or suspend the 2014 ESPP. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Code. Further, our board of directors may not make any amendment that would cause the 2014 ESPP to fail to comply with Section 423 of the Code. Our board of directors may terminate the 2014 ESPP at any time. Upon termination, we will refund all amounts in the accounts of participating employees.

**Director Compensation**

The form and amount of director compensation is reviewed and assessed from time to time by the Compensation Committee with changes, if any, recommended to the Board for action. Director compensation may take the form of cash, equity, and other benefits ordinarily available to directors.

Our board of directors adopted a formal non-employee director compensation policy that became effective upon the closing of our IPO in February 2014. This policy is designed to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors’ interests with those of our stockholders. It provides for non-employee directors to receive an option grant of 11,000 shares upon election to the board, which will vest in equal quarterly installments over a term of three years so long as such person continues to serve as a director; an annual option grant of 5,500 shares upon the annual meeting of stockholders, which will vest in equal quarterly installments over a term of one year so long as such person continues to serve as a director; an annual retainer of $35,000; and a supplemental retainer of $25,000 in the event such director is the chairman or lead director. If the non-employee director is a member of our audit or compensation committee, he or she would receive an additional $5,000 retainer, which would be increased to $10,000 if such director was serving as the chair of such committee. If the non-employee director is a member of our governance and nominating committee, he or she would receive an additional $2,500 retainer, which would be increased to $5,000 if such director was serving as the chair of such committee.

We reimburse each non-employee director for reasonable travel expenses incurred and in connection with attendance at Board and committee meetings on our behalf, and for expenses such as supplies.

The form and amount of director compensation is reviewed and assessed from time to time by our Compensation Committee with changes, if any, recommended to our board of directors for action. Director compensation may take the form of cash, equity, and other benefits ordinarily available to directors.

**Fiscal 2014 Compensation of Non-Employee Directors**

Our non-employee directors received the following aggregate amounts of compensation in respect of the year ended December 31, 2014.

<table>
<thead>
<tr>
<th>Name</th>
<th>Fees Earned or Paid in Cash ($)</th>
<th>Stock Awards ($)</th>
<th>Option Awards ($) (1)</th>
<th>Non-Equity Incentive Plan Compensation ($)</th>
<th>Non-Qualified Deferred Compensation Earnings ($)</th>
<th>All Other Compensation ($)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hubert Birner, Ph.D.</td>
<td>70,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>70,000</td>
</tr>
<tr>
<td>David Gryska (2)</td>
<td>48,917</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>48,917</td>
</tr>
<tr>
<td>Jean Lamarre</td>
<td>50,585</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>50,585</td>
</tr>
<tr>
<td>Andrei Petrov</td>
<td>42,500</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>42,500</td>
</tr>
<tr>
<td>Brian J. Underdown, Ph.D.</td>
<td>50,835</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>50,835</td>
</tr>
<tr>
<td>Sander van Deventer, M.D., Ph.D.</td>
<td>35,000</td>
<td>—</td>
<td>99,084</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>134,084</td>
</tr>
<tr>
<td>Philippe Van Holle (3)</td>
<td>5,543</td>
<td>—</td>
<td>73,704</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>79,247</td>
</tr>
<tr>
<td>Alexey Vinogradov, Ph.D.</td>
<td>35,000</td>
<td>—</td>
<td>99,084</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>134,084</td>
</tr>
</tbody>
</table>

(1) The amounts shown in this column reflect the aggregate grant date fair value of the stock awards and option awards granted to our non-employee directors computed in accordance with FASB ASC Topic 718. The assumptions made in determining the fair values of our stock awards and option awards are set forth in Notes 2 and 12 to our 2014 Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

(2) David Gryska resigned from our board of directors effective October 31, 2014.

(3) Philippe Van Holle joined our board of directors in November 2014.
As of December 31, 2014, our non-employee directors held the following stock options, all of which were granted under the 2014 Plan and the 2008 stock incentive plan:

<table>
<thead>
<tr>
<th>Name</th>
<th>Option Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hubert Birner, Ph.D.</td>
<td>11,000</td>
</tr>
<tr>
<td>Jean Lamarre</td>
<td>16,015</td>
</tr>
<tr>
<td>Andrei Petrov</td>
<td>11,000</td>
</tr>
<tr>
<td>Brian J. Underdown, Ph.D.</td>
<td>11,000</td>
</tr>
<tr>
<td>Sander van Deventer, M.D., Ph.D.</td>
<td>11,000</td>
</tr>
<tr>
<td>Philippe Van Holle</td>
<td>11,000</td>
</tr>
<tr>
<td>Alexey Vinogradov, Ph.D.</td>
<td>11,000</td>
</tr>
</tbody>
</table>

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company. The current members of our compensation committee are Andrei Petrov, Brian J. Underdown, and Philippe Van Holle. David W. Gryska, a former member of our board of directors, served as a member of our compensation committee until October 2014, at which time he ceased to serve as a member of our board of directors.


Securities Authorized for Issuance under Equity Compensation Plan

The following table shows information relating to our equity compensation plans as of December 31, 2014.

<table>
<thead>
<tr>
<th>Plan Category</th>
<th>Equity Compensation Plan Information</th>
<th>Number of securities remaining available for future issuance under equity compensation plans (excluding securities in first column)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity compensation plans approved by security holders</td>
<td>2,929,878 $ 5.98</td>
<td>1,372,394(1)</td>
</tr>
<tr>
<td>Equity compensation plans not approved by security holders</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>2,929,878 $ 5.98</td>
<td>1,372,394</td>
</tr>
</tbody>
</table>

(1) Reflects the total number of shares of our common stock available for issuance under the 2014 Plan and the 2014 – ESPP as of December 31, 2014. Our 2014 Plan contains an “evergreen” provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the plan on the first day of each fiscal year starting in the 2015 fiscal year and on each subsequent anniversary through January 1, 2024, equal to the lowest of 2,309,023 shares of our common stock, 4% of the number of the Company’s outstanding shares of common stock on the first day of each such fiscal year or an amount determined by the Company’s board of directors. On January 1, 2015, 589,722 shares of our common stock were authorized for issuance under the 2014 stock incentive plan.
Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information with respect to the beneficial ownership of our common stock, as of February 28, 2015 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options or warrants that are currently exercisable or exercisable within 60 days of February 28, 2015 are considered outstanding and beneficially owned by the person holding the options or warrants for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable.

Except as otherwise set forth in the footnotes below, the address of the beneficial owner is c/o Argos Therapeutics, Inc., 4233 Technology Drive, Durham, North Carolina 27704.

<table>
<thead>
<tr>
<th>Name and Address of Beneficial Owner</th>
<th>Number of Shares Beneficially Owned</th>
<th>Percentage of Shares Beneficially Owned</th>
</tr>
</thead>
<tbody>
<tr>
<td>5% Stockholders:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmstandard International S.A. (1)</td>
<td>5,983,549</td>
<td>30.41%</td>
</tr>
<tr>
<td>Entities affiliated with Forbion (2)</td>
<td>2,450,144</td>
<td>12.45%</td>
</tr>
<tr>
<td>Wasatch Advisors, Inc. (3)</td>
<td>2,099,767</td>
<td>10.67%</td>
</tr>
<tr>
<td>TVM V Life Science Ventures GmbH &amp; Co. KG (4)</td>
<td>1,471,091</td>
<td>7.48%</td>
</tr>
<tr>
<td>Entities affiliated with Lumira Capital (5)</td>
<td>1,249,572</td>
<td>6.35%</td>
</tr>
<tr>
<td>Entities affiliated with Intersouth Partners (6)</td>
<td>1,069,979</td>
<td>5.44%</td>
</tr>
<tr>
<td><strong>Directors and Named Executive Officers:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Andrei Petrov (7)</td>
<td>5,987,215</td>
<td>30.42%</td>
</tr>
<tr>
<td>Alexey Vinogradov, Ph.D. (7)</td>
<td>5,987,215</td>
<td>30.42%</td>
</tr>
<tr>
<td>Sander van Deventer, M.D., Ph.D. (8)</td>
<td>2,453,810</td>
<td>12.47%</td>
</tr>
<tr>
<td>Hubert Birner, Ph.D. (9)</td>
<td>1,474,757</td>
<td>7.49%</td>
</tr>
<tr>
<td>Brian J. Underdown, Ph.D. (10)</td>
<td>1,253,238</td>
<td>6.37%</td>
</tr>
<tr>
<td>Jeffrey D. Abbey (11)</td>
<td>341,385</td>
<td>1.71%</td>
</tr>
<tr>
<td>Frederick M. Miesowicz, Ph.D. (12)</td>
<td>106,662</td>
<td>0.54%</td>
</tr>
<tr>
<td>Charles A. Nicolette, Ph.D. (13)</td>
<td>163,814</td>
<td>0.83%</td>
</tr>
<tr>
<td>Philippe Van Holle (14)</td>
<td>916</td>
<td>0.00%</td>
</tr>
<tr>
<td>Jean Lamarre (15)</td>
<td>7,287</td>
<td>0.04%</td>
</tr>
<tr>
<td>All executive officers and directors as a group (12 persons) (16)</td>
<td>11,938,472</td>
<td>58.38%</td>
</tr>
</tbody>
</table>

(1) The address of Pharmstandard International S.A. is 65, Boulevard Grande Duchesse Charlotte, L-1331 Luxembourg, Grand Duchy of Luxembourg. Pharmstandard International S.A. is a wholly owned subsidiary of Public Joint Stock Company “Pharmstandard.” As the parent entity, Public Joint Stock Company “Pharmstandard” has voting and investment control over the shares of the Company held by Pharmstandard International S.A.

(2) The address of Forbion is Gooimeer 2-35 1411 DC Naarden, the Netherlands. Consists of (i) 1,254,388 shares of common stock held by Coöperatieve AAC LS U.A. and (ii) 1,195,756 shares of common stock held by Forbion Co-Investment II Coöperatief U.A. Forbion 1 Management B.V., the director of Coöperatieve AAC LS U.A. has voting and investment power over the shares held by Coöperatieve AAC LS U.A., which are exercised through Forbion 1 Management B.V.’s investment committee, consisting of L.P.A. Bergstein, H. A. Slootweg, M. A. van Osch, G. J. Mulder and Sander van Deventer. None of the members of the investment committee has individual voting and investment power with respect to such shares, and the members disclaim beneficial ownership of such shares except to the extent of their pecuniary interests therein. Forbion 1 Co- II Management B.V., the director of Forbion Co-Investment II Coöperatief U.A., has voting and investment power over the shares held by Forbion Co-Investment II Coöperatief U.A., which are exercised through Forbion 1 Co II Management B.V.’s investment committee, consisting of L.P.A. Bergstein, H. A. Slootweg, M. A. van Osch, G. J. Mulder and Sander van Deventer. None of the members of the investment committee has individual voting and investment power with respect to such shares, and the members disclaim beneficial ownership of such shares except to the extent of their pecuniary interests therein.
The address of Wasatch Advisors, Inc. is 505 Wakara Way, 3rd Floor, Salt Lake City, UT 84108. Reference is hereby made to the Schedule 13G/A filed by Wasatch Advisors, Inc. filed on March 10, 2015 for information about the number of shares held by such reporting person and the nature of its beneficial ownership. Wasatch Advisors, Inc.’s beneficial ownership percentage was calculated using the total number of shares of common stock outstanding as of February 28, 2015.

The address of TVM V Life Science Ventures GmbH & Co. KG is Ottostr. 4, 80333 Munich, Germany. The shares represented here are directly held by TVM V Life Science Ventures GmbH & Co. KG (“TVM V”), the managing limited partner of which is TVM V Life Science Ventures Management GmbH & Co. KG (“TVM V Management”), for which Hubert Birner, Stefan Fischer, Alexandra Goll and Alex Polack, each a member of the investment committee of TVM V Management, share voting and investment authority over the shares held by TVM V. Each of TVM V Management, Hubert Birner, Stefan Fischer, Alexandra Goll and Alex Polack disclaims beneficial ownership of these shares, except to the extent of their pecuniary interest therein, if any.

The address of Lumira Capital is 141 Adelaide Street West, Suite 770, Toronto, Ontario, Canada M5H 3L5. The shares represented here are directly and/or beneficially owned by each of, LCC Legacy Holdings Inc., an Ontario corporation (“LCC”), Lumira Capital Investment Management Inc., a Canadian corporation (“LCIM”), Peter van der Velden, as a member of the Board of Directors of LCC and a member of the investment committee of LCIM, Gerald Brunk, as a member of the investment committee of LCIM, Daniel Hetu, as a member of the investment committee of LCIM, Benjamin Rovinski, as a member of the investment committee of LCIM, Brian J. Underdown, as a member of the investment committee of LCIM and Vasco Larcina, as a member of the investment committee of LCIM. Each of the foregoing is referred to as a “Reporting Person” and collectively as the “Reporting Persons.” LCC, acting as the Manager of Lumira Capital I Limited Partnership (“CQ”), has voting and investment power over the securities held by CQ, which is exercised by the investment committee of LCIM, Lumira Capital I Quebec Limited Partnership (“CQ”) and a wholly-owned subsidiary of LCC, has voting and investment power over the shares held by CQ; such investment and voting power is exercised based on the recommendations of the investment committee of LCIM. Voting and investment power over the securities held directly by LCC is exercised by the LCC board of directors. CI directly holds 821,016 shares; CQ directly holds 289,323 shares; LCC directly holds 139,233 shares. Each of the Reporting Persons specifically disclaims beneficial ownership of the securities reported herein that are not directly owned by such Reporting Person, except to the extent of their pecuniary interest therein. Beneficial ownership is derived from a Schedule 13D filed on February 21, 2014.

The address for Intersouth Partners is 102 City Hall Plaza, Suite 200, Durham, North Carolina 27701. The shares represented here are directly and/or beneficially owned by each of Intersouth Partners V, L.P., Intersouth Affiliates V, L.P., Intersouth Associates V LLC, Intersouth Partners IV, L.P., Intersouth Associates IV LLC, Mitch Mumma and Dennis Dougherty. Intersouth Affiliates V, L.P. directly holds 32,999 shares; (ii) Intersouth Partners V, L.P. directly holds 721,884 shares; and (iii) Intersouth Partners IV, L.P. directly holds 315,096 shares. Intersouth Associates V LLC, the general partner of each of Intersouth Partners V, L.P. and Intersouth Affiliates V, L.P., and Intersouth Associates IV LLC, the general partner of Intersouth Partners IV, L.P., may be deemed to share voting and dispositive power over the shares held by each of Intersouth Affiliates V, L.P. and Intersouth Partners V, L.P. and Intersouth Partners IV, L.P., respectively. Dennis Dougherty and Mitch Mumma are both Member Managers of Intersouth Associates V LLC, and Intersouth Associates IV LLC, and share voting and investment power over the shares held by Intersouth Affiliates V, L.P., Intersouth Partners V, L.P. and Intersouth Partners IV, L.P. Beneficial ownership is derived from a Schedule 13G filed on February 18, 2014.

Consists of (i) 5,983,549 shares of common stock beneficially owned by Pharmstandard International S.A. as described in footnote (1) above and (ii) 3,666 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.

Consists of (i) 2,450,144 shares of common stock beneficially owned by Forbion as described in footnote (2) above and (ii) 3,666 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.

Consists of (i) 1,471,091 shares of common stock beneficially owned by TVM V as described in footnote (4) above and (ii) 3,666 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.

Consists of (i) 1,249,572 shares of common stock beneficially owned by the Lumira entities as described in footnote 5 above and (ii) 3,666 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.

Consists of (i) 2,580 shares of common stock and (ii) 338,805 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.
Since January 1, 2014, we engaged in the following transactions, in which the amount involved in the transaction exceeds $120,000 with our directors, executive officers and holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as we could have obtained from unrelated third parties. Compensation arrangements for our directors and named executive officers are described in “Item 11. Executive Compensation.”

(13) Consists of (i) 6,800 shares of common stock and (ii) 157,014 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.
(14) Consists of 916 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.
(15) Consists of 7,287 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.
(16) Includes (i) 11,165,025 shares of common stock and (ii) 773,447 shares of common stock issuable upon exercise of options that are exercisable as of February 28, 2015 or will become exercisable within 60 days after such date.

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

Since January 1, 2014, we engaged in the following transactions, in which the amount involved in the transaction exceeds $120,000 with our directors, executive officers and holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as we could have obtained from unrelated third parties. Compensation arrangements for our directors and named executive officers are described in “Item 11. Executive Compensation.”
Participation in our Initial Public Offering

Our principal stockholders purchased shares in our IPO at the initial public offering price. The number of shares that each of our principal stockholders purchased and the aggregate purchase price paid for such shares is set forth in the table below.

<table>
<thead>
<tr>
<th>Name</th>
<th>Shares of Common Stock Purchased in our IPO</th>
<th>Aggregate Purchase Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entities affiliated with Forbion</td>
<td>36,416</td>
<td>$ 291,328</td>
</tr>
<tr>
<td>Entities affiliated with Intersouth Partners</td>
<td>28,841</td>
<td>$ 230,728</td>
</tr>
<tr>
<td>Entities affiliated with Lumira Capital</td>
<td>40,497</td>
<td>$ 323,976</td>
</tr>
<tr>
<td>TVM V Life Science Ventures GmbH &amp; Co. KG</td>
<td>39,873</td>
<td>$ 318,984</td>
</tr>
<tr>
<td>Pharmstandard International S.A.</td>
<td>1,275,000</td>
<td>$ 10,200,000</td>
</tr>
</tbody>
</table>

Indemnification Agreements

Our certificate of incorporation provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of our directors and executive officers. These agreements may require us, among other things, to indemnify each such director for some expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his service as one of our directors.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds $120,000, and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a “related person,” has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a “related person transaction,” the related person must report the proposed related person transaction to our chief executive officer. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person’s interest in the transaction. As appropriate for the circumstances, the committee will review and consider:

- the related person’s interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person’s interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.
In addition to the transactions that are excluded by the instructions to the SEC’s related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person’s position as an executive officer of another entity (whether or not the person is also a director of such entity), that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction, and (c) the amount involved in the transaction equals less than the greater of $200,000 dollars or 5% of the annual gross revenues of the other entity that is a party to the transaction; and

- a transaction that is specifically contemplated by provisions of our charter or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the compensation committee in the manner specified in its charter.

**Director Independence**

Our board of directors has determined that all of the members of the audit committee, the compensation committee and the nominating and corporate governance committee are independent, as defined under the NASDAQ rules, including, in the case of all the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

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

PricewaterhouseCoopers LLP has been approved by our Audit Committee to continue to act as our independent registered public accounting firm for the year ending December 31, 2015.

Audit and other fees billed to us by PricewaterhouseCoopers, LLP for the years ended December 31, 2014 and 2013 are as follows:

<table>
<thead>
<tr>
<th>Service Description</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit Fees (1)</td>
<td>$379,974</td>
<td>$639,510</td>
</tr>
<tr>
<td>Audit-Related Fees (2)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Tax Fees (3)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>All Other Fees (4)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total Fees for Services Provided</td>
<td>$379,974</td>
<td>$639,510</td>
</tr>
</tbody>
</table>

(1) Audit fees include fees associated with the annual audit, reviews of interim financial statements included in SEC registration statements, accounting and reporting consultations and audits conducted under OMB Circular A-133.

(2) There were no audit-related fees for the fiscal year ended December 31, 2014 or 2013.

(3) There were no tax fees for the fiscal years ended December 31, 2014 or 2013.

(4) Other fees include fees billed for other services rendered not included within Audit Fees, Audit Related Fees or Tax Fees. There were no other fees for the fiscal years ended December 31, 2014 or 2013.

PricewaterhouseCoopers LLP did not perform any professional services related to financial information systems design and implementation for us in the year ended December 31, 2014 or 2013.

The Audit Committee has determined in its business judgment that the provision of non-audit services described above is compatible with maintaining PricewaterhouseCoopers LLP’s independence.
In 2014, the Audit Committee adopted a formal policy concerning approval of audit and non-audit services to be provided to the Company by its independent registered public accounting firm, PricewaterhouseCoopers LLP. The policy requires that all services to be provided by PricewaterhouseCoopers LLP, including audit services and permitted audit-related and non-audit services, must be preapproved by the Audit Committee, provided that de minimis non-audit services may instead be approved in accordance with applicable SEC rules. The Board of Directors preapproved all audit and non-audit services provided by PricewaterhouseCoopers LLP during fiscal year 2014 and fiscal year 2013.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are included in this Annual Report on Form 10-K:

1. The following Report and Consolidated Financial Statements of the Company are included in this Annual Report:
   
   - Report of Independent Registered Public Accounting Firm
   - Consolidated Balance Sheets
   - Consolidated Statements of Operations
   - Consolidated Statements of Comprehensive Loss
   - Consolidated Statements of Changes in Stockholders’ (Deficit) Equity
   - Consolidated Statements of Cash Flows
   - Notes to Consolidated Financial Statements
   - Financial Statement Schedule:
     Schedule II – Valuation and Qualifying Accounts

2. All other schedules are omitted as they are inapplicable or the required information is furnished in the Consolidated Financial Statements or notes thereto.

3. The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K and are incorporated herein.
Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARGOS THERAPEUTICS, INC.

By: /s/ Jeffrey D. Abbey
Name: Jeffrey D. Abbey
Title: President and Chief Executive Officer

Date: March 31, 2015

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on March 31, 2015 in the capacities indicated.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ Jeffrey D. Abbey</td>
<td>President, Chief Executive Officer and Director (Principal Executive Officer)</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Jeffrey D. Abbey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Lori R. Harrelson</td>
<td>Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Lori R. Harrelson</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Hubert Birner, Ph.D.</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Hubert Birner, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Jean Lamarre</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Jean Lamarre</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Andrei Petrov</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Andrei Petrov</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Brian J. Underdown, Ph.D.</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Brian J. Underdown, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Sander van Deventer, M.D., Ph.D.</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Sander van Deventer, M.D., Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Philippe Van Holle</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Philippe Van Holle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Alexey Vinogradov, Ph.D.</td>
<td>Director</td>
<td>March 31, 2015</td>
</tr>
<tr>
<td>Alexey Vinogradov, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Exhibit</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant’s Current Report on Form 8-K (File No. 001-35443) on February 18, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant’s Current Report on Form 8-K (File No. 001-35443) on February 18, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>4.1</td>
<td>Specimen Stock Certificate evidencing the shares of common stock (filed as Exhibit 4.1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>Fifth Amended and Restated Registration Rights Agreement, dated as of August 9, 2013 (filed as Exhibit 4.2 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.1+</td>
<td>1999 Stock Option Plan (filed as Exhibit 10.1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.2+</td>
<td>2008 Stock Incentive Plan, as amended (filed as Exhibit 10.2 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.3+</td>
<td>Form of Incentive Stock Option Agreement under 2008 Stock Incentive Plan (filed as Exhibit 10.3 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.4+</td>
<td>Form of Nonstatutory Stock Option Agreement under 2008 Stock Incentive Plan (filed as Exhibit 10.4 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.5+</td>
<td>2014 Stock Incentive Plan (filed as Exhibit 10.5 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.6+</td>
<td>Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan (filed as Exhibit 10.6 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.7+</td>
<td>Form of Nonstatutory Stock Option Agreement under 2014 Stock Incentive Plan (filed as Exhibit 10.7 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.8</td>
<td>Lease Agreement, dated as of January 16, 2001, between the Registrant and HCP MOP, as amended (filed as Exhibit 10.8 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.9+</td>
<td>Employment Agreement between the Registrant and Jeffrey D. Abbey, dated December 9, 2013 (filed as Exhibit 10.9 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.10+</td>
<td>Employment Agreement between the Registrant and Charles A. Nicolette, dated December 9, 2013 (filed as Exhibit 10.10 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.11+</td>
<td>Employment Agreement between the Registrant and Frederick M. Miesowicz, dated December 9, 2013 (filed as Exhibit 10.11 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.12+</td>
<td>Employment Agreement between the Registrant and Lori R. Harrelson, dated December 9, 2013 (filed as Exhibit 10.12 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.13+</td>
<td>Employment Agreement between the Registrant and Douglas C. Plessinger, dated December 9, 2013 (filed as Exhibit 10.13 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Exhibit</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>10.14</td>
<td>Form of Indemnification Agreement between the Registrant and each director and executive officer (filed as Exhibit 10.14 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.15†</td>
<td>Contract No. HHSN266200600019C, dated September 30, 2006, by and among the Registrant, the National Institutes of Health and the National Institutes of Allergy and Infectious Diseases, as amended (filed as Exhibit 10.15 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.16†</td>
<td>License Agreement, dated August 9, 2013, by and between the Registrant and Pharmstandard S.A. (filed as Exhibit 10.16 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.17†</td>
<td>License Agreement, dated July 31, 2013, by and between the Registrant and Green Cross Corp. (filed as Exhibit 10.17 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.18†</td>
<td>License Agreement, dated July 28, 2011, by and between the Registrant and CellDex Therapeutics, Inc. (filed as Exhibit 10.18 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.19†</td>
<td>License Agreement, dated January 10, 2000, by and between the Registrant and Duke University, as amended (filed as Exhibit 10.19 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.20</td>
<td>Acknowledgement Agreement, dated November 4, 2013, by and between the Registrant and Pharmstandard International S.A. (filed as Exhibit 10.20 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.21†</td>
<td>2014 Employee Stock Purchase Plan (filed as Exhibit 10.21 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-193137) on January 21, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.22</td>
<td>Lease Agreement, dated August 18, 2014, by and between by and between the Registrant and TKC LXXII, LLC (filed as Exhibit 10.1 to the Registrant’s Current Report on Form 8-K on August 22, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.23</td>
<td>Venture Loan and Security Agreement, dated September 29, 2014, by and between the Registrant and Horizon Technology Finance Corporation and Fortress Credit Co LLC (filed as Exhibit 10.1 to the Registrant’s Current Report on Form 8-K on September 30, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.24</td>
<td>Form of Warrant to Purchase Common Stock, issued to Horizon Technology Finance Corporation on September 29, 2014 (filed as Exhibit 10.2 to the Registrant’s Current Report on Form 8-K on September 30, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.25</td>
<td>Form of Warrant to Purchase Common Stock, issued to Drawbridge Special Opportunities Fund LP on September 29, 2014 (filed as Exhibit 10.3 to the Registrant’s Current Report on Form 8-K on September 30, 2014 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>10.26</td>
<td>Development Agreement, dated October 29, 2014, by and between the Registrant and Invetech Lty Ltd (filed as Exhibit 10.5 to the Registrant’s Quarterly Report on Form 10-Q on November 14, 2014 and incorporated by reference)</td>
<td></td>
</tr>
<tr>
<td>10.27*†</td>
<td>Development Agreement dated January 5, 2015, by and between the Registrant and Saint-Gobain Performance Plastics Corporation</td>
<td></td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Exhibit</td>
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</tr>
<tr>
<td>10.28</td>
<td>Purchase and Sale Agreement, dated February 16, 2015, by and between the Registrant and TKC LXXII, LLC (filed as Exhibit 10.1 to the Registrant’s Current Report on Form 8-K on February 20, 2015 and incorporated by reference)</td>
<td></td>
</tr>
<tr>
<td>10.29</td>
<td>Novated, Amended and Restated License Agreement effective as of October 1, 2014, by and between the Registrant and MEDcell Co., Ltd.</td>
<td></td>
</tr>
<tr>
<td>21.1</td>
<td>Subsidiaries of the Registrant (filed as Exhibit 21.1 to the Registrant’s Registration Statement on Form S-1 on December 30, 2013 and incorporated herein by reference)</td>
<td></td>
</tr>
<tr>
<td>23.1*</td>
<td>Consent of PricewaterhouseCoopers, an independent registered public accounting firm</td>
<td></td>
</tr>
<tr>
<td>31.1*</td>
<td>Certification of principal executive officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</td>
<td></td>
</tr>
<tr>
<td>31.2*</td>
<td>Certification of principal financial officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</td>
<td></td>
</tr>
<tr>
<td>32.1*</td>
<td>Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by the Registrant’s principal executive officer and principal financial officer</td>
<td></td>
</tr>
<tr>
<td>101.INS</td>
<td>XBRL Instance Document</td>
<td></td>
</tr>
<tr>
<td>101.SCH</td>
<td>XBRL Taxonomy Extension Schema Document</td>
<td></td>
</tr>
<tr>
<td>101.CAL</td>
<td>XBRL Taxonomy Extension Calculation Linkbase Document</td>
<td></td>
</tr>
<tr>
<td>101.DEF</td>
<td>XBRL Taxonomy Extension Definition Linkbase Document</td>
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</tr>
<tr>
<td>101.LAB</td>
<td>XBRL Taxonomy Extension Label Linkbase Document</td>
<td></td>
</tr>
<tr>
<td>101.PRE</td>
<td>XBRL Taxonomy Extension Presentation Linkbase Document</td>
<td></td>
</tr>
</tbody>
</table>

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
+ Management contract or compensatory plan or arrangement required to be filed as exhibits hereto pursuant to Item 15(a) of Form 10-K.
* Filed herewith.
<table>
<thead>
<tr>
<th>INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Report of Independent Registered Public Accounting Firm</strong></td>
</tr>
<tr>
<td><strong>Consolidated Financial Statements:</strong></td>
</tr>
<tr>
<td>Consolidated Balance Sheets</td>
</tr>
<tr>
<td>Consolidated Statements of Operations</td>
</tr>
<tr>
<td>Consolidated Statements of Comprehensive Loss</td>
</tr>
<tr>
<td>Consolidated Statements of Changes in Stockholders’ (Deficit) Equity</td>
</tr>
<tr>
<td>Consolidated Statements of Cash Flows</td>
</tr>
<tr>
<td>Notes to Consolidated Financial Statements</td>
</tr>
<tr>
<td><strong>Financial Statement Schedule:</strong></td>
</tr>
<tr>
<td>Schedule II – Valuation and Qualifying Accounts</td>
</tr>
</tbody>
</table>

F-1
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive loss, changes in stockholders’ (deficit) equity and cash flows present fairly, in all material respects, the financial position of Argos Therapeutics, Inc. and its subsidiaries (the “Company”) at December 31, 2014 and 2013 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina

March 31, 2015
### ARGOS THERAPEUTICS, INC.
#### CONSOLIDATED BALANCE SHEETS

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

#### December 31,

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$33,297,970</td>
<td>$37,223,590</td>
</tr>
<tr>
<td>Short-term investments</td>
<td>13,659,812</td>
<td>19,016,347</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>629,935</td>
<td>838,420</td>
</tr>
<tr>
<td>Deferred financing costs</td>
<td>1,516,424</td>
<td>309,927</td>
</tr>
<tr>
<td>Other receivables</td>
<td>424,501</td>
<td>129,019</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>$49,528,642</td>
<td>$57,517,303</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>1,602,103</td>
<td>5,513,555</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>—</td>
<td>1,325,000</td>
</tr>
<tr>
<td>Other assets</td>
<td>550</td>
<td>11,020</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$51,131,295</td>
<td>$64,366,878</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Liabilities, Redeemable Convertible Preferred Stock and Stockholders’ (Deficit) Equity</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Current liabilities</td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$1,317,072</td>
</tr>
<tr>
<td>Other accrued expenses</td>
<td>1,800,794</td>
</tr>
<tr>
<td>Current portion of notes payable</td>
<td>45,447</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>$3,163,313</td>
</tr>
<tr>
<td>Long-term portion of notes payable</td>
<td>7,014,106</td>
</tr>
<tr>
<td>Long-term portion of manufacturing research and development obligation</td>
<td>—</td>
</tr>
<tr>
<td>Long-term portion of facility lease obligation</td>
<td>—</td>
</tr>
<tr>
<td>Deferred liability</td>
<td>3,066,000</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>11,243,419</td>
</tr>
<tr>
<td><strong>Series A redeemable convertible preferred stock</strong></td>
<td></td>
</tr>
<tr>
<td>Preferred stock $0.001 par value; 1,200,000 and 0 shares authorized as of December 31, 2013 and 2014; 1,040,216 and 0 shares issued and outstanding as of December 31, 2013, and 2014; liquidation preference of $332,869 as of December 31, 2013</td>
<td>332,869</td>
</tr>
<tr>
<td><strong>Total stockholders’ (deficit) equity</strong></td>
<td></td>
</tr>
<tr>
<td>Preferred stock $0.001 par value; 0 and 5,000,000 shares authorized as of December 31, 2013 and 2014; 0 shares issued and outstanding as of December 31, 2013 and 2014</td>
<td>—</td>
</tr>
<tr>
<td><strong>Common stock</strong></td>
<td></td>
</tr>
<tr>
<td>Preferred stock $0.001 par value; 120,000,000 and 200,000,000 shares authorized as of December 31, 2013 and 2014; 235,707 and 19,657,412 shares issued and outstanding as of December 31, 2013 and 2014</td>
<td>236</td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(102,531)</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>75,189,950</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(150,864,248)</td>
</tr>
<tr>
<td><strong>Total stockholders’ (deficit) equity</strong></td>
<td>(75,776,593)</td>
</tr>
<tr>
<td><strong>Total liabilities, redeemable convertible preferred stock and stockholders’ (deficit) equity</strong></td>
<td>$51,131,295</td>
</tr>
</tbody>
</table>

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

F-3
ARGOS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

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

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$7,039,010</td>
<td>$4,421,689</td>
<td>$1,974,019</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>17,616,892</td>
<td>23,991,151</td>
<td>45,498,916</td>
</tr>
<tr>
<td>General and administrative</td>
<td>6,135,581</td>
<td>4,662,317</td>
<td>8,599,359</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>23,752,473</td>
<td>28,653,468</td>
<td>54,098,275</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(16,713,463)</td>
<td>(24,231,779)</td>
<td>(52,124,256)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest income</td>
<td>4,604</td>
<td>7,184</td>
<td>66,580</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(292,496)</td>
<td>(4,705)</td>
<td>(1,123,579)</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>4,916,785</td>
<td>355,352</td>
<td>—</td>
</tr>
<tr>
<td>Derivative (expense) income</td>
<td>1,036,403</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Investment tax credits</td>
<td>694,331</td>
<td>—</td>
<td>140,556</td>
</tr>
<tr>
<td>Other expense</td>
<td>(117,494)</td>
<td>(47,615)</td>
<td>(265,239)</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>6,242,133</td>
<td>310,216</td>
<td>(1,181,682)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(10,471,330)</td>
<td>(23,921,563)</td>
<td>(53,305,938)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock (See Note 19)</td>
<td>(351,371)</td>
<td>4,772,991</td>
<td>(863,226)</td>
</tr>
<tr>
<td>Less: Preferred stock dividend due to exchanges of preferred shares (See Note 19)</td>
<td>—</td>
<td>(14,726,088)</td>
<td>—</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$(10,822,701)</td>
<td>$(33,874,660)</td>
<td>$(54,169,164)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders per share, basic and diluted</td>
<td>$ (54.58)</td>
<td>$(147.37)</td>
<td>$(3.12)</td>
</tr>
<tr>
<td>Weighted average shares outstanding, basic and diluted</td>
<td>198,306</td>
<td>229,865</td>
<td>17,367,665</td>
</tr>
</tbody>
</table>

F-4
ARGOS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$(10,471,330)</td>
<td>$(23,921,563)</td>
<td>$(53,305,938)</td>
</tr>
<tr>
<td>Other comprehensive loss:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation (loss) gain</td>
<td>(180,049)</td>
<td>(8,264)</td>
<td>(10,382)</td>
</tr>
<tr>
<td>Unrealized (loss) on short-term investments</td>
<td>—</td>
<td>—</td>
<td>(11,928)</td>
</tr>
<tr>
<td>Total comprehensive loss</td>
<td>$(10,651,379)</td>
<td>$(23,929,827)</td>
<td>$(53,328,248)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
ARGOS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS’ (DEFICIT) EQUITY

<table>
<thead>
<tr>
<th></th>
<th>Common Stock Shares</th>
<th>Common Stock Amount</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Other Comprehensive Income (Loss)</th>
<th>Accumulated Deficit</th>
<th>Noncontrolling Interest</th>
<th>Total Stockholders’ (Deficit) Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance as of December 31, 2011</td>
<td>122,345</td>
<td>$122</td>
<td>$29,413,821</td>
<td>$85,782</td>
<td>$128,828,989</td>
<td>$2,974,158</td>
<td>$96,355,106</td>
</tr>
<tr>
<td>Issuance of restricted stock</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of options to nonemployees</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,042,989</td>
<td>—</td>
<td>1,042,989</td>
</tr>
<tr>
<td>Conversion of preferred stock into common stock</td>
<td>104,494</td>
<td>105</td>
<td>8,067,829</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>8,067,934</td>
</tr>
<tr>
<td>Accretion of preferred stock</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(351,371)</td>
<td>—</td>
<td>(351,371)</td>
</tr>
<tr>
<td>Extinguishment of preferred shares</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Purchase of noncontrolling interest’s shares</td>
<td>—</td>
<td>—</td>
<td>2,974,158</td>
<td>—</td>
<td>—</td>
<td>(2,974,158)</td>
<td>—</td>
</tr>
<tr>
<td>Cumulative translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(180,049)</td>
<td>—</td>
<td>—</td>
<td>(180,049)</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(10,471,330)</td>
<td>—</td>
<td>(10,471,330)</td>
</tr>
<tr>
<td>Balance as of December 31, 2012</td>
<td>226,839</td>
<td>$227</td>
<td>$58,469,015</td>
<td>$(94,267)</td>
<td>$(126,942,685)</td>
<td>—</td>
<td>$(68,567,710)</td>
</tr>
<tr>
<td>Exercise of common stock options</td>
<td>1,379</td>
<td>2</td>
<td>5,791</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>5,793</td>
</tr>
<tr>
<td>Issuance of restricted stock</td>
<td>7,571</td>
<td>7</td>
<td>16,493</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>16,493</td>
</tr>
<tr>
<td>Issuance of common warrants</td>
<td>—</td>
<td>—</td>
<td>618,155</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>618,155</td>
</tr>
<tr>
<td>Distribution of shares to affiliates</td>
<td>(7)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Surrender of shares</td>
<td>(75)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>1,053,163</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,053,163</td>
</tr>
<tr>
<td>Reversal of prior accretion</td>
<td>—</td>
<td>—</td>
<td>5,657,638</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>5,657,638</td>
</tr>
<tr>
<td>Accretion of preferred stock</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>884,647</td>
<td>—</td>
<td>884,647</td>
</tr>
<tr>
<td>Exchange of preferred shares</td>
<td>—</td>
<td>—</td>
<td>(14,726,088)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(14,726,088)</td>
</tr>
<tr>
<td>Reduction of liquidation value</td>
<td>—</td>
<td>—</td>
<td>24,980,430</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>24,980,430</td>
</tr>
<tr>
<td>Cumulative translation adjustment</td>
<td>—</td>
<td>—</td>
<td>(8,264)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(8,264)</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(23,921,563)</td>
<td>—</td>
<td>(23,921,563)</td>
</tr>
<tr>
<td>Balance as of December 31, 2013</td>
<td>235,707</td>
<td>$236</td>
<td>$75,189,950</td>
<td>$(102,531)</td>
<td>$(150,864,248)</td>
<td>—</td>
<td>$(75,776,593)</td>
</tr>
<tr>
<td>Issuance of common stock</td>
<td>6,228,725</td>
<td>6,229</td>
<td>49,823,571</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>49,829,800</td>
</tr>
<tr>
<td>Common stock issuance costs</td>
<td>—</td>
<td>—</td>
<td>(6,391,588)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(6,391,588)</td>
</tr>
<tr>
<td>Exercise of common stock options</td>
<td>3,050</td>
<td>3</td>
<td>12,807</td>
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<td>—</td>
<td>—</td>
<td>12,810</td>
</tr>
<tr>
<td>Conversion of warrants into common stock</td>
<td>1,679</td>
<td>1</td>
<td>(1)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>3,013,284</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3,013,284</td>
</tr>
<tr>
<td>Accretion of preferred stock</td>
<td>—</td>
<td>—</td>
<td>(865,226)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(865,226)</td>
</tr>
<tr>
<td>Conversion of preferred stock into common stock</td>
<td>13,188,251</td>
<td>13,188</td>
<td>114,514,257</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>114,527,455</td>
</tr>
<tr>
<td>Issuance of warrants</td>
<td>—</td>
<td>—</td>
<td>328,110</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>328,110</td>
</tr>
<tr>
<td>Cumulative translation adjustment</td>
<td>—</td>
<td>—</td>
<td>(10,382)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(10,382)</td>
</tr>
<tr>
<td>Unrealized loss on short-term investments</td>
<td>—</td>
<td>—</td>
<td>(11,928)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(11,928)</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(53,305,938)</td>
<td>—</td>
<td>(53,305,938)</td>
</tr>
<tr>
<td>Balance as of December 31, 2014</td>
<td>19,657,412</td>
<td>$19,657</td>
<td>$235,627,174</td>
<td>$(124,841)</td>
<td>$(204,170,186)</td>
<td>—</td>
<td>$(31,351,804)</td>
</tr>
</tbody>
</table>

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

F-6
ARGOS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

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

F-7
1. Organization

Argos Therapeutics, Inc. (the “Company”), was incorporated in the State of Delaware on May 8, 1997. The Company is a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer and infectious diseases based on its proprietary technology platform called Arcelis. The Company’s most advanced product candidate is AGS-003, which the Company is developing for the treatment of metastatic renal cell carcinoma (mRCC), and other cancers. The Company is developing a second Arcelis-based product candidate, AGS-004, for the treatment of HIV.

Initial Public Offering

In February 2014, the Company issued and sold 6,228,725 shares of its common stock, including 603,725 shares of common stock sold pursuant to the underwriters’ exercise of their option to purchase additional shares, in the Company’s initial public offering, at a public offering price of $8.00 per share, for aggregate gross proceeds of $49.8 million. The net offering proceeds to the Company, after deducting underwriting discounts and commissions of approximately $3.5 million and offering expenses of approximately $2.9 million, were approximately $43.4 million. Upon the closing of the initial public offering, all of the then-outstanding shares of the Company’s redeemable convertible preferred stock automatically converted into 13,188,251 shares of common stock.

In connection with the initial public offering, the Company paid a former lender a $200,000 under a Loan and Security Agreement entered into with two lending institutions in April 2007. The Loan and Security Agreement terminated in April 2010, and the Company repaid all amounts owing under the Loan and Security Agreement. In connection with the Loan and Security Agreement, the Company was required to pay a success fee of $200,000 upon consummation of a liquidity event, including an initial public offering. Accordingly, the Company paid this fee in March 2014. The Company recorded this fee in Other expense on the Condensed Consolidated Statements of Operations during the year ended December 31, 2014.

There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company’s business, results of operations and financial condition. The Company expects to continue to incur losses and require additional financial resources to advance its products to either commercial stage or liquidity events.

Capitalization

In connection with the Company’s initial public offering in February 2014, the Company effected a one–for-six reverse split of its common stock. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in these consolidated financial statements and notes to consolidated financial statements have been restated to reflect the reverse split on a retroactive basis.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts and results of operations of the Company and DC Bio, formerly Merix Canada Corp., an unlimited liability corporation incorporated in the Province of Nova Scotia. Prior to October 26, 2012, the Company consolidated DC Bio under ASC 810-10-50, Consolidation of Variable Interest Entities (“VIE”), as DC Bio met the requirements of a VIE. As of December 31, 2012, the Company owned 100% of DC Bio through the repurchase of the noncontrolling interests of DC Bio. All intercompany balances and transactions have been eliminated in consolidation.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and, therefore, basic and diluted net loss per share were the same for all periods presented.
Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less as of the date of purchase to be cash equivalents. Cash deposits are all in financial institutions in the United States of America or Canada. The Company maintains cash in accounts which are in excess of federally insured limits. As of December 31, 2013 and December 31, 2014, $33,047,970 and $36,973,590, respectively, in cash and cash equivalents was uninsured.

Short-Term Investments

All investments with original maturities less than one year from the balance sheet date are considered short-term investments. All short-term investments are classified as available-for-sale and therefore carried at fair value. Generally, the fair value of short-term investments approximates amortized cost. The Company primarily invests in high-quality marketable debt securities issued by high quality financial and industrial companies.

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and short-term investments. Total cash and cash equivalent balances have exceeded insured balances by the Federal Depository Insurance Company (“FDIC”).

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Property and equipment held under capital leases and leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income. Repairs and maintenance costs are expensed as incurred.

Impairment of Long-Lived Assets

The Company periodically assesses the impairment of long lived assets in accordance with ASC Topic 360, Property Plant and Equipment. When indicators of impairment are present, the Company evaluates the carrying value of these assets in relation to the operating performance of the business and future undiscounted cash flows expected to result from the use of these assets. No such impairments have been recognized during the years ended December 31, 2012, 2013 or 2014.

Revenue Recognition

The Company recognizes revenue in accordance with the FASB Accounting Standards Codification 605, Revenue Recognition, or ASC 605. The Company recognizes revenue when the following criteria are met: persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable, and collectability is reasonably assured.

The Company has entered into license agreements with collaborators. The terms of these agreements have included nonrefundable signing and licensing fees, as well as milestone payments and royalties on any future product sales developed by the collaborators under such licenses. The Company assesses these multiple elements in accordance with ASC 605, to determine whether particular components of the arrangement represent separate units of accounting.

These collaboration agreements will be accounted for in accordance with Accounting Standards Update, or ASU, No. 2009-13, Topic 605 – Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. This guidance requires the application of the “relative selling price” method when allocating revenue in a multiple deliverable arrangement. The selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists; otherwise, third-party evidence of selling price shall be used. If neither exists for a deliverable, the vendor shall use its best estimate of the selling price for that deliverable. The Company recognizes upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations cannot be determined, such obligations are accounted for separately as the obligations are fulfilled. If the license is considered to either not have stand-alone value or have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement is accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.
When the Company determines that an arrangement should be accounted for as a single unit of accounting, the Company must determine the period over which the performance obligations will be performed and revenue will be recognized, to the extent this is determinable. If the timing and the level of effort to complete performance obligations under the arrangement is not estimable, then the Company recognizes revenue under the arrangement on a straight-line basis over the period that the Company expects to complete such performance obligations.

The Company’s license agreements with Pharmstandard International S.A. (“Pharmstandard”), Medinet Co., Ltd. (“Medinet”) and Green Cross Corp. (“Green Cross”) contain, and other agreements it enters into may also contain, milestone payments. Revenues from milestones, if they are non-refundable and considered substantive, are recognized upon successful accomplishment of the milestones. If not considered substantive, milestones are initially deferred and recognized over the remaining performance obligation.

The Company’s current license agreements with Pharmstandard, Medinet and Green Cross and any future license agreements the Company may enter into may provide for royalty payments. Royalty revenue is recognized upon the sale of the related products, provided there are no remaining performance obligations under the arrangement. To date, the Company has not received any royalty payments.

The Company conducted AGS-004 a phase 2b clinical trial of AGS-004 that was funded entirely by the National Institutes of Health (“NIH”) and National Institute of Allergy and Infectious Diseases (“NIAID”). Under the NIH and NIAID agreement, as amended, the Company is entitled to receive reimbursement of its direct expenses and allocated overhead and general and administrative expenses of up to $38.4 million and payment of other specified amounts totaling up to $1.4 million upon its achievement of specified development milestones. These reimbursable expenses and allocated overhead are directly related to the development of novel HIV immunotherapy candidates and are recognized as revenue based on the reimbursable expenses that have accrued in accordance with the contractual terms in the arrangement. The Company recognizes revenues from the achievement of milestones under the NIH contract upon the accomplishment of any such milestone.

**Income Taxes**

The Company provides for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

**Segment and Geographic Information**

Operating segments are defined as components of an enterprise engaging in business activities from which it may earn revenues and incur expenses, for which discrete financial information is available and whose operating results are regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment and all of the Company operations are in North America.

**Research and Development**

Research and development costs include all direct costs related to the development of the Company’s technology, including salaries and related benefits of research and development (“R&D”) personnel, depreciation of laboratory equipment, fees paid to consultants and contract research organizations, stock-based compensation for R&D personnel, sponsored research payments and license fees. R&D costs are expensed as incurred.

**Redeemable Convertible Preferred Stock**

The carrying value of redeemable convertible preferred stock is increased by periodic accretions so that the carrying amount will equal the redemption amount as of the redemption date. These increases were recorded through charges against additional paid-in capital, to the extent it was available, or the accumulated deficit.

**Warrant Liability**

Warrants to purchase the Company’s convertible preferred stock were classified as liabilities and recorded at their estimated fair value. In each reporting period, any change in fair value of the freestanding warrants are recorded as expense in the case of an increase in fair value and income in the case of a decrease in fair value.
**Other Receivables**

The Company has recorded other receivables of $424,501 and $129,019 as of December 31, 2013 and 2014. These receivables are primarily related to amounts due under the NIH contract as of such dates. The Company assesses the recoverability of other receivables as of each balance sheet date.

**Stock-Based Compensation**

The Company estimates the grant date fair value of its share-based awards and amortizes this fair value to compensation expense over the requisite service period or vesting term (see Note 12).

**Investment Tax Credits**

Other income of $694,331, $0 and $140,556 was recognized during the years ended December 31, 2012, 2013 and 2014, respectively, for scientific research and experimental development (“SR&ED”) investment tax credits in Canada. Under Canadian and Ontario law, the Company’s Canadian subsidiary is entitled to SR&ED. Because these credits are subject to a claims review, the Company recognizes such credits when received.

**Comprehensive Income (Loss)**

ASC 220, *Comprehensive Income*, establishes standards for reporting and display of comprehensive income and its components in a full set of financial statements. The Company’s other comprehensive income (loss) is related to foreign currency translation adjustments and unrealized gain (loss) on short-term investments.

**Foreign Currency Translation**

Gains and losses from foreign currency transactions are reflected in income currently.

The Company has identified the functional currency of its subsidiaries with foreign operations as the applicable local currency. The translation from the applicable local currency to United States dollars is performed using the exchange rate in effect as of the balance sheet date. Revenue and expense accounts are translated using the average exchange rate experienced during the period. Adjustments resulting from the translation of the Company’s subsidiaries’ financial statements from its functional currency to the United States dollar are not included in determining net loss, but are reported as accumulated other comprehensive gain (loss), a separate component of stockholders’ (deficit) equity.

**Derivatives**

The Company issued a put option to exchange certain shareholders’ stock in DC Bio for stock in the Company (see Note 5). Derivatives are recorded in the balance sheet at fair value as of each balance sheet date utilizing pricing models for nonexchange traded contracts (see Note 9). The Company does not use derivative financial instruments for speculative purposes. As of December 31, 2013 and 2014, there were no derivatives outstanding.

**Interest Expense**

During the year ended December 31, 2014, interest expense primarily resulted from accrued interest on our note payable to Medinet, which was issued in December 2013, and interest from a venture loan and security agreement entered into in September 2014 with two financial institutions (see Note 8).

**Recently Issued Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board (“FASB”) issued a new accounting standard update pertaining to disclosures for development stage entities. The new guidance eliminates the distinction of a development stage entity and certain related disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders’ equity. The new standard is effective prospectively for annual reporting beginning after December 15, 2014, and interim periods within those annual periods, but early adoption is permitted. The Company adopted this new accounting standard during the three months ended June 30, 2014.

In May 2014, the FASB issued a new accounting standard update pertaining to accounting for revenue from contracts with customers. The new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP. The standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2016, which is effective for the Company for the year ending December 31, 2017. The Company is currently evaluating the impact that the implementation of this standard will have on the Company’s consolidated financial statements.

In August 2014, the FASB issued a new standard update that specifies the responsibility that an entity’s management has to evaluate whether there is substantial doubt about the entity’s ability to continue as a going concern. The standard is effective for interim and annual periods beginning after December 15, 2016, and is not expected to have an effect on the Company’s financial statements.
In July 2013, the FASB issued a new accounting standard update on the financial statement presentation of unrecognized tax benefits. The new guidance provides that a liability related to an unrecognized tax benefit would be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The new guidance became effective for the Company on January 1, 2014 and it was applied prospectively to unrecognized tax benefits that existed as of the effective date with retrospective application permitted. This updated standard did not have a material impact on the Company’s condensed consolidated financial statements.

3. Fair Value of Financial Instruments

The estimated fair values of all of the Company’s financial instruments, excluding long-term debt, approximate their carrying amounts in the Consolidated Balance Sheets as of December 31, 2013 and 2014.

As of December 31, 2013 and December 31, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis. These assets include money market funds included in cash equivalents and short-term investments in corporate debt securities. The valuation of these financial instruments uses a three tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company’s own assumptions, consistent with reasonably available assumptions made by other market participants.

The Company’s Level 1 assets consist of money-market funds and the method used to estimate the fair value of the Level 1 assets is based on observable market data as these money-market funds are publicly-traded. The Company’s Level 2 assets consist of short-term debt instruments in corporate debt securities valued using independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. As of each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.
As of December 31, 2013 and December 31, 2014, these financial instruments and respective fair values have been classified as follows:

<table>
<thead>
<tr>
<th></th>
<th>Quoted Prices in Active Markets for Identical Assets (Level 1)</th>
<th>Significant Other Observable Inputs (Level 2)</th>
<th>Significant Unobservable Inputs (Level 3)</th>
<th>Balance as of December 31, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money-market funds</td>
<td>$ 22,891,418</td>
<td>$ —</td>
<td>$ —</td>
<td>$ 22,891,418</td>
</tr>
<tr>
<td>Corporate debt securities – short-term</td>
<td>—</td>
<td>13,659,812</td>
<td>—</td>
<td>13,659,812</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$ 22,891,418</td>
<td>$ 13,659,812</td>
<td>—</td>
<td>$ 36,551,230</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Quoted Prices in Active Markets for Identical Assets (Level 1)</th>
<th>Significant Other Observable Inputs (Level 2)</th>
<th>Significant Unobservable Inputs (Level 3)</th>
<th>Balance as of December 31, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money-market funds</td>
<td>$ 35,541,595</td>
<td>$ —</td>
<td>$ —</td>
<td>$ 35,541,595</td>
</tr>
<tr>
<td>Corporate debt securities – short-term</td>
<td>—</td>
<td>20,266,243</td>
<td>—</td>
<td>20,266,243</td>
</tr>
<tr>
<td>Restricted cash – long-term</td>
<td>1,325,000</td>
<td>—</td>
<td>—</td>
<td>1,325,000</td>
</tr>
<tr>
<td><strong>Total assets at fair value</strong></td>
<td>$ 36,866,595</td>
<td>$ 20,266,243</td>
<td>—</td>
<td>$ 57,132,838</td>
</tr>
</tbody>
</table>

During the years ended December 31, 2013 and 2014, there were no transfers between Levels 1 and 2 assets.

The changes in the balance of Level 3 liabilities for the year ended December 31, 2013 were as follows:

<table>
<thead>
<tr>
<th><strong>Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</strong></th>
<th>Beginning Balance</th>
<th>Net Change in Unrealized (Gains) Losses</th>
<th>Reduction</th>
<th>Ending Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warrant Liability</td>
<td>$ 6,392,652</td>
<td>$ (355,352)</td>
<td>$ (6,037,300)</td>
<td>$ —</td>
</tr>
<tr>
<td></td>
<td>$ 6,392,652</td>
<td>$ (355,352)</td>
<td>$ (6,037,300)</td>
<td>$ —</td>
</tr>
</tbody>
</table>

During the year ended December 31, 2013, all outstanding warrants to purchase preferred stock were cancelled. As a result, there were no warrants to purchase preferred stock outstanding as of December 31, 2013 or 2014, and there were no Level 3 assets or liabilities outstanding during the year ended December 31, 2014.

The fair value of the Company’s long-term debt was derived by evaluating the nature and terms of each note, considering the prevailing economic and market conditions as of each balance sheet date and based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology. The fair value of the Company’s long-term debt as of December 31, 2013 approximated its carrying value of $7.0 million. The fair value of the Company’s long-term debt as of December 31, 2014 was approximately $19.4 million compared with its carrying value of $19.8 million.
4. Property and Equipment

Property and equipment consist of the following:

<table>
<thead>
<tr>
<th>Useful Life (Years)</th>
<th>December 31, 2013</th>
<th>December 31, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office furniture and equipment</td>
<td>7</td>
<td>$528,732</td>
</tr>
<tr>
<td>Computer equipment</td>
<td>3</td>
<td>712,609</td>
</tr>
<tr>
<td>Computer software</td>
<td>3</td>
<td>540,809</td>
</tr>
<tr>
<td>Laboratory equipment</td>
<td>7</td>
<td>5,264,952</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>5</td>
<td>2,643,023</td>
</tr>
<tr>
<td>Asset related to facility lease obligation</td>
<td>—</td>
<td>3,380,223</td>
</tr>
<tr>
<td>Construction of manufacturing facility in progress</td>
<td>76,010</td>
<td>500,093</td>
</tr>
<tr>
<td>Less: Accumulated depreciation and amortization</td>
<td>(8,164,032)</td>
<td>(8,236,329)</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>$1,602,103</td>
<td>$5,513,555</td>
</tr>
</tbody>
</table>

Assets related to the Company’s facility lease obligation and construction of manufacturing facility in progress were primarily recognized during the year ended December 31, 2014 due to the Company deemed to be the accounting owner of the facility during its construction period under build-to-suite lease accounting (see Note 16).

Depreciation and amortization expense was as follows:

<table>
<thead>
<tr>
<th>Year ended December 31</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>505,261</td>
</tr>
<tr>
<td>2013</td>
<td>611,421</td>
</tr>
<tr>
<td>2014</td>
<td>566,117</td>
</tr>
</tbody>
</table>

5. Noncontrolling Interest

Prior to October 2012, the Company owned 49.94% of the total capital stock of DC Bio. As of December 31, 2011, the other shareholders’ ownership interests in DC Bio were represented on the consolidated balance sheet by noncontrolling interest as a separate component of stockholders’ (deficit) equity. In October 2012 and December 2012, DC Bio repurchased the noncontrolling interests from these shareholders. Subsequent to these transactions, the Company owned 100% of DC Bio and eliminated its equity attributable to non-controlling interest through additional paid-in capital.

6. Income Taxes

No provision for U.S. federal, state or foreign income taxes has been recorded as the Company has incurred net operating losses since its inception in 1997.
Significant components of the Company’s deferred tax assets and liabilities consist of the following:

<table>
<thead>
<tr>
<th>Category</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. federal and state net operating loss carryforwards</td>
<td>$41,359,722</td>
<td>$59,689,264</td>
</tr>
<tr>
<td>Foreign net operating loss carryforwards</td>
<td>1,827,221</td>
<td>1,743,603</td>
</tr>
<tr>
<td>Contribution carryforwards</td>
<td>3,055</td>
<td>4,245</td>
</tr>
<tr>
<td>Research and development credits</td>
<td>4,061,844</td>
<td>5,253,055</td>
</tr>
<tr>
<td>Investment tax credits</td>
<td>38,175</td>
<td>35,108</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>22,282</td>
<td>462,796</td>
</tr>
<tr>
<td>Patents and other intangibles</td>
<td>2,967</td>
<td>611</td>
</tr>
<tr>
<td>Other accruals</td>
<td>97,157</td>
<td>125,614</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>—</td>
<td>372,040</td>
</tr>
<tr>
<td>Property and equipment</td>
<td>532,316</td>
<td>510,466</td>
</tr>
<tr>
<td>Total deferred tax assets</td>
<td>47,944,739</td>
<td>68,196,802</td>
</tr>
<tr>
<td>Valuation allowance for deferred assets</td>
<td>(47,944,739)</td>
<td>(68,196,802)</td>
</tr>
<tr>
<td>Net deferred tax assets</td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>

As of December 31, 2013 and 2014, the Company provided a full valuation allowance against its net deferred tax assets since as of that time, the Company could not assert that it was more likely than not that these deferred tax assets would be realized. There was an increase in the valuation allowance in the year ended December 31, 2014 of $20,252,063, all of which was allocable to current operating activities.

As of December 31, 2014, the Company had U.S. federal and state, and Canadian federal and provincial net operating loss carryforwards of approximately $158,406,400, $176,699,700, $6,579,600, and $6,579,600, respectively. These net operating loss carryforwards begin to expire in 2018, 2017, 2015 and 2015, respectively. As of December 31, 2014, the Company had U.S. federal and state tax credit carryforwards of approximately $5,028,400 and $340,400, respectively. These credit carryforwards begin to expire in 2020 and 2019, respectively. As of December 31, 2014, the Company had Canadian investment tax credit carryforwards of approximately $35,100 that begin to expire in 2024. The utilization of the net operating loss and tax credit carryforwards may be subject to limitation under the rules regarding a change in stock ownership as determined by the Internal Revenue Code, and state and foreign tax laws. Section 382 of the Internal Revenue Code of 1986, as amended, imposes annual limitations on the utilization of net operating loss (“NOL”) carryforwards, other tax carryforwards, and certain built-in losses upon an ownership change as defined under that section. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain stockholders in the Company’s stock by more than 50 percentage points over a three year testing period. If the Company has undergone a Section 382 ownership change, an annual limitation would be imposed on certain of the Company’s tax attributes, including NOL and capital loss carryforwards, and certain other losses, credits, deductions or tax basis. As of December 31, 2014, the Company has not completed a formal study to determine whether there are 382 limitations that apply.

As of December 31, 2014, the Company had no foreign unremitted earnings from DC Bio, its Canadian subsidiary.
Taxes computed at the statutory U.S. federal income tax rate of 34.0% are reconciled to the provision for income taxes for the years ended December 31, 2012, 2013 and 2014 as follows:

The research and development credit, which had previously expired on December 31, 2011, was reinstated as part of the American Taxpayer Relief Act of 2012 enacted on January 2, 2013. This legislation retroactively reinstated and extended the credit from the previous expiration date through December 31, 2013. As a result, the Company adjusted its deferred tax assets in 2013 for the 2012 and 2013 research and development credits, net of the gross unrecognized tax benefit, which resulted in an increase to the deferred tax assets and a corresponding increase to the valuation allowance of approximately $298,000 and $585,700, respectively.

On July 23, 2013, the State of North Carolina enacted House Bill 998, which reduced the corporate income tax rate from 6.9% in 2013 to 6% in 2014 and to 5% in 2015. As a result of the new enacted tax rate, the Company adjusted its deferred tax assets in 2013 by applying the lower rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately $1,349,100.

The Company had gross unrecognized tax benefits of approximately $1,644,000 as of January 1, 2014. As of December 31, 2014, the total gross unrecognized tax benefits were approximately $2,155,000 and of this total, none would affect the Company’s effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company’s effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next 12 months.

The Company’s policy is to recognize interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2013 and 2014, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to United States federal, state, and local tax examinations by tax authorities for years before 2011 although carryforward attributes that were generated prior to 2011 may still be adjusted upon examination by the Internal Revenue Service if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.
The following is a tabular reconciliation of the Company’s change in gross unrecognized tax positions during the years ended December 31, 2012, 2013 and 2014:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance</td>
<td>$1,272,800</td>
<td>$1,265,700</td>
<td>$1,644,500</td>
</tr>
<tr>
<td>Gross increase for tax positions related to current periods</td>
<td>—</td>
<td>378,800</td>
<td>474,300</td>
</tr>
<tr>
<td>Gross (decrease) increase for tax positions related to prior periods</td>
<td>(7,100)</td>
<td>—</td>
<td>36,200</td>
</tr>
<tr>
<td>Ending balance</td>
<td>$1,265,700</td>
<td>$1,644,500</td>
<td>$2,155,000</td>
</tr>
</tbody>
</table>

### 7. Convertible Term Notes

On September 9, 2010, the Company entered into a convertible note and warrant purchase agreement with a group of existing preferred stockholders, which provided for a total of up to $6,000,000 in borrowings by the Company. On September 9, 2010 and December 15, 2010, the Company received the proceeds under the agreement in two separate tranches of $4,872,066 and $1,127,925, respectively. The convertible notes issued pursuant to the agreement bore interest at a rate of 10% and provided for conversion into series C preferred stock of the Company. The note purchasers were also issued warrants to purchase series C preferred stock of the Company (Note 11). The proceeds from the convertible notes were allocated among the notes and the associated warrants based on the fair value of the warrants with the residual balance assigned to the convertible notes. The Company increased the value assigned to the convertible notes through interest expense using the effective interest method such that the value of the convertible notes will equal the accrued principal and interest of $6,603,333 as of maturity. The Company recognized $193,402 of interest expense related to the convertible notes during the years ended December 31, 2012.

On July 27, 2011, the Company entered into a convertible note and warrant purchase agreement with a group of existing preferred stockholders, which provided for a total of up to $3,500,000 in borrowings by the Company. On July 27, 2011, the Company received the proceeds under the agreement of $3,500,000. The convertible notes bore interest at a rate of 10% and provided for conversion into series C preferred stock of the Company. The note purchasers were also issued warrants to purchase series C preferred stock of the Company (Note 11). The proceeds from the convertible notes were allocated among the notes and the associated warrants based on the fair value of the warrants with the residual balance assigned to the convertible notes. The Company increased the value assigned to the convertible notes through interest expense using the effective interest method such that the value of the convertible notes will equal the accrued principal and interest of $3,686,250 as of maturity. The Company recognized $98,662 of interest expense related to the July 2011 convertible notes during the years ended December 31, 2012.

In December 2011, the Company and the holders of the 2010 convertible notes and the July 2011 convertible notes agreed to extend the maturity dates of the notes to March 31, 2012. The Company did not record any gain or loss in connection with the extension of the maturity date of the notes because it determined that the extension of the maturity date of the notes met the criteria of a troubled debt restructuring outlined in ASC Topic 470-60, Troubled Debt Restructurings. The Company recognized $292,064 of interest expense related to the 2010 convertible notes and the July 2011 convertible notes during the year ended December 31, 2012.

On April 10, 2012, the principal and interest on the convertible term notes totaling $10,668,185 converted into an aggregate of 3,023,661 shares of series D preferred stock of the Company (see Note 10).
8. Notes Payable

Notes payable consist of the following:

<table>
<thead>
<tr>
<th>Notes payable under the venture loan and security agreement</th>
<th>December 31, 2013</th>
<th>December 31, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>$</td>
<td>$</td>
<td>$12,500,000</td>
</tr>
<tr>
<td>Less related debt discount</td>
<td>0</td>
<td>(373,756)</td>
</tr>
<tr>
<td>Notes payable under the venture loan and security agreement, net of debt discount</td>
<td>—</td>
<td>12,126,244</td>
</tr>
<tr>
<td>Promissory note payable to Medinet including accrued interest</td>
<td>6,936,466</td>
<td>7,623,546</td>
</tr>
<tr>
<td>Other notes payable</td>
<td>123,087</td>
<td>77,640</td>
</tr>
<tr>
<td>Total notes payable</td>
<td>7,059,553</td>
<td>19,827,430</td>
</tr>
<tr>
<td>Less current portion</td>
<td>(45,447)</td>
<td>(30,885)</td>
</tr>
<tr>
<td>Long-term portion of notes payable</td>
<td>$7,014,106</td>
<td>$19,796,545</td>
</tr>
</tbody>
</table>

On September 29, 2014, the Company entered into a venture loan and security agreement (the “Loan Agreement”) with Horizon Technology Finance Corporation and Fortress Credit Co LLC (together, the “Lenders”) under which the Company may borrow up to $25.0 million in two tranches of $12.5 million each (the “Loan Facility”).

The Company borrowed the first tranche of $12.5 million upon the closing of the transaction on September 29, 2014. Subject to certain other funding conditions, the second tranche of $12.5 million will be available for drawdown at any time commencing on the date the Company completes the enrollment and randomization of patients in the Company’s phase 3 clinical trial of AGS-003 and continuing until September 30, 2015. The per annum interest rate for each tranche will be a floating rate equal to 9.25% plus the amount by which the one-month London Interbank Offered Rate (“LIBOR”) exceeds 0.50% (effectively a floating rate equal to 8.75% plus the one-month LIBOR Rate). The total per annum interest rate shall not exceed 10.75%.

The Company incurred $449,796 for costs in connection with the closing of the Loan Agreement. These costs were capitalized as deferred financing costs and amortized to interest expense over the terms of the related debt.

The Company has agreed to repay the first tranche of $12.5 million on an interest only basis monthly until September 30, 2016, followed by monthly payments of principal and accrued interest through the scheduled maturity date for the first tranche loan on September 30, 2018. In addition, a final payment for the first tranche loan equal to $625,000 will be due on September 30, 2018, or such earlier date specified in the Loan Agreement. The Company has agreed to repay any amounts advanced under the second tranche of $12.5 million in 18 monthly payments of interest only followed by 24 monthly payments of principal and accrued interest through the scheduled maturity date for the second tranche loan, which is 42 months following the date the Company draws down the second tranche loan. In addition, a final payment equal to 5.0% of the amount drawn down under the second tranche loan will be due on the scheduled maturity date for such loan, or such earlier date specified in the Loan Agreement. In addition, if the Company repays all or a portion of the loan prior to the applicable maturity date, it will pay the Lenders a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs on or before 24 months after the funding date, 2% if the prepayment occurs more than 24 months after, but on or before 36 months after, the funding date thereof, or 1% if the prepayment occurs more than 36 months after the funding date thereof.

The Company’s obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company also has agreed not to pledge or otherwise encumber its intellectual property assets, subject to certain exceptions.

The Loan Agreement includes customary affirmative and restrictive covenants, but does not include any covenants to attain or maintain certain financial metrics, and also includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

F-18
In connection with the Loan Agreement, the Company issued to the Lenders and their affiliates warrants to purchase a total of 82,780 shares of Common Stock at a per share exercise price of $9.06 (the “Warrants”). The Lenders may not exercise the warrants for more than 41,390 of such shares of Common Stock until the earliest to occur of (i) a merger or consolidation of the Company, or a sale of all or substantially all of its assets, (ii) the Company’s satisfaction of the conditions precedent to the making of the second tranche loan, and (iii) the funding of the second tranche loan. The Warrants will terminate on September 29, 2021 or such earlier date as specified in the Warrants. The Company recorded a debt discount of $338,673 equal to the value of these warrants. This debt discount is offset against the note payable balance and included in additional paid-in capital on the Company’s balance sheet.

In December 2013, in connection with the license agreement with Medinet, as described in Note 9, the Company borrowed $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0% per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. The Company has the right to prepay the loan at any time. If the Company has not repaid the loan by December 31, 2018, then the Company has agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 18, 2018 may constitute pre-paid royalties under the license or would be due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If the Company and Medinet cannot agree on the royalty rate, they have agreed to submit the matter to arbitration. Because the $9.0 million promissory note was issued at a below market interest rate, the Company allocated the proceeds of the loan between the license agreement and the debt at the time of issuance. Accordingly, as of December 31, 2013, the Company recorded $6.9 million to notes payable, based upon an effective interest rate of 8.0%, and $2.1 million as a deferred liability. As of December 31, 2014, the Company recorded $7.6 million to notes payable, including $0.7 million accrued interest recorded during the year ended December 31, 2014. The total deferred liability was $3.1 million as of December 31, 2014 including the $1.0 million received by the Company for a manufacturing license (see Note 10).

The Company entered into a Master Lease Agreement in July 2012 with a lending institution, which provides for the Company to borrow funds up to $100,000 to finance computer equipment. Through December 31, 2014, the Company has borrowed $95,756 under this agreement, of which $48,429 and $16,356 was outstanding as of December 31, 2013 and December 31, 2014, respectively. Borrowings are collateralized by substantially all of the computer equipment financed under the agreement, bear interest at a rate of 0.98% per annum and are to be repaid in 36 equal monthly installments commencing on the date of borrowing. During November 2013, the Company borrowed $77,832 from a lending institution to finance the purchase of additional computer equipment, of which $74,658 and $61,284 in principal was outstanding as of December 31, 2013 and December 31, 2014, respectively. Borrowings are collateralized by substantially all of the computer equipment financed under the agreement, bear interest at a rate of 8.31% per annum and are to be repaid in 60 equal monthly installments commencing on the date of borrowing.

9. Derivatives

In conjunction with the DC Bio transaction on December 7, 2004 (see Note 5), the Company issued a put option whereby in the event DC Bio has not been acquired or had not completed an initial public offering by December 7, 2007, the other shareholders of DC Bio would have the right to put their DC Bio Class A preferred shares and Class B preferred shares to the Company for shares of the Company’s stock. As of December 31, 2011, the Company had reserved 652,608 shares of series C preferred stock, 419,768 shares of series B preferred stock and 23,703 shares of its common stock for issuance upon the exchange of Class A and Class B preferred shares of DC Bio should such put option be exercised. The Company recorded a liability of $1,036,403 as of December 31, 2011 based on the fair market value of the put option, which was calculated based on the fair market value of the Company’s stock issuable upon exercise of the put option, less the fair market value of the DC Bio shares held by such shareholders, as described above. For purposes of this calculation, the Company determined that the fair market value of the Company’s stock issuable upon exercise of the put option was $1,487,668 as of December 31, 2011 and that the fair market value of the DC Bio shares was $451,265 as of December 31, 2011. The value of the DC Bio shares held by the other shareholders was valued under the income approach utilizing a discounted cash flow model. The discount rate reflects the risk in the cash flows. The change in fair value of the put was recorded as derivative (expense) income. The Company terminated the put option in October 2012 when DC Bio repurchased the noncontrolling interests for a total of approximately $180,000.

10. Common Stock, Redeemable Convertible Preferred Stock and Preferred Stock

As of December 31, 2013 and 2014, the Company was authorized to issue 120,000,000 and 200,000,000 shares of common stock, 160,700,000 and 0 shares of redeemable convertible preferred stock, 0 and 5,000,000 shares of preferred stock, respectively.

F-19
In February 2014, the Company issued and sold 6,228,725 shares of its common stock, including 603,725 shares of common stock sold pursuant to the underwriters’ exercise of their option to purchase additional shares, in the Company’s initial public offering, at a public offering price of $8.00 per share, for aggregate gross proceeds of $49.8 million. The net offering proceeds to the Company, after deducting underwriting discounts and commissions of approximately $3.5 million and offering expenses of approximately $2.9 million, were approximately $43.4 million. Upon the closing of the initial public offering, all of the then-outstanding shares of the Company’s redeemable convertible preferred stock automatically converted into 13,188,251 shares of common stock. Accordingly, as of December 31, 2014, the Company has no redeemable convertible preferred stock outstanding and no shares of preferred stock have been issued since their authorization in 2014.

Redeemable Convertible Preferred Stock

In April 2012, the Company sold shares of its series D preferred stock in a private placement to certain of its existing holders of preferred stock and additional accredited investors for an aggregate purchase price of $19.7 million. Included in this amount was $10.7 million of outstanding principal and interest on various convertible notes which converted to series D preferred stock in this financing.

In August 2012, the Company sold 3,716,935 shares of its series D-1 preferred stock in a private placement to certain of its existing holders of preferred stock and other accredited investors for $4.298725 per share for an aggregate purchase price of $16.0 million.

In July 2013, all 7,433,870 shares of series D-1 preferred stock outstanding were exchanged for 16,151,212 shares of series D preferred stock. In addition, in connection with the exchange, the liquidation preference and the redemption price of the series D preferred stock were reduced to $1.978565 per share. As a result of the reduction in the liquidation preference of the series D preferred stock, the Company issued an aggregate of 6,373,782 additional shares of series D preferred stock to the holders that had purchased shares of series D preferred stock prior to such reduction for no additional consideration.

The Company recorded the reduction to liquidation preference as a reversal to prior accretion taken on each series of preferred stock impacted, which reduced net loss attributable to common stockholders in the earnings per share calculation (see Note 19). The Company recorded any remaining reduction in liquidation preference as an increase to additional paid-in capital. In addition, the Company recorded the fair value of the incremental series D preferred stock shares issued in these exchanges in additional paid-in capital as a preferred stock dividend, which increased net loss attributable to common stockholders in the earnings per share calculation (see Note 19).

In August 2013, the Company sold 16,898,436 shares of series E preferred stock for an aggregate purchase price of $22,007,404.

In October 2013 and November 2013, the Company sold 921,423 shares of its series E preferred stock for an aggregate purchase price of $1,200,000 and 19,037,063 shares of its series E preferred stock for an aggregate purchase price of $24,792,595, respectively.

In connection with the issuance and sale of series E preferred stock, in December 2013, the Company issued a warrant to purchase 9,598 shares of its common stock, at an exercise price of $6.60 per share, to a placement agent.

Upon the closing of the Company’s initial public offering, all of the outstanding shares of redeemable convertible preferred stock automatically converted into 13,188,251 shares of the Company’s common stock.
The table below represents a rollforward of the redeemable convertible preferred stock:

<table>
<thead>
<tr>
<th>Series A Preferred</th>
<th>Series B Preferred</th>
<th>Series B-I Preferred</th>
<th>Series C Preferred</th>
<th>Series D Preferred</th>
<th>Series D-1 Preferred</th>
<th>Series E Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
</tr>
<tr>
<td>1,276,103</td>
<td>$1,276,103</td>
<td>24,326,574</td>
<td>$ 42,814,762</td>
<td>917,771</td>
<td>$ 1,615,276</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of shares</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Conversion of bridge note</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Conversion of accrued services</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Pull through of existing preferred</td>
<td>—</td>
<td>—</td>
<td>(3,652,680)</td>
<td>(6,428,717)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stock issuance costs</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(128,275)</td>
</tr>
<tr>
<td>Shares converted to common</td>
<td>—</td>
<td>—</td>
<td>(124,050)</td>
<td>(124,050)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Accretion</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Series A Preferred</th>
<th>Series B Preferred</th>
<th>Series B-I Preferred</th>
<th>Series C Preferred</th>
<th>Series D Preferred</th>
<th>Series D-1 Preferred</th>
<th>Series E Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
</tr>
<tr>
<td>1,152,053</td>
<td>1,152,053</td>
<td>18,491,318</td>
<td>32,544,713</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Exchange of Series D-I</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(16,151,212)</td>
</tr>
<tr>
<td>Issuance of shares</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Exchange of Series D</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(12,607,779)</td>
</tr>
<tr>
<td>Pull through of existing preferred</td>
<td>(111,837)</td>
<td>(35,788)</td>
<td>(6,878,630)</td>
<td>(4,892,873)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Reduction of liquidation value</td>
<td>—</td>
<td>(783,396)</td>
<td>(18,001,661)</td>
<td>—</td>
<td>—</td>
<td>(6,195,373)</td>
</tr>
<tr>
<td>Stock issuance costs</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(64,530)</td>
</tr>
<tr>
<td>Reversal of prior accretion</td>
<td>—</td>
<td>—</td>
<td>(4,128,742)</td>
<td>—</td>
<td>—</td>
<td>(1,528,896)</td>
</tr>
<tr>
<td>Accretion</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>74,152</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Series A Preferred</th>
<th>Series B Preferred</th>
<th>Series B-I Preferred</th>
<th>Series C Preferred</th>
<th>Series D Preferred</th>
<th>Series D-1 Preferred</th>
<th>Series E Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
<td>Amount</td>
<td>Shares</td>
</tr>
<tr>
<td>1,040,216</td>
<td>332,869</td>
<td>9,803,688</td>
<td>5,521,437</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Accretion</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Shares converted to common</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(1,040,216)</td>
</tr>
<tr>
<td>Stock issuance costs</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

F-21
11. Warrants

In connection with the issuance and sale of series E preferred stock, in December 2013, the Company issued a warrant to purchase 9,598 shares of its common stock, at an exercise price of $6.60 per share, to a placement agent. During the year ended December 31, 2014, warrants to purchase 9,598 shares of the Company’s common stock at $6.60 per share were settled in a cashless exercise for 1,679 shares of common stock in conjunction with the closing of the Company’s initial public offering in February 2014.

As discussed in Note 8 regarding the Company’s notes payable, in connection with the Company’s Loan Agreement signed in September 2014, the Company issued warrants to purchase a total of 82,780 shares of Common Stock at a per share exercise price of $9.06. The warrants may not be exercised for more than 41,390 of such shares of Common Stock until the earliest to occur of (i) a merger or consolidation of the Company, or a sale of all or substantially all of its assets, (ii) the Company’s satisfaction of the conditions precedent to the making of the second tranche loan, and (iii) the funding of the second tranche loan. The warrants will terminate on the earlier of September 29, 2021 or such earlier date as specified in the warrants.

In conjunction with entering into a loan agreement with a bank in December 2000, the Company issued warrants to purchase shares of its common stock, all of which expired as of December 31, 2012, except for one warrant. This warrant to purchase one share of the Company’s common stock, at an exercise price of $23,894.34 per share, remained outstanding as of December 31, 2013 and 2014.

Outstanding warrants to purchase the Company’s common stock as of December 31, 2013 were as follows. There were no warrants to purchase preferred stock as of December 31, 2013.

<table>
<thead>
<tr>
<th>Type of Warrant</th>
<th>Number of Shares</th>
<th>Exercise Price</th>
<th>Expiration Date(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common</td>
<td>1</td>
<td>$23,894.34</td>
<td>7/13/16</td>
</tr>
<tr>
<td>Common</td>
<td>9,598</td>
<td>$6.60</td>
<td>12/20/23</td>
</tr>
</tbody>
</table>

Outstanding warrants to purchase the Company’s common stock as of December 31, 2014 were as follows. There were no warrants to purchase preferred stock as of December 31, 2014.

<table>
<thead>
<tr>
<th>Type of Warrant</th>
<th>Number of Shares</th>
<th>Exercise Price</th>
<th>Expiration Date(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common stock</td>
<td>1</td>
<td>$23,894.34</td>
<td>7/13/16</td>
</tr>
<tr>
<td>Common stock</td>
<td>82,780</td>
<td>$9.06</td>
<td>9/29/21</td>
</tr>
</tbody>
</table>

In November 2013, the Company entered into an agreement with Pharmstandard under which Pharmstandard purchased additional shares of the Company’s series E preferred stock. Upon the closing of the Company’s initial public offering, all of the outstanding shares of redeemable convertible preferred stock automatically converted into 13,188,251 shares of the Company’s common stock. Under this agreement, the Company agreed to enter into a manufacturing rights agreement for the European market with Pharmstandard and that the manufacturing rights agreement would provide for the issuance of warrants to Pharmstandard to purchase 499,788 shares of the Company’s common stock at an exercise price of $5.82 per share. As of March 31, 2015, the Company had not entered into this manufacturing rights agreement or issued the warrants.

12. Stock Options and Employee Stock Purchase Plan

In January 2014, the Company’s board of directors and stockholders approved, effective upon the closing of the Company’s initial public offering, the 2014 Stock Incentive Plan (the “2014 Plan”). Under the 2014 Plan, the Company may grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards for the purchase of that number of shares of Common Stock equal to the sum of 1,951,182 shares, plus such number of shares, up to 357,841 shares, as is equal to the sum of the number of shares reserved for issuance under the Company’s 2008 Stock Incentive Plan (the “2008 Plan”) that remained available for grant under the 2008 Plan immediately prior to the closing of the Company’s initial public offering on February 12, 2014 (381,250 shares) and the number of shares subject to outstanding awards under the 2008 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right, plus an annual increase, to be added on the first day of the 2015 fiscal year and each subsequent anniversary through January 1, 2024, equal to the lowest of 2,309,023 shares of Common Stock, 4% of the number of the Company’s outstanding shares on the first day of each such fiscal year and an amount determined by the Company’s board of directors.

F-22
Also in January 2014, the Company’s board of directors and stockholders approved, effective upon the closing of the Company’s initial public offering, a 2014 Employee Stock Purchase Plan (the “2014 ESPP”). Under the 2014 ESPP, on the offering commencement date of each plan period (the “Purchase Plan Period”), the Company will grant to each eligible employee who is then a participant in the 2014 ESPP an option to purchase shares of Common Stock. The employee may authorize up to a maximum of 10% of his or her base pay to be deducted by the Company during the Purchase Plan Period. Each employee who continues to be a participant in the 2014 ESPP on the last business day of the Purchase Plan Period is deemed to have exercised the option, to the extent of accumulated payroll deductions within the 2014 ESPP ownership limits.

Under the terms of the 2014 ESPP, the option exercise price shall be determined by the Company’s board of directors for each Purchase Plan Period and the option exercise price will be at least 85% of the applicable closing price of the Common Stock. The option exercise price will be 85% of the lower of the Company’s closing stock price on the first and last business day of each Purchase Plan Period. The Company’s first Purchase Plan Period commenced on September 2, 2014. Based upon 85% of the lower of the closing price at the beginning of the current offering period of $9.83 and the closing price on December 31, 2014 of $10.00, approximately 9,000 shares could be purchased based upon employee withholdings as of December 31, 2014.

Upon the exercise of stock options, vesting of other awards and purchase of shares through the Company’s 2014 ESPP under the 2014 Plan, the Company issues new shares of common stock to the Company’s employees. All awards that are canceled prior to vesting or expire unexercised are returned to the approved pool of reserved shares under the 2014 Plan and made available for future grants. As of December 31, 2014, common stock remaining available for future issuance under the Company’s stock incentive plans totaled 4,200,717 shares and under the 2014 ESPP was 346,353 shares.

As of December 31, 2011, substantially all of the Company’s employee stock option grants outstanding had exercise prices ranging from $10.86 to $36.66 per share. On March 31, 2012, the Board of Directors approved the repricing of stock options to purchase approximately 201,000 shares of the Company’s common stock at an exercise price of $4.20 per share. The revaluation of this modification of the exercise price of employee stock options did not result in additional stock compensation expense.

The Company recorded the following stock-based compensation expense:

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
</tr>
<tr>
<td>Research and development</td>
<td>$511,860</td>
</tr>
<tr>
<td>General and administrative</td>
<td>531,129</td>
</tr>
<tr>
<td>Total stock-based compensation expense</td>
<td>$1,042,989</td>
</tr>
</tbody>
</table>

Allocations to research and development and general and administrative expense are based upon the department to which the associated employee reported. No related tax benefits of the stock-based compensation expense have been recognized. Stock-based payments issued to nonemployees are recorded at their fair values, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.
Valuation Assumptions for Stock Option Plans

The employee stock-based compensation expense recognized was determined using the Black-Scholes option valuation model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted average assumptions used were as follows:

<table>
<thead>
<tr>
<th>Assumption</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>1.20%</td>
<td>2.12%</td>
<td>2.26%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Expected option term (in years)</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>94%</td>
<td>94%</td>
<td>96%</td>
</tr>
</tbody>
</table>

The risk-free interest rate is based on the U.S. Treasury yield curve in effect on the date of grant. The dividend yield percentage is zero because the Company neither currently pays dividends nor intends to do so during the expected option term. The Company’s historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore the Company estimates the expected term by using the simplified method allowed by the SEC. Expected stock price volatility is based on an average of several peer public companies. For purposes of identifying peer companies, the Company considered characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. Upon the adoption of ASC 718, the Company was also required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that ultimately expect to vest. The Company performed a historical analysis of option awards that were forfeited prior to vesting and recorded total stock option expense that reflected this estimated forfeiture rate.

The following table summarizes the Company’s stock option activity:

<table>
<thead>
<tr>
<th></th>
<th>Number of Shares</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Contractual Term (in years)</th>
<th>Aggregate Intrinsic Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding as of December 31, 2013</td>
<td>1,957,069</td>
<td>$ 5.48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>967,903</td>
<td>$ 6.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(3,050)</td>
<td>$ 4.20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancelled</td>
<td>(74,825)</td>
<td>$ 4.94</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding as of December 31, 2014</td>
<td>2,847,097</td>
<td>$ 5.89</td>
<td>8.65</td>
<td>$ 11,796,921</td>
</tr>
<tr>
<td>Exercisable as of December 31, 2014</td>
<td>897,294</td>
<td>$ 5.04</td>
<td>7.54</td>
<td>$ 4,509,931</td>
</tr>
<tr>
<td>Vested and expected to vest as of December 31, 2014</td>
<td>2,716,363</td>
<td>$ 5.86</td>
<td>8.62</td>
<td>$ 11,255,225</td>
</tr>
</tbody>
</table>

The aggregate intrinsic value of stock options in the table above represents the difference between the $10.00 closing price of the Company’s common stock as of December 31, 2014 and the exercise price of outstanding, exercisable, and vested and expected to vest in-the-money stock options.

Included in amounts in the table above, the Company granted performance-based options to five executives to purchase a total of 160,500 shares of the Company’s common stock at an exercise price of $6.09 per share in July 2014. These options vest based on the successful completion of various performance requirements of each of the five executives at various times through December 31, 2018.

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The following table summarizes information about the Company’s stock options as of December 31, 2014:

<table>
<thead>
<tr>
<th>Exercise Price or Range of Exercise Price</th>
<th>Options Outstanding</th>
<th>Weighted Average Contractual Life (Years)</th>
<th>Options Exercisable</th>
</tr>
</thead>
<tbody>
<tr>
<td>$4.20</td>
<td>553,434</td>
<td>6.64</td>
<td>521,718</td>
</tr>
<tr>
<td>$5.82</td>
<td>1,219,689</td>
<td>8.85</td>
<td>333,785</td>
</tr>
<tr>
<td>$5.98 to $6.62</td>
<td>869,525</td>
<td>9.50</td>
<td>—</td>
</tr>
<tr>
<td>$7.32 to $11.09</td>
<td>203,172</td>
<td>9.10</td>
<td>40,514</td>
</tr>
<tr>
<td>$35.30 to $36.66</td>
<td>1,271</td>
<td>6.70</td>
<td>1,271</td>
</tr>
<tr>
<td>$35.78 to $4.615.92</td>
<td>6</td>
<td>0.83</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>2,847,097</td>
<td>8.65</td>
<td>897,294</td>
</tr>
</tbody>
</table>

As of December 31, 2014, the Company had a total of $8,944,203 in unrecognized compensation expense from nonvested stock option awards, of which $3,069,553 is expected to be recognized in 2015, $2,898,537 in 2016, $2,427,924 in 2017, and $548,189 in 2018.

13. Revenue and Concentration of Credit Risk

In September 2006, the Company entered into a multi-year research contract with NIH and NIAID to design, develop and clinically test an autologous HIV immunotherapy capable of eliciting therapeutic immune responses. The Company is using funds from this contract to develop AGS-004. Under this contract, as amended, the NIH and NIAID have committed to fund up to a total of $39.8 million, including reimbursement of direct expenses and allocated overhead and general and administrative expenses of up to $38.4 million and payment of other specified amounts totaling up to $1.4 million upon the Company’s achievement of specified development milestones. Since September 2010, the Company has received reimbursement of its allocated overhead and general and administrative expenses at provisional indirect cost rates equal to negotiated provisional indirect cost rates agreed to with the NIH and NIAID in September 2010. These provisional indirect cost rates are subject to adjustment based on the Company’s actual costs pursuant to the agreement with the NIH and NIAID. This commitment originally extended until May 2013. The Company agreed to an additional modification of the Company’s contract with the NIH and the NIAID under which the NIH and the NIAID agreed to increase their funding commitment to the Company by an additional $5.4 million in connection with the extension of the contract from May 2013 to September 2015. Additionally, a contract modification for a $0.5 million increase was agreed to by the NIH on September 18, 2014 to cover a portion of the manufacturing costs of the planned phase 2 clinical trial of AGS-004 for long-term viral control in pediatric patients. The NIH’s commitment under the contract extends to July 2016. The Company has agreed to a statement of work under the contract, and is obligated to furnish all the services, qualified personnel, material, equipment, and facilities, not otherwise provided by the U.S. government, needed to perform the statement of work.

For the years ended December 31, 2012, 2013 and 2014, the Company recorded revenue under this agreement of $7,032,760, $4,421,689 and $1,797,054, respectively. The Company has recorded total revenue of $36.8 million through December 31, 2014 under the NIH agreement. As of December 31, 2014, there was up to $3.0 million of potential revenue remaining to be earned under the agreement with the NIH. As of December 31, 2013 and 2014, the Company recorded a receivable from the NIH and NIAID of $424,501 and $129,019, respectively, and a payable to subcontractors of $27,925 and $8,493, respectively.

The Company’s grant revenue is earned under this contract with NIH and NIAID. The concentration of credit risk is equal to the outstanding accounts receivable and unbilled balances and such risk is subject to the credit worthiness of the NIH and NIAID. There have been no credit losses under this arrangement.


14. License Agreement

In July 2011, the Company entered into an agreement with Celldex Therapeutics, Inc. (“Celldex”), pursuant to which Celldex granted the Company a nonexclusive license to specified patents and patent applications regarding actions necessary or helpful for processing dendritic cells. Upon the execution of the agreement, the Company paid Celldex $50,000 of a $100,000 up front license fee. The Company paid the balance of this fee on January 31, 2012. Under this agreement, the Company is required to pay:

- a $75,000 annual license fee;
- a specified milestone payment based on the achievement of a specified regulatory milestone; and
- a specified dollar amount per dose of AGS-003 the Company sells.

The agreement will terminate on a country-by-country basis upon the expiration of the last to expire of the patent rights licensed under the agreement in a country. The latest date of expiration of the licensed Celldex patents is 2016.

15. Collaboration Agreements

Pharmstandard License Agreement

In August 2013, Pharmstandard, purchased shares of the Company’s series E preferred stock. Concurrently with such purchase, the Company entered into an exclusive royalty-bearing license agreement with Pharmstandard. Under this license agreement, the Company granted Pharmstandard and its affiliates a license, with the right to sublicense, to develop, manufacture and commercialize AGS-003 and other products for the treatment of human diseases, which are developed by Pharmstandard using the Company’s personalized immunotherapy platform, in the Russian Federation, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, which the Company refers to as the Pharmstandard Territory. The Company also provided Pharmstandard with a right of first negotiation for development and commercialization rights in the Pharmstandard Territory to specified additional products the Company may develop.

Under the terms of the license agreement, Pharmstandard licensed the Company rights to clinical data generated by Pharmstandard under the agreement and granted the Company an option to obtain an exclusive license outside of the Pharmstandard Territory to develop and commercialize improvements to the Company’s Arcelis technology generated by Pharmstandard under the agreement, a non-exclusive worldwide royalty-free license to Pharmstandard improvements to manufacture products using the Company’s Arcelis technology and a license to specified follow-on licensed products generated by Pharmstandard outside of the Pharmstandard Territory, each on terms to be negotiated upon the Company’s request for a license. In addition, Pharmstandard agreed to pay the Company pass-through royalties on net sales of all licensed products in the low single digits until it has generated a specified amount of aggregate net sales. Once the net sales threshold is achieved, Pharmstandard will pay the Company royalties on net sales of specified licensed products, including AGS-003, in the low double digits below 20%. These royalty obligations last until the later of the expiration of specified licensed patent rights in a country or the twelfth anniversary of the first commercial sale in such country on a country by country basis and no further royalties on specified other licensed products. Under this agreement, the Company may terminate the agreement if Pharmstandard challenges or assists a third party in challenging specified patent rights of ours. If Pharmstandard terminates the agreement upon the Company’s material breach or bankruptcy, Pharmstandard is entitled to terminate the Company’s licenses to improvements generated by Pharmstandard, upon which the Company may come to rely for the development and commercialization of AGS-003 and other licensed products outside of the Pharmstandard Territory, and to retain its licenses from the Company and to pay the Company substantially reduced royalty payments following such termination.

In November 2013, the Company entered into an agreement with Pharmstandard under which Pharmstandard purchased additional shares of the Company’s series E preferred stock. Under this agreement, the Company agreed to enter into a manufacturing rights agreement for the European market with Pharmstandard and that the manufacturing rights agreement would provide for the issuance of warrants to Pharmstandard to purchase 499,788 shares of the Company’s common stock at an exercise price of $5.82 per share. The Company has not entered into this manufacturing rights agreement or issued the warrants. On February 12, 2014, all outstanding shares of the Company’s preferred stock converted into shares of its common stock upon the closing of its initial public offering.

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Green Cross License Agreement

In July 2013, the Company entered into an exclusive royalty-bearing license agreement with Green Cross. Under this agreement the Company granted Green Cross a license to develop, manufacture and commercialize AGS-003 for mRCC in South Korea. The Company also provided Green Cross with a right of first negotiation for development and commercialization rights in South Korea to specified additional products the Company may develop.

Under the terms of the license, Green Cross has agreed to pay the Company $500,000 upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $500,000 upon the initial regulatory approval of a licensed product in South Korea and royalties ranging from the mid-single digits to low double digits below 20% on net sales until the fifteenth anniversary of the first commercial sale in South Korea. In addition, Green Cross has granted the Company an exclusive royalty free license to develop and commercialize all Green Cross improvements to the Company’s licensed intellectual property in the rest of the world, excluding South Korea, except that, as to such improvements for which Green Cross makes a significant financial investment and that generate significant commercial benefit in the rest of the world, the Company is required to negotiate in good faith a reasonable royalty that the Company will be obligated to pay to Green Cross for such license. Under the terms of the agreement, the Company is required to continue to develop and to use commercially reasonable efforts to obtain regulatory approval for AGS-003 in the United States.

The agreement will terminate upon expiration of the royalty term, which is 15 years from the first commercial sale, upon which all licenses will become fully paid up perpetual non-exclusive licenses. Either party may terminate the agreement for the other party’s uncured material breach or if specified conditions occur relating to the other party’s insolvency or bankruptcy and the Company may terminate the agreement if Green Cross challenges or assists a third party in challenging specified patent rights of ours. If Green Cross terminates the agreement upon the Company’s material breach or bankruptcy, Green Cross is entitled to terminate the Company’s licenses to improvements and retain its licenses from the Company and to pay the Company substantially reduced milestone and royalty payments following such termination.

Medinet License Agreement

In December 2013, the Company entered into a license agreement with Medinet. Under this agreement, the Company granted Medinet an exclusive, royalty-free license to manufacture in Japan AGS-003 and other products using the Company’s Arcelis technology solely for the purpose of the development and commercialization of AGS-003 and these other products for the treatment of mRCC. The Company refers to this license as the manufacturing license. In addition, under this agreement, the Company granted Medinet an option to acquire a nonexclusive, royalty-bearing license under the Company’s Arcelis technology to sell in Japan AGS-003 and other products for the treatment of mRCC. The Company refers to the option as the sale option and the license as the sale license.

Under the manufacturing license, if Medinet does not exercise the sale option, Medinet may only manufacture AGS-003 and these other products for the Company or its designee. If Medinet does not exercise the sale option, the Company and Medinet have agreed to negotiate in good faith a supply agreement under which Medinet would supply the Company or its designee with AGS-003 and these other products for development and sale for the treatment of mRCC in Japan. If Medinet exercises the sale option, it may only manufacture AGS-003 and these other products for itself, its related parties and its sublicensees. During the term of the manufacturing license, the Company may not manufacture AGS-003 or these other products for the Company or any designee for development or sale for the treatment of mRCC in Japan.

Medinet may exercise the option at any time until the earlier of December 31, 2015 and the date 30 days after the Company has provided Medinet with an interim report on the Company’s phase 3 clinical trial of AGS-003 following such time as 50% of the required events in the trial have occurred.

In consideration for the manufacturing license, Medinet paid the Company $1.0 million. Medinet also loaned the Company $9.0 million in connection with the Company entering into the agreement. The Company has agreed to use these funds in the development and manufacturing of AGS-003 and the other products. Medinet also agreed to pay the Company milestone payments of up to a total of $9.0 million upon the achievement of developmental and regulatory milestones and $5.0 million upon the achievement of a sales milestone related to AGS-003 and these products. If Medinet exercises the sale option, it will pay the Company $1.0 million, as well as royalties on net sales at a rate to be negotiated until the later of the expiration of the licensed patent rights in Japan and the twelfth anniversary of the first commercial sale in Japan. If the Company and Medinet cannot agree on the royalty rate, the Company and Medinet have agreed to submit the matter to arbitration.
In December 2013, in connection with the manufacturing license agreement with Medinet, the Company borrowed the $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0% per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the manufacturing license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. The Company has the right to prepay the loan at any time. If the Company has not repaid the loan by December 31, 2018, then the Company has agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 18, 2018 may constitute pre-paid royalties under the license or would be due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If the Company and Medinet cannot agree on the royalty rate, Company and Medinet have agreed to submit the matter to arbitration. The Company recorded the $1.0 million payment from Medinet as a deferred liability. In addition, because the $9.0 million promissory note was issued at a below market interest rate, the Company allocated the proceeds of the loan between the manufacturing license agreement and the debt at the time of issuance. Accordingly, as of December 31, 2013, the Company recorded $6.9 million to notes payable, based upon an effective interest rate of 8.0%, and $2.1 million as a deferred liability. As of December 31, 2014, the Company recorded $7.6 million to notes payable, including $0.7 million accrued interest recorded during the year ended December 31, 2014. The total deferred liability was $3.1 million as of December 31, 2014 including the $1.0 million received by the Company for the manufacturing license.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid up, perpetual non-exclusive licenses. Either party may terminate the agreement for the other party’s uncured material breach or if specified conditions occur relating to the other party’s insolvency or bankruptcy, and the Company may terminate the agreement if Medinet challenges or assists a third party in challenging specified patent rights of the Company. If Medinet terminates the agreement upon the Company’s material breach or bankruptcy, Medinet is entitled to terminate the Company’s licenses to improvements and retain its royalty-bearing licenses from the Company.

16. Facility Lease Obligation

On August 18, 2014, the Company entered into a Lease Agreement (the “Lease Agreement”) with TKC LXXII, LLC, a North Carolina limited liability company (“TKC”).

Under the Lease Agreement, the Company agreed to lease certain land and an approximately 120,000 square-foot building to be constructed on approximately 11 acres in Durham County, North Carolina. This facility will house the Company’s corporate headquarters and primary manufacturing facility. The Lease Agreement is intended to replace the Company’s existing lease, located at 4233 Technology Drive, Durham North Carolina, which currently expires in November 2016. The shell of the new facility will be constructed on a build-to-suit basis by TKC, at its expense, in accordance with agreed upon specifications and plans as set forth in the Lease Agreement.

The term of the Lease Agreement will be 10 years from the commencement date for the initial term, currently estimated to be May 1, 2015, with the Company having the option to extend the Lease Agreement by six five-year renewal terms. Initial rent will be approximately $46,917 per month, subject to certain fixed increases over the course of the term as set forth in the Lease Agreement and to adjustment based on the Company’s use of certain amounts allocated for upfitting the interior of the facility.

The Lease Agreement required us to provide the landlord with a letter of credit. We have provided the bank that issued the letter of credit on our behalf a security deposit of $1.325 million to guarantee the letter of credit. The deposit is recorded as a long-term investment as of December 31, 2014 on our consolidated balance sheet.
Under the Lease Agreement, the Company had an option to purchase the property for an amount estimated at $7.6 million. On February 16, 2015, the Company entered into a Purchase and Sale Agreement (the “Purchase Agreement”) with TKC which represented the Company’s exercise of its purchase option under the Lease Agreement. The purchase price to be paid by the Company is $7.6 million plus the amount of any additional costs incurred by TKC as a result of changes requested by the Company and the amount of any improvement allowances advanced to the Company by TKC prior to the closing. The Purchase Agreement is expected to close in the second half of 2015. Upon the closing, the Lease Agreement will terminate.

Under the Lease Agreement, the Company is deemed to be the owner of this facility during its construction period under build-to-suit lease accounting. The Company therefore recorded an asset related to the facility lease obligation included in property and equipment of $3.4 million during the year ended December 31, 2014. The facility lease obligation on the Company’s consolidated balance sheet is $3.4 million as of December 31, 2014.

If the Purchase Agreement is not executed, future minimum payments due under the Lease Agreement are as follows as of December 31, 2014:

<table>
<thead>
<tr>
<th>Year ending December 31:</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>375,333</td>
</tr>
<tr>
<td>2016</td>
<td>571,445</td>
</tr>
<tr>
<td>2017</td>
<td>584,303</td>
</tr>
<tr>
<td>2018</td>
<td>597,449</td>
</tr>
<tr>
<td>2019</td>
<td>610,892</td>
</tr>
<tr>
<td>Thereafter</td>
<td>3,496,201</td>
</tr>
<tr>
<td>Total future minimum lease payments</td>
<td>$ 6,235,623</td>
</tr>
</tbody>
</table>

17. Manufacturing Research and Development Obligation

On October 29, 2014, the Company entered into a development agreement (the “Invetech Development Agreement”) with Invetech Pty Ltd (“Invetech”). The Invetech Development Agreement supersedes and replaces the development agreement entered into by the parties as of July 20, 2005. Under the Invetech Development Agreement, Invetech will continue to develop and provide prototypes of the automated production system to be used for the manufacture of the Company’s Arcelis-based products, or the Production Systems. Development services will be performed on a proposal by proposal basis.

Invetech will defer 30% of its fees, but such deferral will not exceed $5,000,000. Deferred fees (plus interest of 7% per annum) would become payable either, at the Company’s option, in lump sum within 90 days of the “Sunset Date Trigger Event” or pursuant to an installment plan (either in four installments payable within the first year or eight installments payable within the first two years after the “Sunset Date Trigger Event”). The “Sunset Date Trigger Event” is June 30, 2016 if our current Phase 3 ADAPT clinical trial (the “Trial”) is closed early indicating positive efficacy; otherwise, December 31, 2016. Invetech is entitled to a 10% bonus payment if the Trial is closed early indicating positive efficacy and Invetech has timely completed all activities up to the time of such early closure.

As of December 31, 2014, the Company has recorded a long-term portion of this manufacturing research and development obligation on its consolidated balance sheet totaling $3.5 million representing $2.5 million in deferred fees, $0.9 million in estimated bonus payments and $34,330 in accrued interest.

The Invetech Development Agreement requires the parties to discuss in good faith Invetech’s supply of Production Systems for use in manufacturing commercial product. The Company has an obligation to purchase $25.0 million worth of Production Systems, components, subsystems and spare parts for commercial use. Once that obligation has been satisfied, the Company has the right to have a third party supply Production Systems for use in manufacturing commercial product provided that Invetech has a right of first refusal with respect to any offer by a third party and the Company may not accept an offer from a third party unless that offer is at a price that is less than that offered by Invetech and otherwise under substantially the same or better terms. The Company will own all intellectual property arising from the development services (with the exception of existing Invetech intellectual property incorporated therein-under which the Company will have a license). The Invetech Development Agreement will continue until the completion of the development of the Production Systems. The Invetech Development Agreement can be terminated early by either party because of a technical failure or by the Company without cause.
18. Commitments

The Company rents laboratory and office space and equipment under operating leases that expire in various years through 2017. Future minimum lease payments under noncancelable operating leases as of December 31, 2014 are as follows:

<table>
<thead>
<tr>
<th>Year</th>
<th>Minimum Lease Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>$394,089</td>
</tr>
<tr>
<td>2016</td>
<td>435,359</td>
</tr>
<tr>
<td>2017</td>
<td>79,688</td>
</tr>
<tr>
<td><strong>Total minimum lease payments</strong></td>
<td><strong>$909,136</strong></td>
</tr>
</tbody>
</table>

Rent expense related to operating leases for the years ended December 31, 2012, 2013 and 2014 was $361,356, $348,191 and $447,918, respectively.

The Company has entered into various licensing agreements with universities and other research institutions under which the Company receives substantially all rights of the inventors or co-assignee to produce and market technology protected by certain patents and patent applications. The Company also entered into various assignment agreements with a scientist under which the Company receives exclusive rights to produce and market technology protected by certain patents and patent applications.

The Company is generally required to make royalty payments ranging from 1% to 4% of future sales of products employing the technology or falling under claims of a patent. If future sales require the use of technology licensed from multiple different sources, the total royalty rates could be higher. As royalty payments are directly related to future sales volume, future commitments cannot be determined. No accrual for future payments under these agreements has been recorded, as the Company cannot estimate if, when or in what amount payments may become due.

In connection with the Loan and Security Agreement with two lending institutions in April 2007, the Company is required to pay a success fee of $200,000 upon consummation of a liquidity event, including an initial public offering. This was paid in March 2014 upon the successful completion of the Company’s initial public offering.

19. Employee Benefit Plan

The Company provides a retirement plan qualified under section 401(k) of the Internal Revenue Code of 1986, as amended (“IRC”). Participants may elect to contribute a portion of their annual compensation to the plan, after complying with certain limitations set by the IRC. All employees are eligible to participate in the plan after attaining the age of 21. The Company matched 25% of the first 6% contributed by eligible participants in the plan during the years ended December 31, 2012, 2013 and 2014, or $71,571, $101,700 and $121,399, respectively.

20. Net Loss Per Share

Basic and diluted net loss per common share was determined by dividing net loss attributable to common stockholders by the weighted average common shares outstanding during the period. The Company’s potentially dilutive shares, which include redeemable convertible preferred stock, common stock options and warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive.
The following table presents the computation of basic and diluted net loss per share of common stock:

<table>
<thead>
<tr>
<th>Year Ended December 31,</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$ (10,471,330)</td>
<td>$ (23,921,563)</td>
<td>$ (53,305,938)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock</td>
<td>(351,371)</td>
<td>(884,647)</td>
<td>(863,226)</td>
</tr>
<tr>
<td>Reverse prior accretion on redeemable preferred stock due to reduction in liquidation value of Series A, B, and C</td>
<td>—</td>
<td>5,657,638</td>
<td>—</td>
</tr>
<tr>
<td>Preferred stock dividend due to exchanges of preferred shares</td>
<td>—</td>
<td>(14,726,088)</td>
<td>—</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$ (10,822,701)</td>
<td>$ (33,874,660)</td>
<td>$ (54,169,164)</td>
</tr>
<tr>
<td>Weighted average common shares outstanding, basic and diluted</td>
<td>198,306</td>
<td>229,865</td>
<td>17,367,665</td>
</tr>
<tr>
<td>Net loss per share attributable to common stockholders, basic and diluted</td>
<td>$ (54.58)</td>
<td>$ (147.37)</td>
<td>$ (3.12)</td>
</tr>
</tbody>
</table>

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

<table>
<thead>
<tr>
<th>Year Ended December 31,</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redeemable convertible preferred stock</td>
<td>2,167,143</td>
<td>6,322,747</td>
<td>—</td>
</tr>
<tr>
<td>Stock options outstanding</td>
<td>366,389</td>
<td>767,510</td>
<td>2,847,097</td>
</tr>
<tr>
<td>Warrants outstanding</td>
<td>316,184</td>
<td>424,961</td>
<td>82,781</td>
</tr>
</tbody>
</table>
21. Selected Quarterly Data (unaudited)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$798,788</td>
<td>$473,163</td>
<td>$398,615</td>
<td>$303,453</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>8,472,195</td>
<td>10,569,134</td>
<td>12,998,409</td>
<td>13,459,178</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,933,476</td>
<td>1,865,822</td>
<td>2,320,036</td>
<td>2,480,025</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(9,606,883)</td>
<td>(11,961,793)</td>
<td>(14,919,830)</td>
<td>(15,635,750)</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>(394,097)</td>
<td>(21,738)</td>
<td>(181,187)</td>
<td>(584,660)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(10,000,980)</td>
<td>(11,983,531)</td>
<td>(15,101,017)</td>
<td>(16,220,410)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock</td>
<td>(863,226)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$ (10,864,206)</td>
<td>(11,983,531)</td>
<td>(15,101,017)</td>
<td>(16,220,410)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders per share, basic and diluted</td>
<td>$(1.05)</td>
<td>$(0.61)</td>
<td>$(0.77)</td>
<td>$(0.83)</td>
</tr>
<tr>
<td>Weighted average shares outstanding, basic and diluted</td>
<td>10,376,561</td>
<td>19,655,187</td>
<td>19,655,561</td>
<td>19,656,209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$1,461,687</td>
<td>$1,263,008</td>
<td>$981,247</td>
<td>$715,747</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>5,189,461</td>
<td>6,102,320</td>
<td>5,630,219</td>
<td>7,069,151</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,078,357</td>
<td>939,725</td>
<td>1,024,167</td>
<td>1,620,068</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(4,806,131)</td>
<td>(5,779,037)</td>
<td>(5,673,139)</td>
<td>(7,973,472)</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>356,929</td>
<td>196</td>
<td>541</td>
<td>(47,450)</td>
</tr>
<tr>
<td>Net loss</td>
<td>(4,449,202)</td>
<td>(5,778,841)</td>
<td>(5,672,598)</td>
<td>(8,020,922)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock</td>
<td>(64,940)</td>
<td>(10,446)</td>
<td>5,325,406</td>
<td>(477,029)</td>
</tr>
<tr>
<td>Less: Preferred stock dividend due to exchanges of preferred shares</td>
<td>—</td>
<td>—</td>
<td>(14,726,088)</td>
<td>—</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$ (4,514,142)</td>
<td>$ (5,789,287)</td>
<td>$ (15,073,280)</td>
<td>$ (8,497,951)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders per share, basic and diluted</td>
<td>$(19.91)</td>
<td>$(25.53)</td>
<td>$(65.23)</td>
<td>$(36.19)</td>
</tr>
<tr>
<td>Weighted average shares outstanding, basic and diluted</td>
<td>226,757</td>
<td>226,757</td>
<td>231,084</td>
<td>234,789</td>
</tr>
</tbody>
</table>
### Deferred Tax Asset Valuation Allowance

Information presented below is in thousands:

<table>
<thead>
<tr>
<th></th>
<th>Balance at Beginning of Year</th>
<th>Additions</th>
<th></th>
<th>Balance at End of Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Charged to Expenses</td>
<td>Charged to Other Accounts</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year Ended December 31, 2014</td>
<td>$47,945</td>
<td>$20,252</td>
<td></td>
<td>$68,197</td>
</tr>
<tr>
<td>Year Ended December 31, 2013</td>
<td>$39,134</td>
<td>$8,811</td>
<td></td>
<td>$47,945</td>
</tr>
<tr>
<td>Year Ended December 31, 2012</td>
<td>$36,515</td>
<td>$2,619</td>
<td></td>
<td>$39,134</td>
</tr>
</tbody>
</table>

(a) Impact of providing full valuation allowance against all deferred tax assets since the Company could not assert that it was more likely than not that these deferred tax assets would be realized.
This Development Agreement (the “Agreement”) is entered by and between SAINT-GOBAIN PERFORMANCE PLASTICS CORPORATION, a California corporation having an office at 1199 South Chillicothe Road, Aurora, OH 44202 (“SGPPL”), and ARGOS THERAPEUTICS, INC., a Delaware corporation having an office at 4233 Technology Drive, Durham, NC 27704 (“Argos”), as of the 5th day of January 2015 (the “Effective Date”). SGPPL and Argos are hereafter referred to collectively as the “Parties,” “Other Party,” or individually as a “Party”, as applicable.

WHEREAS

A. SGPPL specializes in the development, manufacture, sale, research, design, engineering, testing, and prototyping of products for life sciences and other industrial applications.

B. Argos specializes in the development of and commercialization of personalized immunotherapies for the treatment of cancer and infectious diseases.

C. Argos desires for SGPPL, and SGPPL is willing, to develop Products (defined in Section 1) for use in connection with Argos’ AGS-003 clinical stage therapeutic product candidate for the treatment of metastatic renal cell carcinoma and potentially other oncology applications.

D. In consideration of the Parties’ investment and time in developing the Products, SGPPL and Argos desire to enter into a Supply Agreement whereby SGPPL will serve as the exclusive manufacturer and supplier of the Products to Argos and its licensees for use in the Field of Application (defined in Section 1), which the Parties will negotiate in good faith as more fully set forth herein (the “Supply Agreement”).

E. Additionally, SGPPL and Argos desire to set forth intellectual property protections and each Party’s responsibilities, including certain cost allocations relating to the materials and equipment required for the Project (defined in Section 1).

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:

1. DEFINITIONS

1.1 “Affiliate” means, as to a Party or other entity, a company or other entity directly or indirectly Controlling, Controlled by or under common Control with such Party or other entity during the time such Control exists. For purposes of this definition, “Control,” “Controlling” or “Controlled” means the ability to determine the management policies of a company or other entity through ownership of a majority of shares, by control of the board of management, by agreement or otherwise.

1.2 “Agreement” means this Development Agreement and its exhibits.
1.3 “Arcelis Technology” means Argos’ Arcelis Personalized Immunotherapy Platform for the treatment of cancer, including but not limited to the technology described on Exhibit A attached hereto and the automated equipment, devices, tools, systems, methods and designs developed for Argos by Invetech Pty Ltd or its Affiliates (collectively, “Invetech”).

1.4 “Argos Results” means all Results related to dendritic cell treatments and vaccines for cancer and infectious diseases, including compositions and methods of manufacturing Arcelis Technology based products and all Results that rely on or necessarily incorporate Arcelis Technology and any related technology independently developed. For the avoidance of doubt, Argos Results shall include all Results that are not SGPPL Results.

1.5 “Background Information” means, as to either Party, any invention, whether or not patentable, invention disclosures, know-how, trade secrets, data, technical information, method, process, article of manufacture or composition of matter, or any improvement thereof (whether or not patentable) created, developed or owned by that Party or licensed to that Party by a third party prior to the Effective Date, or after the Effective Date but in such case outside the scope of the Results.

1.6 “Components” means individual parts that combine to form a Product. For example, Components include, but are not limited to injection molded parts, tubing assemblies, bags, sensors, filters, formulations, sterile welding/sealing techniques, connectors, retainers, manifolds, multi-lumen tubing, any assemblies to be designed thereof and any clean room assemblies, including packaging and RFID/bar coding.

1.7 “Field of Application” or “FOA” means for the treatment of metastatic renal cell carcinoma and other solid tumor applications.

1.8 “IP Rights” means all forms of intellectual property rights and protections including, without limitation, all right, title and interest (including license rights) in and to all (i) patents, patent applications, utility models, continuations, continuations-in-part (except for any claims therein that are supported only by new matter not otherwise subject to this Agreement), divisionals, reexaminations and reissues, and (ii) inventions and know-how.

1.9 “NDA” means the Confidential Disclosure Agreement entered by and between the Parties having an effective date of May 22, 2014.

1.10 “Products” means the disposable sets to be used for cellular and RNA automated processing developed in connection with the Project. The Parties understand that Products will include not only the specific Product in question, but any obvious and/or minor modifications of the Product in question.
1.11 “Project” means the joint development work to design, integrate and scale the production of the Products which are to be integrated with Arcelis Technology to manufacture cell-based immunotherapies using SGPPL manufacturing technology for use in the FOA.

1.12 “Project Plan” means the description, orientation and time framework of the Project, and the division of work between the Parties, described in Exhibit B.

1.13 “Results” means any invention, whether or not patentable, invention disclosures, know-how, trade secrets, data, technical information, method, process, article of manufacture or composition of matter, or any improvement thereof (whether or not patentable) that are acquired or invented by one or both of the Parties in the course of work under the Project. For the avoidance of doubt, Results shall not include any of the foregoing if first acquired or invented by Invetech.

1.14 “SGPPL Results” means all Results related to (i) Components in developing and producing disposable systems, including manufacturing processes thereof; (ii) the technology know-how related to fluid transfer assemblies and systems; (iii) testing capabilities and know-how and test results related thereto; and (iv) any related technology independently developed by SGPPL or its Affiliates. SGPPL Results shall exclude any Results related to Argos Results and any Results that incorporate Argos Background Information and/or Arcelis Technology.

1.15 “Technical Specifications” shall be jointly-agreed in writing. The Parties understand that the Technical Specifications will evolve during the course of the Project by jointly-agreed written modifications, based on an improved understanding of the requirements of the Project and manufacturing constraints.

2. PURPOSE OF THE AGREEMENT – PROJECT OBLIGATIONS

2.1 The purpose of this Agreement is to (i) set forth the terms and conditions under which the Parties will carry out the joint-development work necessary to develop the Products; (ii) provide for the ownership of the Results; and (iii) provide the basic principles for the Supply Agreement.

2.2 From the effective date until [**], SGPPL shall not knowingly carry out cell therapy-related automation projects with any third party for use in the treatment of Renal Cell Cancer (RCC) and neither SGPPL nor its Affiliates may knowingly commercialize disposable automated systems for the production of cell therapies for the treatment of RCC. During the Term, Argos will not enter into discussions or collaborations with any third parties for projects similar to the concept of the Project in the Field of Application and will work solely with SGPPL for the development and supply of disposable sets in the Field of Application.
3. COMMITMENTS AND COSTS

3.1 Tooling and Equipment. Except as otherwise agreed by the Parties in writing and as set forth in this Section 3.1, SGPPL will manufacture or purchase and own (a) all of the tooling required to produce Products, including all of the tooling listed on Exhibit C (the “Tooling”), (b) the specific equipment listed on Exhibit D (the “Listed Equipment”), and (c) all of the other equipment required to produce the Products. Notwithstanding the foregoing, Argos shall deliver to SGPPL, and, as between Argos and SGPPL, Argos shall continue to own, the tooling and equipment listed on Exhibit E (the “Argos Provided Tooling and Equipment”). SGPPL shall use the Argos Provided Tooling and Equipment solely for the performance of this Agreement. The Tooling, Listed Equipment and Argos Provided Tooling and Equipment are collectively referred to in this Agreement as the “Tooling and Equipment”. In the event the Parties fail to enter into a Supply Agreement, SGPPL shall deliver, at Argos’ sole cost and expense, the (a) Argos Provided Tooling and Equipment to Argos upon the termination of this Agreement or the expiration of the Term and (b) the Tooling and Listed Equipment at such time as Argos has paid all amounts due hereunder, including all deferred amounts and interest. SGPPL shall bear the risk of loss as to the Tooling and Equipment while it is in SGPPL’s possession. SGPPL shall be responsible for maintenance of the Tooling and Equipment while it is in SGPPL’s possession. In the event any or all of the Tooling and Equipment need to be refurbished or have reached the end of useful life, SGPPL will procure replacements or refurbish such Tooling and Equipment and will invoice Argos at cost for such refurbishment or replacement.

3.2 Transfer to Argos. At such time as Argos has paid all of the amounts due to SGPPL pursuant to Section 3.5, SGPPL will transfer, convey and assign ownership of the Listed Equipment and Tooling to Argos, free and clear of all liens, claims and encumbrances.

3.3 Facilities. SGPPL will provide the facilities needed to produce the Products.

3.4 Budget. Except as provided in the following sentence, a detailed budget for the development of the Products, including the cost of purchase of the Tooling and Listed Equipment, is attached as Exhibit F (the “Budget”). The Parties acknowledge that the Budget does not include the costs of the items not yet designed (the “Omitted Budget Items”) and agree to negotiate in good faith as to the costs of the Omitted Budget Items and, upon reaching a written agreement, each such cost will become part of the Budget. The Parties agree that Omitted Budget Items included any costs incurred to refurbish or replace any of the Tooling and Equipment. Notwithstanding the preceding sentence, SGPPL will not be required to incur any costs or expenses relating to any Omitted Budget Items until the Parties agree on such cost. SGPPL will not incur aggregate costs chargeable to Argos in connection with the Project beyond the amounts set forth in the Budget absent the prior written consent of Argos, which consent will not be unreasonably withheld or delayed (“Cost Increases”). Except as expressly provided in this Agreement, SGPPL will pay all costs relating to the development of the Products, including all amounts required to manufacture and/or purchase the Tooling and the Listed Equipment. The Budget shall not exceed $6,000,000 exclusive of the Omitted Budget Items without the prior written authorization of Argos.

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3.5 Payments by Argos. In exchange for SGPPL’s performance under this Agreement, Argos has paid and will pay fees to SGPPL as follows:

(a) $400,000 to SGPPL prior to the Effective Date, the receipt of which is acknowledged by SGPPL, which shall be credited toward the first invoice(s) under section 3.5(b);

(b) During the term, SGPPL shall invoice Argos, at a frequency not to exceed [*], for the expenses actually incurred in accordance with the Budget. Argos shall pay one-half of all invoiced amounts within [**] days of the date of each invoice with payment of the other one-half of such invoice deferred and paid pursuant to Section 3.5(c) or Section 3.5(d), as applicable. Notwithstanding the foregoing, SGPPL shall not be required to continue to incur expenses in excess of the Budget once the total amount deferred pursuant to the preceding sentence expenses reaches $3,000,000.

(c) The outstanding amount of the expenses actually incurred in accordance with the Budget, as amended pursuant to the written agreements of the Parties, and all interest which has accrued thereon pursuant to Section 3.5(f), will be paid by Argos to SGPPL on or before September 30, 2016.

(d) All amounts remaining due pursuant to Sections 3.5(b) and 3.5(c), including any accrued interest thereon, will become due on the date on which Argos, (i) from the Effective Date, raises additional capital in an aggregate amount exceeding $60,000,000, regardless of whether such additional capital is raised by the sale of shares of stock or other ownership interests, the sale of bonds or other debt instruments, borrowing or by other means and regardless of whether such amounts are raised in one or more transactions or (ii) is acquired or merged into a third party (in either case, a “Capital Transaction”), and will be paid by Argos to SGPPL within [**] days of the date of such Capital Transaction. Thereafter, Sections 3.5(b) and 3.5(c) shall be of no further force or effect and Argos will pay SGPPL for any additional amounts due pursuant to the Budget, as amended pursuant to the written agreements of the Parties, within [**] days of the date of invoice.
(e) Argos may prepay the amounts due under Sections 3.5(b) and (c), including any accrued interest thereon, in whole or in part at any time without penalty.

(f) All invoiced amounts for which payment is deferred pursuant to Section 3.5(b) will accrue interest until such amounts are paid at a rate equal to [**] percent per annum. Interest on the unpaid principal balance of this Note, from time to time outstanding, at the above rate, will be calculated on the basis of the actual number of days elapsed during a year consisting of 365 days or 366 days, as the case may be.

4. REPRESENTATIONS AND WARRANTIES.

4.1 Argos Representations. Argos represents and warrants that:

A. Argos (i) is, and will continue to be, organized and existing under the laws of its state of organization and qualified to conduct business in all jurisdictions where it conducts business; and (ii) has the right and authority to execute this Agreement;

B. Argos’s execution, delivery and performance of this Agreement do not conflict with, or create a default or require consent under, any agreement binding Argos or affecting any of its property; and

C. Argos shall perform the Project in accordance with all applicable laws, rules and regulations.

4.2 SGPPL Representations. SGPPL represents and warrants that:

A. SGPPL (i) is, and will continue to be, organized and existing under the laws of its state of organization and qualified to conduct business in all jurisdictions where it conducts business; and (ii) has the right and authority to execute this Agreement;

B. SGPPL’s execution, delivery and performance of this Agreement do not conflict with, or create a default or require consent under, any agreement binding SGPPL or affecting any of its property;

C. SGPPL shall perform the Project in accordance with all applicable laws, rules and regulations; and

D. SGPPL shall use commercially reasonable best efforts to ensure that the Products meet the Technical Specifications.

4.3 EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NONINFRINGEMENT.
5. **SUPPLY AGREEMENT**

5.1 **Negotiation of Supply Agreement**. The Parties will commence good faith negotiations of the Supply Agreement by [**].

5.2 **Terms of Supply Agreement**. The Supply Agreement will provide that:

A. SGPPL will be the exclusive supplier of Products in the Field of Application to Argos and its licensees for a period of not less than 15 years from the effective date of the Supply Agreement;

B. Argos will not compete with SGPPL in the manufacture, sale or distribution of products which are competitive with the Products during the term of the Supply Agreement except that Argos may sell the Products to its licensees;

C. During the term of the Supply Agreement, neither SGPPL nor its Affiliates will supply Products to any third party.

D. The prices charged to Argos and its licensees by SGPPL under the Supply Agreement will equal a specified gross margin over SGPPL’s reasonable documented cost of manufacture or acquisition of (i) [**] percent for Products and (ii) [**] percent for specified Components which are acquired but not manufactured by SGPPL. SGPPL may adjust the prices charged for the Products (but not the specified percentages of the gross margins) no more frequently than [**] period and will provide Argos with not less than [**] days prior written notice of any such price adjustment. At the request of Argos, a mutually agreeable third party auditor may audit SGPPL’s cost of manufacture to determine compliance with the price provisions of the Supply Agreement but shall only report to the accuracy of such pricing to Argos and SGPPL and will not disclose any of SGPPL’s costs or records to Argos.

E. SGPPL will meet Argos and its licensee’s requirements for Products, provided that such requirements are forecasted by Argos in good faith and in advance in writing to SGPPL such that SGPPL can use reasonable commercial efforts to ensure adequate manufacturing capacity. The parties will meet no less than [**] to discuss the forecasted requirements. SGPPL shall promptly notify Argos if SGPPL has reason to believe it cannot meet the forecasted requirements of Argos and its licensees. If SGPPL cannot meet the forecasted requirements for Products of Argos and its licensees for any reason, including without limitation during a force majeure, Argos and its licensees may purchase products competitive with the Products from third parties in quantities equal to the quantity which SGPPL is unable to supply. For this purpose, Argos may engage a third party supplier of Products and transfer all necessary Argos Provided Tooling, as well as Tooling and Listed Equipment owned by Argos in accordance with Section 3.2, to such third party so that such third party can supply in a timely manner Products that SGPPL is unable to supply; however, SGPPL shall not be required to transfer its trade secret information, which, for the sake of clarity, includes but is not limited to any inventions, ideas, know-how, whether or not patentable, or Background Information, to such third party unless otherwise agreed by SGPPL in its sole discretion.

Nothing in the Supply Agreement shall be construed as prohibiting Argos from purchasing the minimum required volume of Product for qualifying and maintaining such third party supplier during any period for which SGPPL cannot meet the forecasted requirements of Argos and its licensees.
6. **PROJECT MANAGEMENT**

6.1 **Project Managers.** Each Party will appoint one (1) individual within its staff as being responsible for the overall management of the Project (each a “Project Manager”). Each Party will be entitled to change its Project Manager at any time during the term of this Agreement upon [**] days prior written notice to the other Party as provided in Section 11.4 below.

6.2 **Duties of Project Managers.** The Project Managers will (a) monitor the progress of the Project and may agree to convene meetings from time to time upon reasonable prior written notice, in a place agreed by both Parties or by conference call; and (b) define and agree on proposed modifications and extensions to the Project for written approval by the Parties. For the avoidance of doubt, the Project Managers may not amend any portion of this Agreement.

6.3 **Reports of Decisions.** Either Project Manager may make a written record of the decisions taken and send it to the other Project Manager without delay by electronic mail. If there is no written objection sent via electronic mail by the other Project Manager regarding the content of the written record within [**] working days of its receipt, the content of the written record will be deemed approved by the other Party.

6.4 **Periodic Reporting.** At the end of each phase of the Project, the Parties will make a written report.

7. **INTELLECTUAL PROPERTY OWNERSHIP**

7.1 **Background Information.** Each Party retains ownership (or license rights, as the case may be) of its respective Background Information and of any IP Rights in and to its Background Information. Except as otherwise expressly provided herein, nothing in this Agreement will be construed as granting or conferring any rights by license or otherwise or as an assignment of a Party’s Background Information and/or IP Rights in and to that Party’s Background Information to the other Party.
7.2 **Argos Results**. All Argos Results and all IP Rights in and to the Argos Results will be the property of Argos. Argos will be entitled to seek and maintain all IP Rights in the Argos Results at its own expense.

SGPPL hereby irrevocably agrees that Argos is the sole and exclusive owner of all its right, title and interest in any Argos Results, including but not limited to, all IP Rights in and to the Argos Results. SGPPL agrees to execute such other documents or take such other actions as Argos may reasonably request to perfect Argos’s ownership of any such Argos Results.

SGPPL irrevocably (i) agrees to assign and transfer, and does hereby assign and transfer, to Argos any rights, title and interest in any Argos Results and (ii) undertakes and guarantees to obtain from its employees that may be involved in the development of the Argos Results, assignment of their IP Rights in and to the Argos Results so as to perfect Argos’s rights, at no cost for Argos.

SGPPL will have no rights or interests in any Argos Results except as may be otherwise agreed in writing by the Parties.

7.3 **SGPPL Results**. All SGPPL Results and all IP Rights in and to the SGPPL Results will be the property of SGPPL. SGPPL will be entitled to seek and maintain all IP Rights in the SGPPL Results at its own expense.

Argos hereby irrevocably agrees that SGPPL is the sole and exclusive owner of all its right, title and interest in any SGPPL Results, including but not limited to, all IP Rights in and to the SGPPL Results. Argos agrees to execute such other documents or take such other actions as SGPPL may reasonably request to perfect SGPPL’s ownership of any such SGPPL Results.

Argos irrevocably (i) agrees to assign and transfer, and does hereby assign and transfer, to SGPPL any rights, title and interest in any SGPPL Results and (ii) undertakes and guarantees to obtain from its employees that may be involved in the development of the SGPPL Results, assignment of their IP Rights in and to the SGPPL Results so as to perfect the SGPPL’s rights, at no cost for SGPPL.

Argos will have no rights or interests in any SGPPL Results except as may be otherwise agreed in writing by the Parties.

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8. **CONFIDENTIALITY**

8.1 Confidentiality

8.1.1 For the purposes of this Article 8.1, the terms with the first letter in capitals will, as applicable, have the meaning ascribed to such terms under the NDA.

8.1.2 The Parties agree that the terms and conditions of the NDA are incorporated by reference into this Agreement for the time period specified under Article 8.1.4 below. In the event of conflict between the NDA and the terms and conditions set forth in this Article 8, this Article 8 will control.

8.1.3 The Receiving Party will: (a) hold the Disclosing Party’s Confidential Information to itself and restrict access thereto to such of its employees who need to know it for the purpose of its performance under this Agreement, (b) not use Confidential Information disclosed to it pursuant to the Agreement for any purpose other than for its performance under this Agreement, and (c) not disclose any Confidential Information disclosed to it pursuant to the Agreement to any third party, other than to legal and financial advisors and investors and potential investors of the Receiving Party who are bound by confidentiality, nondisclosure and nonuse obligations substantially similar to those set forth herein, without the Disclosing Party’s prior consent in writing therefore. The Receiving Party will use at least as great a standard of care in protecting the Confidential Information of the Disclosing Party as it uses to protect its own Confidential Information of like character but not less than a reasonable degree of care. Notwithstanding the foregoing, a Receiving Party is permitted to disseminate Confidential Information to employees of any of its Affiliates, on a need to know basis, for the purpose of the Receiving Party’s performance under this Agreement, provided such employees are made fully aware of the obligation of confidentiality and restricted use contained in this Agreement and are bound by confidentiality, nondisclosure and restricted use obligations substantially equivalent to, and in any event ensuring the same protection as, those set forth in this Agreement.

(d) When the Receiving Party is provided with samples or prototypes of the Disclosing Party’s products, such receipt is exclusively for testing to the exclusion of commercial use or sale. The purpose of such testing is to determine the suitability of the Disclosing Party concerned products for future use as part of the Receiving Party’s requirements. The Receiving Party agrees that it will neither take nor permit any action (sample and prototypes analysis, disclosure of evaluation data, disclosure of written or oral information, use or sale) that would jeopardize the Disclosing Party’s intellectual property rights in any country. The Parties further agree that no samples or portions thereof of the Products or any data or know-how pertaining to such Products will be provided by the Receiving Party to any third parties.
8.1.4 Unless otherwise agreed in writing by the Parties or as provided in the following sentence, and subject to the terms of the NDA, each Party undertakes to adhere to the obligations of Article 8.1.3, and to keep the terms and conditions of this Agreement strictly confidential, for the period the Agreement is in force and for a further period of [**] years following the expiration or termination of this Agreement and the Supply Agreement. However, the obligation of confidentiality, nondisclosure and nonuse shall not expire with respect to trade secrets, provided such trade secrets are disclosed in (a) a form suitable for marking (e.g., written, sample, electronic) and conspicuously marked “TRADE SECRET” or (b) another form, noted at the time of disclosure to be a trade secret, and confirmed as such in writing by the Disclosing Party to the Receiving Party within [**] days. Notwithstanding the preceding sentence and the terms of the NDA, either Party may disclose Confidential Information in accordance with section 8.1.6 and issue press releases and otherwise market that the Parties have entered into an arrangement whereby SGPPL will be the exclusive developer of Products for Argos but shall not disclose the commercial terms of such arrangements other than the length of same. Any such press releases require the prior approval of both Parties, which shall not be unreasonably withheld or delayed.

8.1.5 Both Parties agree that, the following information shall be deemed to be included in the Confidential Information of the applicable Party:

(a) Testing capabilities, test results, and the conditions related thereto developed by SGPPL, including but not limited to the price models and prices, is the proprietary information of SGPPL and will be treated as Confidential Information subject to the provisions of paragraphs 8.1.1 to 8.1.4 hereinabove.

(b) All information related to the Arcelis Technology and Argos’ programs related thereto are proprietary information of Argos and will be treated as Confidential Information subject to the provisions of paragraphs 8.1.1 to 8.1.4 hereinabove.

(c) The cellular automation equipment and the related tools, designs and methods developed by Invetech on behalf of Argos are Argos’ TRADE SECRET.

8.1.6 If a Party is required by law or the requirements of a securities exchange upon which such Party is listed to disclose any Confidential Information of the Other Party to a third person (including, but not limited to, government), that Party before doing so must use its best efforts to:

(a) notify the Other Party; and

(b) give the Other Party a reasonable opportunity to take any steps that the Other Party considers necessary to protect the confidentiality of that information and provide reasonable assistance so that the Other Party may take such steps; and

(c) notify the third person that the information is Confidential Information of the Other Party.
9. **TERM AND TERMINATION**

9.1 **Term.** This Agreement will commence on the Effective Date and will remain in force until December 31, 2016 unless prior to such date the term of this Agreement is (a) mutually extended or terminated by written agreement of the Parties or (b) terminated pursuant to the provisions of Section 9.3 (the “Term”). Notwithstanding the foregoing sentence, this Agreement will automatically terminate on December 31, 2015, unless the Parties (y) have entered into the Supply Agreement by such date or (z) mutually agree in writing to waive such automatic termination.

9.2 **Events of Default.** A Party will be in default under this Agreement if such Party (each a “Default”):

A. fails to perform or observe any material covenant or agreement made in this Agreement or any other agreement between the Parties;

B. fails to achieve any of its material Performance Milestones as defined, and by the date provided, in Exhibit B where as such fault is not attributable to the other Party;

C. any representation or warranty made by such Party in this Agreement or in any other agreement between the Parties is untrue or incorrect in any material respect when made; or

D. commences or becomes the subject of any bankruptcy or insolvency proceeding, including making an assignment for the benefit of creditors, allowing the entry against it of a judgment, decree or order for relief by a court in an involuntary case commenced under any bankruptcy or insolvency law (which involuntary case is not dismissed within 30 days of filing) or the appointment of a receiver, trustee, or similar official for any of its assets, or has a final judgment entered against it.

9.3 **Remedies.**

A. Upon the occurrence of a Default, the Party which has not committed the Default may send written notice of its intent to terminate this Agreement to the Party in Default and this Agreement will terminate without further action by either Party if such Default is not cured on or before the [**] day following the date of such notice, except that a Party may terminate this Agreement immediately upon written notice following a Default by the other Party pursuant to Section 9.2.D above. Upon the termination of this Agreement following a Default, the non-defaulting Party may pursue any remedies available hereunder or pursuant to applicable law.

B. Neither Party shall be liable under this Agreement for any consequential, indirect, remote, speculative, special, incidental, punitive or exemplary damages under any theory, arising out of activities or obligations under or related to this Agreement, regardless of the acts, omissions, negligence or fault of any person or entity.
9.4 *Argos Change of Control*. In the event Argos undergoes a change of control, other than as a consequence of an equity investment by a venture capital or other financial institution, the Parties will meet in order to discuss whether they will continue this Agreement. This Agreement will continue in effect unless and until the Parties otherwise mutually agree in writing.

9.5 *Survival*. The provisions of Articles 4, 7, 8, 9.5, 10 and 11 will survive the expiration or earlier termination of this Agreement for any reason and will remain in full force and effect until the duties recited therein expire according to their terms or are specifically terminated by mutual written agreement of the Parties. Additionally, the expiration or earlier termination of this Agreement will not relieve Argos of its obligation to pay any and all amounts which are owed to SGPPL under Article 3.

10. **APPLICABLE LAW – DISPUTE RESOLUTION**

10.1 *Governing Law*. This Agreement will be governed and construed in accordance with the laws of New York to the exclusion of its conflict of law provisions.

10.2 *Discussion and Arbitration*. Both Parties shall use reasonable commercial efforts to resolve any dispute, controversy or claim arising in connection with this Agreement (a “Dispute”). Except with respect to seeking injunctive relief or specific performance in connection with a Party’s obligations regarding protection of Confidential Information or intellectual property or disputes involving third parties, any Dispute initiated by either Party arising out of or relating to this Agreement, its negotiations, execution or interpretation, or the performance by either Party of its obligations under this Agreement, whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party decides to institute arbitration proceedings, it shall give prompt written notice to that effect to the other Party. Any such arbitration shall be conducted pursuant to the prevailing rules of the American Arbitration Association pursuant to the Commercial Arbitration Rule. Any such arbitration shall be held in New York City, New York. Such arbitration shall be conducted by a single arbitrator and the arbitrator shall be either mutually acceptable or, if the Parties cannot agree on an arbitrator within [**] days after the matter is referred to arbitration, the single arbitrator shall be a person selected by the applicable rules. The arbitrator shall be a person knowledgeable as to the subject matter of this Agreement who is not employed by, or has a financial relationship with, either Party or any of their respective Affiliates. The arbitration award rendered pursuant to this provision shall be enforceable by any court having jurisdiction. Unless otherwise provided for in the arbitral award, each Party shall be responsible for its own attorneys’ fees and costs incurred in connection with the arbitration. Unless otherwise determined by the arbitrator, each Party shall pay an equal share of the fees and costs of the arbitrator.
11. MISCELLANEOUS PROVISIONS

11.1 Amendment. No amendment to this Agreement will be binding upon the Parties unless such amendment is reduced to writing and executed by both Parties.

11.2 Assignment. Neither Party will be entitled to assign or transfer this Agreement or any rights and obligations arising hereunder to any third party without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

11.3 Entire Agreement. This Agreement constitutes the entire understanding between the Parties as to the subject matter hereof and supersedes all prior agreements and understandings whether written or oral between the Parties in relation to its subject matter. The Exhibits are integral part of this Agreement. In case of discrepancy between any of the Exhibits and the provisions of the main body of this Agreement, the latter will prevail.

11.4 Notices. Notices, requests and other communications relating to this Agreement will be in writing (including telecopy, email, or similar writing) and will be given:
If to Argos:
Argos Therapeutics, Inc.
4233 Technology Drive
Durham, NC 27704
Attention: President
Facsimile: (919) 287-6336
Email: jabbey@argostherapeutics.com

If to SGPPL:
Mr. Benjamin Le Quere
Saint-Gobain Performance Plastics Corporation
1199 S. Chillicothe Rd.
Aurora, OH 44202
Phone: (216) 539-4385
Fax: (314) 762-4750
Email: benjamin.lequere@saint-gobain.com

or to such other street or email address or telecopy number and with such other copies, as such Party may hereafter specify in writing for the purpose by notice to the other Parties. Each such notice, request or other communication will be effective (i) if given by telecopy, when such telecopy is transmitted to the telecopy number specified in this Article 11.4 and evidence of receipt is received or (ii) if given by any other means upon delivery or refusal of delivery at the street or email address specified in this Article 11.4.

11.5 Headings. The headings of this Agreement will be for reference purposes only and will not affect the meaning of any provision under the heading.

11.6 No waiver. No delay in or failure to exercise of any right under this Agreement by a Party will impair such right or be construed as a waiver or continuing waiver of such right or acquiescence in any default or preclude any subsequent exercise of such right. No right or Default under this Agreement will be deemed to have been definitely waived by either Party unless such waiver is expressed in writing and signed by such Party in which event such waiver will be effective only in the specified instance and for the specific purpose for which it is given.

11.7 Usury Laws. The Parties, intending to comply with applicable usury laws, agree that notwithstanding any contrary term in this Agreement or in any related agreement, no term will require the payment or permit the collection of interest in excess of the maximum permitted by applicable law. If excessive interest is provided for, then: (a) this paragraph will govern and control; (b) neither Argos nor its successors or assigns will be obligated to pay interest to the extent it exceeds the maximum amount permitted by applicable law; (c) any excess interest that may be collected will, at the option of the party to which such obligation is due, be either applied as a credit against the unpaid principal amount of the obligations or refunded to Argos; and (d) the effective rate of interest will be automatically reduced to the maximum amount permitted by applicable usury laws.
11.8 **Cumulative Remedies**. The rights and remedies provided in this Agreement are cumulative and in addition to, and not exclusive or in substitution, novation or discharge of, any rights or remedies provided by law or any other agreement between the Parties.

11.9 **Costs and Expenses**. Each Party will bear its own costs and expenses in carrying out the Project, unless stipulated otherwise in accordance with this Agreement. Neither Party will incur any legal obligation as to any supplemental or follow-up agreements, whether or not contemplated hereunder, unless and until such agreements have been finalized and signed on behalf of both Parties.

11.10 **Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document.

[Rest of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in duplicate by their respective duly authorized representatives on the dates written hereunder.

Date: 1-5-15

SAINT-GOBAIN PERFORMANCE PLASTICS CORPORATION

/s/ Stephen E. Maddox
Name: Stephen E. Maddox
Title: General Manager, Life Sciences

Date: 1-5-15

ARGOS THERAPEUTICS, INC.

/s/ Jeffrey D. Abbey
Name: Jeffrey D. Abbey
Title: Chief Executive Officer

17/25
Arcelis is Argos’ proprietary active immunotherapy technology platform for generating fully personalized RNA-loaded dendritic cell immunotherapies. Argos uses the Arcelis platform to manufacture AGS-003, which is initially being developed for the treatment of mRCC, and AGS-004, which is being developed for the treatment of HIV.

The Arcelis platform is focused on dendritic cells that present antigens to the attention of the immune system and are critical to the human immune system’s recognition of the presence of proteins derived from cancer cells or virus-infected cells. Dendritic cells are capable of internalizing cancer protein antigens or virus protein antigens and displaying fragments of these protein antigens on their surface as small peptides. The dendritic cells then present these peptide antigens to T-cells capable of binding to these peptide antigens and producing a large complement of molecular factors that, in the case of cancer, lead to direct cancer cell death and, in the case of infectious disease, kill virus-infected cells to control the spread of infectious pathogens.

The following graphic illustrates the processes comprising our Arcelis platform:

As shown in the graphic above, the Arcelis platform requires two components derived from the particular patient to be treated, specifically:

- a disease sample from the patient — tumor cells in the case of cancer or a blood sample containing virus in the case of infectious disease — which is generally collected at the time of diagnosis or initial treatment, and
- dendritic cells derived from the patient’s monocytes, a particular type of white blood cell, which are obtained from the patient through a laboratory procedure called leukapheresis that occurs after diagnosis and at least four weeks prior to the initiation of our immunotherapy.
The tumor cells, or the blood sample containing the virus, and the leukapheresis product are shipped separately following collection from the clinical site to a centralized manufacturing facility where we use standard methods to isolate the patient’s mRNA, which is a key component of the genetic code, from the disease sample and amplify the mRNA. In parallel, we take the monocytes from the leukapheresis product and culture them using a proprietary process to create mature dendritic cells. Argos then immerses the mature dendritic cells in a solution of the patient’s isolated mRNA and a synthetic RNA that encodes a protein known as CD40 ligand, or CD40L, and apply a brief electric pulse to the solution, in a process referred to as electroporation. This process enables the patient’s isolated mRNA and the CD40L protein to pass into, or load, the dendritic cells. Argos then further cultures the mRNA-loaded dendritic cells so that these cells allow for antigen expression from the patient’s mRNA and presentation in the form of peptides on the surface of the dendritic cells. These mature, loaded dendritic cells are formulated into the patient’s plasma that was collected during the leukapheresis to become the Arcelis-based drug product. Argos then vials, freezes and ships the drug product to the clinic, which thaws the drug product and administers it to the patient by intradermal injection.

Upon injection into the skin of the patient, the antigen-loaded dendritic cells in the drug product migrate to the lymph nodes near the site of the injection. It is at these lymph nodes that the drug product comes into contact with T-cells. Argos believes that through this interaction the loaded dendritic cells orchestrate the differentiation, expansion and education, of antigen-specific T-cells. A unique property of the dendritic cells is that they result in the generation of CD8+ central and effector memory T-cells. Once activated and expanded, these T-cells are able to seek out and kill cancer or virus-infected cells that express the identical antigens as those displayed on the surface of the dendritic cells. Because the generation of these T-cells is dependent on secretion of IL-12 from the dendritic cells, measurement of IL-12 is a marker for potency of AGS-003 and potentially other Arcelis-based products.
Saint-Gobain is responsible for providing to Argos fully sterilized, packaged, tested and assembled product in support of the Project (i.e., the Steinman) program per the design requirements and specifications provided by Invetech and approved by Argos. Argos is responsible for providing to Saint-Gobain the proper guidance on quality and testing requirements, sterilization validation, Rnase, RNA, Dnase, DNA, Pyrogen and Endotoxin-free certification.

**Key milestones and indicative dates for project:**

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1 In these Exhibits, the term “Saint-Gobain” is used instead of SGPPL to refer to Saint-Gobain Performance Plastics Corporation.
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23/25
### Exhibit E
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NOVATED, AMENDED AND RESTATED LICENSE AGREEMENT

by and between

ARGOS THERAPEUTICS, INC.,

MEDINET CO., LTD.

and

MEDCELL CO., LTD.
NOVATED, AMENDED AND RESTATED LICENSE AGREEMENT

THIS NOVATED, AMENDED AND RESTATED LICENSE AGREEMENT (the “Agreement”), effective as of October 1, 2014 (the “Effective Date”), is by and between Argos Therapeutics, Inc., a corporation organized and existing under the laws of Delaware (“Argos”), Medinet Co., Ltd., a corporation organized and existing under the laws of Japan (“Medinet”) and MEDcell Co., Ltd., a corporation organized and existing under the laws of Japan.

RECITALS:

WHEREAS, Medinet has established MEDcell as a wholly-owned subsidiary on December 9, 2013 to develop, manufacture, sell, import and export cell therapeutics products and Medinet will focus primarily on cell processing as a contract manufacturing organization;

WHEREAS, Argos and Medinet entered into a License Agreement effective as of December 27, 2013 as amended or supplemented (the “Original License Agreement”);

WHEREAS, in order to reflect the different functions of Medinet and MEDcell, Argos, Medinet and MEDcell have agreed to novate, amend and restate the Original License Agreement as provided herein;

WHEREAS, Argos controls a proprietary immunotherapy system referred to as “Arcelis®” for the production of personalized therapeutic products for the treatment of cancer and infectious disease;

WHEREAS, Argos is developing a proprietary therapeutic product referred to as “AGS-003” based on the Arcelis® system targeting the treatment of metastatic renal cell carcinoma (“mRCC”), including through the conduct of a Phase III clinical study sponsored by Argos and referred to as “ADAPT”;

WHEREAS, MEDcell desires to develop and manufacture the AGS-003 product for the treatment of mRCC in Japan;

WHEREAS, MEDcell desires an option to commercialize the AGS-003 products for the treatment of mRCC as set forth in this Agreement in Japan;

WHEREAS, Medinet as a contract manufacturing organization desires to manufacture the AGS-003 products for the treatment of mRCC in Japan for MEDcell.

WHEREAS, the parties desire for MEDcell to loan Argos funds in order to enable Argos to accelerate the development of the product based on Arcelis® system; and

WHEREAS, Argos, Medinet and MEDcell believe that a license, option and loan for such purposes on the terms and conditions of this Agreement would be desirable.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:
1. DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 “Affiliate” means a corporation or non-corporate business entity that, directly or indirectly, controls, is controlled by, or is under common control with the Person specified, for so long as such control continues. An entity will be regarded as in control of another entity if: (a) it owns, directly or indirectly, at least 50% of the voting securities or capital stock of such entity, or has other comparable ownership interest with respect to any entity other than a corporation; or (b) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.

1.2 “Argos Indemnitees” has the meaning set forth in Section 12.5.1.

1.3 “Argos In-License” means an agreement between Argos and a Third Party pursuant to which Argos has rights and obligations with respect to, or which otherwise Cover, the Licensed Product and is necessary to Develop, Commercialize and/or Manufacture the Licensed Product in the Field in the Territory.

1.4 “Argos Know-How” means Know-How Controlled by Argos during the Term that is reasonably necessary or useful for MEDcell and its Related Parties to perform their obligations or exploit their rights under this Agreement with respect to products incorporating Argos’ Arcelis Personalized Immunotherapy Platform for the treatment of tumors or pathogen infection, as such platform is more particularly described on Schedule A attached hereto. For the avoidance of doubt, Argos Know-How shall not include Know-How associated with or relating to Automated Systems, dendritic cell transfected with IL4 RNA for the treatment of unwanted autoimmune responses, anti-interferon alpha antibodies, soluble CD83 or regulatory T cells.

1.5 “Argos Patent Rights” means those Patent Rights Controlled by Argos during the Term that relate to Argos’ Arcelis Personalized Immunotherapy Platform for the treatment of tumors and that are reasonably necessary or useful for MEDcell and its Related Parties to perform their obligations or exploit their rights under this Agreement with respect to the Licensed Product in the Field in the Territory, including without limitation, the Patent Rights set forth in Schedule B of this Agreement. For the avoidance of doubt, Argos Patent Rights shall not include patent rights associated with or relating to dendritic cell transfected with IL4 RNA for the treatment of unwanted autoimmune responses, anti-interferon alpha antibodies, soluble CD83 or regulatory T cells.


1.7 “Argos Trademark” has the meaning set forth in Section 13.8.2.

1.8 “Automated Systems” means the automated cellular and RNA systems used from time to time to Manufacture Licensed Product, as such systems are generally described in Schedule C attached hereto.

1.9 “Bankrupt Party” has the meaning set forth in Section 14.2.3(c).
1.10  “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of the Term shall end on the last day of the Term, and (b) the first Calendar Quarter of a Royalty Term for the Licensed Product shall begin on the First Commercial Sale of the Licensed Product and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of a Royalty Term shall end on the last day of such Royalty Term.

1.11  “Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term, and (b) the first Calendar Year of a Royalty Term for the Licensed Product shall begin on the First Commercial Sale of the Licensed Product and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of such Royalty Term.

1.12  “CMO License” has the meaning set forth in Section 2.1.

1.13  “Code” has the meaning set forth in Section 14.2.3(c).

1.14  “Commercialization” or “Commercialize” means any and all activities directed to Developing, marketing, promoting, distributing, importing, exporting, offering to sell and/or selling the Licensed Product, including the activities directed to obtaining pricing and reimbursement approvals, as applicable.

1.15  “Commercialization License” has the meaning set forth in Section 3.2.

1.16  “Commercialization Plan” has the meaning set forth in Section 10.3.

1.17  “Commercially Reasonable Efforts” means the carrying out of obligations in a diligent and sustained manner using such effort and employing such resources as would normally be exerted or employed by a similarly situated pharmaceutical company for a product of similar market or profit potential or strategic value at a similar stage of its product life.

1.18  “Commitment Fee” has the meaning set forth in Section 9.1.

1.19  “Conditional Regulatory Approval” means the granting of Regulatory Approval of the Licensed Product for the Field in the Territory that requires the holder of such Regulatory Approval to conduct more safety and/or efficacy studies after the initial marketing of the Licensed Product.

1.20  “Confidential Information” means any and all information and data, including without limitation all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial, trade secret and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement. Argos Technology is Confidential Information of Argos. MEDcell Improvements are Confidential Information of MEDcell. Joint IP is the Confidential Information of Argos and MEDcell.
1.21 “Control”, “Controls” or “Controlled by” means, with respect to any (a) material, Know-How or other information or (b) intellectual property right, the possession of (whether by ownership or license, other than pursuant to this Agreement), or the ability of a Party or its Affiliates to assign, transfer, grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to assign, transfer or grant the other Party such access or license or sublicense.

1.22 “Cover,” “Covering” or “Covers” means that in the absence of a license granted under a Valid Claim, the Development, Manufacture or Commercialization of the Licensed Product would or is reasonably likely to infringe such Valid Claim.

1.23 “Current Medinet Facility” means Medinet’s operating facility located at Shin-yokohama, Osaka, Fukuoka, and Tokyo Univ.

1.24 “Data” means all manufacturing, non-clinical and clinical data related to the Licensed Product in the Field.

1.25 “Development,” “Developing” or “Develop” means the research and development activities related to the generation, characterization, optimization, construction, expression, use production, seeking Regulatory Approval of the Licensed Product, any other research and development activities related to the pre-clinical testing and qualification of the Licensed Product for clinical testing, and such other tests, studies and activities as may be required or recommended from time to time by any Regulatory Authority to obtain Regulatory Approval of the Licensed Product, including toxicology studies, statistical analysis and report writing, pre-clinical testing, clinical studies and regulatory affairs, product approval and registration activities.

1.26 “Dispute” has the meaning set forth in Section 15.11.1.

1.27 “Effective Date” has the meaning set forth in the preamble.

1.28 “Excluded Claim” has the meaning set forth in Section 15.11.1.

1.29 “Field” means the treatment of mRCC using dendritic cells loaded with RNA encoding Uncharacterized Antigens.

1.30 “First Commercial Sale” means, with respect to the Licensed Product, the first sale for end use or consumption of such Licensed Product after all required Regulatory Approvals have been granted by the Regulatory Authority.

1.31 “GAAP” means generally accepted accounting principles in the United States, or internationally, as appropriate, consistently applied.

1.32 “ICC” has the meaning set forth in Section 15.11.1.
1.33 “IND” means an Investigational New Drug application, Clinical Trial Application or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.34 “Indemnitee” has the meaning set forth in Section 12.5.4.

1.35 “Infringement Claim” has the meaning set forth in Section 13.5.1.

1.36 “In-Licenses” means, collectively, the Argos In-Licenses and the MEDcell In-Licenses.

1.37 “Joint IP” has the meaning set forth in Section 13.2.

1.38 “Know-How” means all biological materials and other tangible materials, inventions, practices, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, assays, skills, experience, techniques and results of experimentation and testing, including without limitation pharmacological, toxicological and pre-clinical and clinical test data and stability, analytical and quality control data, patentable or otherwise.

1.39 “Knowledge,” with respect to a Party, means the actual knowledge of any of the executive officers of such Party.

1.40 “Licensed Product” means any product developed, manufactured or sold utilizing the Argos Technology.

1.41 “Licensed Product Trademarks” has the meaning set forth in Section 13.8.2.

1.42 “Losses” has the meaning set forth in Section 12.5.1.

1.43 “Manufacturing” or “Manufacture” means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of the Licensed Product, including process and formulation development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

1.44 “MEDcell Improvements” mean any improvements, ideas, inventions, developments, derivatives, modifications, technologies, discoveries, know-how and techniques, whether or not patentable, conceived or reduced to practice by MEDcell or Related Parties during the Term that cover or relate to Argos Technology, the Automated System or Licensed Product.

1.45 “MEDcell Indemnitees” has the meaning set forth in Section 12.5.2.

1.46 “MEDcell In-License” means an agreement between MEDcell or Related Parties and a Third Party pursuant to which MEDcell or Related Parties has rights and obligations with respect to, or which otherwise Cover, the Licensed Product, its Manufacture, or a reagent or component for its Manufacture and is necessary to Develop, Commercialize and/or Manufacture such Licensed Product in the Field.
1.47 “MEDcell Trademark” has the meaning set forth in Section 13.8.2.

1.48 “Milestone Payment” has the meaning set forth in Section 9.2.3.

1.49 “mRCC” has the meaning set forth in the recitals.

1.50 “Necessary Third Party IP” means Know-How or Patent Rights owned or controlled by a Third Party that Cover the Development, Manufacturing and/or Commercialization of the Licensed Product.

1.51 “Net Sales” means the total amount actually received by MEDcell or its Related Parties in connection with sales of the Licensed Product to any Third Party, after deduction of all the following to the extent applicable to such sales:

(a) all trade, case and quantity credits, discounts, refunds or rebates, including without limitation rebates accrued, incurred or paid to any governmental agency and any other price reductions required by any governmental agency;

(b) allowances or credits for returns, including without limitation amounts received for sales which become the subject of a subsequent temporary or partial recall by a regulatory agency for safety or efficacy reasons outside the control of a Party, and retroactive price reductions (including Medicaid, managed care and similar types of rebates);

(c) cost of freight, postage, and freight insurance, (if paid by seller);

(d) sales taxes, value added taxes, excise taxes, and customs duties; and

(e) cost of export licenses and any taxes (excluding income taxes or similar taxes), fees or other charges associated with the exportation or importation of Licensed Product.

Net Sales shall be calculated in accordance with GAAP.

A sale or transfer to a Related Party for re-sale by such Related Party shall not be considered a sale for the purpose of this provision but the resale by such Related Party to a Third Party shall be a sale for such purposes. Any amounts received by MEDcell or its Related Parties in exchange for Licensed Product transferred or provided to any person or entity for use in testing, clinical trials for obtaining Regulatory Approval, compassionate use, or as marketing samples to develop or promote the Licensed Product are expressly excluded from the definition of Net Sales. In the event that the Licensed Product is sold in conjunction with a product or service (e.g., as a bundled or combination therapy) that is not the Licensed Product, “Net Sales” with respect to such conjoined sale shall be deemed to mean that portion of the total proceeds proportionate to the value attributable to the Argos Technology that Covers such bundled or combination therapy. In the event of a dispute with respect to the proper allocation of value, the provisions of Section 15.11 shall apply.

1.52 “New Medinet Facility” has the meaning set forth in Section 2.3.2.
1.53 “Option” has the meaning set forth in Section 3.1.

1.54 “Non-Bankrupt Party” has the meaning set forth in Section 14.2.3(c).

1.55 “Party” means Medinet, MEDcell or Argos; “Parties” means Medinet, MEDcell and Argos.

1.56 “Patent Expenses” has the meaning set forth in Section 13.3.6.

1.57 “Patent Rights” means all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, invalidations, supplementary protection certificates and patents of addition) and patent applications (including all provisional applications, requests for continuation, continuations, continuations-in-part and divisions) and all foreign equivalents of the foregoing.

1.58 “Person” means any individual, corporation, company, partnership, trust, incorporated or unincorporated association, joint venture or other entity of any kind.

1.59 “Pharmacovigilance Agreement” has the meaning set forth in Section 10.9.2.

1.60 “Promissory Note” has the meaning set forth in Section 9.1.

1.61 “Promotional Materials” has the meaning set forth in Section 10.6.

1.62 “Recoveries” has the meaning set forth in Section 13.4.4.

1.63 “Regulatory Approval” means any and all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the Development, Commercialization and Manufacture of the Licensed Product.

1.64 “Regulatory Authority” means any applicable government regulatory authority involved in granting approvals for the Development, Manufacturing, Commercialization, reimbursement and/or pricing of the Licensed Product.

1.65 “Related Party” means a Party’s Affiliates and Sublicensees.

1.66 “Royalty Term” has the meaning set forth in Section 9.2.9.

1.67 “Sublicense Agreement” means a written agreement between MEDcell or its Affiliate, on the one hand, and a Third Party, on the other hand, in which MEDcell (or its Affiliate) grants a sublicense to such Third Party of rights licensed by Argos to MEDcell pursuant to this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, the agreement between MEDcell and Medinet entered into pursuant to Section 4.5 shall be deemed to be a “Sublicense Agreement.”

1.68 “Sublicensee” means Medinet in the context of the Sublicense Agreement entered into pursuant to Section 4.5, and a Third Party to whom MEDcell grants a sublicense under the rights granted to MEDcell by Argos hereunder.
1.69 “Term” has the meaning set forth in Section 14.1.

1.70 “Territory” means Japan.

1.71 “Third Party” means an entity other than a Party and its Affiliates.

1.72 “United States” means the United States of America and its territories, possessions and commonwealths.

1.73 “Uncharacterized Antigen” means any unknown or uncharacterized antigen. For the avoidance of doubt, a preparation, or any fractional preparation of total tumor RNA is a preparation that contains exogenous Uncharacterized Antigens.

1.74 “Upfront Option Fee” has the meaning set forth in Section 9.2.1.

1.75 “Valid Claim” means a claim of: (a) an issued and unexpired Argos Patent Right, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a patent application for a patent included within the Argos Patent Rights which has been pending for less than [***] years and that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

2. MANUFACTURING LICENSE

2.1 License Grant. Subject to the terms and conditions of this Agreement, Argos hereby grants MEDcell an exclusive, royalty-free license under and to Argos Technology to Manufacture the Licensed Product in the Territory solely for the purpose of the Commercialization of the Licensed Product in the Territory in the Field (the “CMO License”). Prior to MEDcell’s exercise of the Option and payment of the Upfront Option Fee, unless otherwise agreed by Argos in writing, the CMO License (i) shall be used by MEDcell solely to supply Argos or its designee with Licensed Product for Commercialization in the Territory, and (ii) shall not be sublicensable to Third Parties. Upon MEDcell’s exercise of the Option and payment of the Upfront Option Fee, unless otherwise agreed by Argos in writing, the CMO License (i) shall be used by MEDcell solely to supply MEDcell or its Related Parties with Licensed Product for Commercialization in the Territory in the Field, and (ii) shall include the right to grant sublicenses as provided in Article 4 below. For the avoidance of doubt, the license granted pursuant to this Section 2.1 shall not include the right to Manufacture or have Manufactured Automated Systems or components thereof, and shall not preclude Argos from Manufacturing or having Manufactured Licensed Product outside the Territory for Commercialization outside the Territory. Argos may request MEDcell to manufacture Licensed Product in the Territory for Development or Commercialization of the Licensed Product outside the Territory in order to enable Argos to execute the Argos Retained Right defined in Section 3.3.

2.2 Supply Agreement. In the event MEDcell does not exercise the Option, the Parties would use good faith efforts to negotiate and sign a supply agreement no later than [***] months prior to the expected receipt of the Regulatory Approval of the Licensed Product for the Field in the Territory, under which MEDcell would supply Argos or its designee with 100% of its or its designee’s requirements of Licensed Product for Commercialization in the Territory in the Field (“Supply Agreement”). The Supply Agreement would include industry standard terms and conditions, and Licensed Product would be supplied at a transfer price mutually agreed in good faith by the Parties.

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2.3 **Technology Transfer**

2.3.1 Immediately after the execution of this Agreement, provided that the timing accommodates Argos’ manufacturing schedule for the Phase 3 ADAPT trial, Argos shall transfer the non-automated Argos Technology to the Current Medinet Facility where Medinet, as a Sublicensee of MEDcell pursuant to Section 4.5, would Manufacture Licensed Product based on the current, non-automated, manufacturing system. Upon completion of the Automated System, Argos shall transfer the technology necessary to Manufacture the Licensed Product using the Automated System to the New Medinet Facility (defined in 2.3.2) Medinet would reimburse Argos for reasonable costs incurred to complete any technology transfer, the level of costs to be discussed by the Parties prior to initiation of the technology transfer. Medinet and MEDcell would not sell or administer any Licensed Product to humans until Argos has determined that the Technology has been satisfactorily transferred.

2.3.2 Medinet, as a Sublicensee of MEDcell pursuant to Section 4.5, shall build a new manufacturing facility ("New Medinet Facility") with capacity sufficient to produce Licensed Product volumes for the Field in Territory based on its commercially reasonable projections agreed in good faith by the Parties. The New Medinet Facility shall be completed on or before [**]. Medinet shall be responsible at its sole cost and expense to transfer the technology from the Medinet Current Facility to the New Medinet Facility.

2.3.3 MEDcell shall, at its sole cost, acquire Regulatory Approval to Manufacture the Licensed Product for Commercialization of the Licensed Product in the Field in the Territory.

2.3.4 As of the Effective Date, Argos is developing the Automated System and Argos anticipates development completion between [**]. Upon completion of the development of the Automated System and the approval of its use by applicable Regulatory Authorities in the Territory, Medinet shall use the Automated System to Manufacture Licensed Product. Costs to purchase the Automated Systems and installation fees shall be borne by Medinet. Argos shall supply Medinet’s requirements for instruments and disposables for Automated Systems pursuant to a supply agreement to be negotiated in good faith by the Parties; provided, however, that the price of such instruments and disposables for Automated Systems to be included in such supply agreement shall be Argos’ fully burdened cost of supplying the Automated Systems.

2.3.5 Notwithstanding the foregoing, Argos shall transfer all the clinical and non-clinical data necessary for the technology transfer of Argos Technology under this Section 2.3 to MEDcell and MEDcell shall transfer such data to Medinet to the extent necessary to Manufacture the Licensed Products.
3. OPTION; COMMERCIALIZATION LICENSE

3.1 Option Grant. Argos hereby grants MEDcell an option (the “Option”), exercisable from the Effective Date until 30 days after Argos provides MEDcell with a summary interim report following 50% of events (deaths) of study subjects in Argos’ ADAPT study (the “Option Period”), to acquire a nonexclusive, royalty-bearing license under the Argos Technology to use, sell and offer to sell Product solely for the Field in the Territory. Notwithstanding the foregoing, in any event the Option Period shall end on December 31, 2015. The Option must be exercised by MEDcell, if at all, by providing written notice to Argos within the Option Period.

3.2 Commercialization License Grant. Upon MEDcell’s timely exercise of the Option and Payment of the Upfront Option Fee, Argos shall grant MEDcell a nonexclusive, royalty-bearing license under the Argos Technology to use, sell and offer to sell Licensed Product solely for the Field in the Territory (the “Commercialization License”). The Commercialization License shall include the right to grant sublicenses as provided in Article 4 below.

3.3 Argos Retained Rights. Notwithstanding anything in this Agreement to the contrary and for clarity, Argos retains the full right to import (and have imported) from the Territory, and export (and have exported) to outside the Territory, Licensed Product (and components thereof) for Development or Commercialization of the Licensed Product outside the Territory. Argos shall not have rights to Manufacture the Licensed Products in the Territory.

4. SUBLICENSES

4.1 Sublicense of MEDcell’s Rights. Subject to the terms of Section 4.2, MEDcell is entitled to grant sublicenses of all or any portion of their rights under the Commercialization License and, upon exercise of the Option, the CMO License; provided, however, that MEDcell may not grant a sublicense under the Commercialization License to more than one (1) Third Party in the Territory unless it has received the prior written consent of Argos which shall not be unreasonably withheld. Consent shall be presumed and deemed given if Argos does not provide a written objection within [**] days of Argos’ receipt of a written request for consent.

4.2 Sublicensing Terms. Each sublicense granted by MEDcell pursuant to this Article 4 shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement. MEDcell shall promptly provide Argos with a copy of the executed Sublicense Agreement with any Sublicensee which shall contain the identity of the Sublicensee and shall provide sufficient information to show that the following provisions have been imposed on the Sublicensee: (a) a requirement that such Sublicensee submit applicable sales or other reports consistent with those required under this Agreement; (b) the audit requirement set forth in Section 9.8; (c) a requirement that such Sublicensee comply with the confidentiality and non-use provisions of Article 11 with respect to both Parties’ Confidential Information; (d) that the Sublicense Agreement will automatically terminate upon Argos’ exercise of the Revocation Right, as applicable; and (e) any other provisions required under any Argos In-License subject to Argos’ compliance with Section 6.1 hereof. In the event MEDcell becomes aware of a material breach of any Sublicense Agreement by a Sublicensee that has not been cured pursuant to the terms of such Sublicense Agreement, MEDcell shall promptly notify Argos of the particulars of same and shall enforce the terms of such Sublicense Agreement. If MEDcell does not cause the Sublicensee to comply with the terms of the Sublicense Agreement within [**] days of Argos’ request, MEDcell shall, upon Argos’ written direction, terminate the Sublicense Agreement.
4.3 **Liability.** MEDcell shall at all times be responsible for the performance of its Sublicensees under this Agreement.

4.4 **Termination of Sublicenses.** In the event Argos exercises its Revocation Right with respect to the CMO License and/or Commercialization License, all Sublicense Agreements shall immediately terminate.

4.5 **Sublicensing to Medinet.** Notwithstanding Section 4.1, but subject to the rest of this Article 4, MEDcell shall enter into a Sublicensing Agreement with Medinet under which MEDcell outsources the Manufacturing of Licensed Products to Medinet by granting sublicenses under the CMO License. MEDcell shall provide a copy of executed Sublicensing Agreement to Argos. Argos shall have the right to terminate the Sublicense Agreement between MEDcell and Medinet upon written notice in the event Medinet is no longer an Affiliate of MEDcell.

5. **REVOCATION RIGHT.**

5.1 Notwithstanding anything in this Agreement to the contrary, but subject to Section 9.3, Argos may revoke the CMO License and/or the Commercialization License (the “Revocation Right”) as follows: (i) if MEDcell has not exercised the Option (or the Potion Period has lapsed without MEDcell having exercised the Option) as of the date Argos exercise the Revocation Right, Argos may revoke the CMO License; and (ii) if MEDcell has exercised the Option as of the date Argos exercises the Revocation Right, Argos may revoke (A) the Commercialization License only, or (B) the CMO License and the Commercialization License together. Argos may exercise the Revocation Right by providing written notice to MEDcell.

5.2 In the event Argos exercises the Revocation Right, MEDcell shall, unless prohibited by law or practically impossible, take the following actions at Argos’ cost:

(i) as promptly as practicable transfer and assign to Argos or Argos’ designee:

(A) possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including without limitation all Regulatory Approvals and pricing and reimbursement approvals) relating to, if the Commercialization License is revoked, the Commercialization, and, if the CMO License is revoked, the Manufacture, of the Licensed Product and all Licensed Product Trademarks and execute any and all documents and carry out any other actions as may be requested by Argos to assist Argos with all regulatory filings with the applicable Regulatory Authorities to ensure that all Regulatory Approvals in the Territory can be transferred or issued to Argos or Argos’ designee; and

(B) copies of all data, reports, records and materials in MEDcell’s possession or Control relating to, if the Commercialization License is revoked, the Commercialization, and, if the CMO License is revoked, the Manufacture, of the Licensed Product, including without limitation all non-clinical and clinical data relating to the Licensed Product, including without limitation customer lists and customer contact information and all adverse event data in MEDcell’s possession or Control;
(ii) as promptly as practicable appoint Argos or Argos’ designee as MEDcell’s and/or MEDcell’s Related Parties’ agent for all Licensed Product-related matters involving Regulatory Authorities in the Territory until all Regulatory Approvals and other regulatory filings have been transferred to Argos or its designee;

(iii) as promptly as practicable appoint Argos as its exclusive distributor of the Licensed Product in the Territory and grant Argos the right to appoint sub-distributors, until such time as all Regulatory Approvals in the Territory have been transferred to Argos or its designee;

(iv) if Argos so requests, transfer to Argos any Third Party agreements relating to, if the Commercialization License is revoked, the Commercialization, and, if the CMO License is revoked, the Manufacture, of the Licensed Product to which MEDcell is a party, subject to any required consents of such Third Party, which MEDcell shall use Commercially Reasonable Efforts to obtain promptly; and

(v) unless otherwise agreed by Argos in writing, all Sublicense Agreements related to, if the Commercialization License is revoked, the Commercialization, and, if the CMO License is revoked, the Manufacture, of Licensed Product shall automatically terminate. MEDcell shall execute all documents and take all such further actions as may be reasonably requested by Argos in order to give effect to the foregoing clauses (i) through (v).

5.3 In the event the following conditions (i), (ii) and (iii) are met, then Argos shall, at Argos’ sole option, take one of the actions listed as (x), (y) or (z).

(i) Argos exercises the Revocation Right with respect to the CMO License;

(ii) the Revocation Right is exercised after the first to occur of the grant of:

(A) Regulatory Approval; or

(B) Conditional Regulatory Approval of the Licensed Product for the Field in the Territory, and;

(iii) the New Medinet Facility has been completed and is solely dedicated to the Manufacture of Licensed Product.

(x) if Medinet then owns the New Medinet Facility accept an assignment of the New Medinet Facility on terms and conditions to be negotiated in good faith by the Parties;

(y) if Medinet leases the New Medinet Facility from a Third Party, assume Medinet’s obligations under such lease; or

(z) purchase its, or cause its Related Party to purchase, the requirements for the Licensed Product for the Field in the Territory for one year following the exercise of the Revocation Right.
5.4 Upon the expiration of the last Valid Claim of the Argos Patent Rights, MEDcell shall have the right under and to such expired Argos Patent Rights for its own purposes even if the Revocation Right is exercised.

6. **THIRD PARTY IP; MEDCELL IMPROVEMENTS**

6.1 **In-Licenses.** All licenses and other rights granted to MEDcell under this Agreement are subject to the rights and obligations of Argos under the Argos In-Licenses. During the Term, Argos shall maintain the Argos In-Licenses in full force and effect with respect to the rights granted to MEDcell under this Agreement. MEDcell shall comply with all applicable terms and conditions of the Argos In-Licenses, and shall perform and take such actions as may be required to allow Argos to comply with its obligations thereunder, including but not limited to, obligations relating to sublicensing, patent matters, confidentiality, reporting, audit rights, indemnification and diligence. Argos agrees to provide MEDcell with copies of any Argos In-Licenses that are relevant to the rights granted to MEDcell under this Agreement. Confidential Information of Argos or the counterparty may be redacted from such copies, except to the extent that such information is required in order to enable MEDcell to comply with its obligations under this Section 6.1 with respect to such Argos In-License.

6.2 **Licenses of Necessary Third Party IP.** During the Term, MEDcell shall be responsible for obtaining licenses of any Necessary Third Party IP for the Territory that it does not Control (other than Necessary Third Party IP for the Territory sublicensed to MEDcell pursuant to an Argos In-License), and shall notify Argos in writing and provide Argos with a copy of any license of Necessary Third Party IP entered into by MEDcell after the Effective Date. If, during the Term, Argos obtains a license to Necessary Third Party IP for the Territory that is not already Controlled by MEDcell or Argos, then Argos shall notify MEDcell in writing and include in such notification a summary of such Necessary Third Party IP, the commercial and sublicensing terms of the license and any other relevant information together with a copy of the fully executed license. MEDcell will have [**] days thereafter to notify Argos of its desire to obtain a sublicense to such Necessary Third Party IP. Upon receipt of such written notice from MEDcell, Argos shall grant to MEDcell a sublicense of such Necessary Third Party IP, which shall include any terms that Argos is required to impose on its Sublicensees pursuant to the relevant in-license, but shall include no incremental compensation to Argos. Upon execution of such supplemental agreement, Argos’ license of such Necessary Third Party IP will be deemed an Argos In-License and Schedule D will be updated accordingly.

6.3 **License under MEDcell Improvements.** MEDcell hereby grants to Argos a royalty-free, sublicensable, transferable, exclusive license under MEDcell Improvements to make, have made, use, sell, offer to sell and import (i) Licensed Product for the Field outside the Territory, (ii) Licensed Product for the Field in the Territory if the Commercialization License is not in effect after the option period, and (iii) Licensed Product anywhere in the world outside of the Field.

7. **EXPANSION OF THE FIELD.** The Parties shall from time to time discuss the addition of new indications to the Field. Such discussions would include the terms upon which an indication would be added, including without limitation, commitment fees, upfront option fees, milestones, royalties and the Development of Licensed Product for such new indications. For clarification, Argos shall have no obligation to agree to add any new indications to the Field.
8. **NO OTHER RIGHTS.** Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party hereto, as a result of this Agreement, obtain any ownership interest or other right in any Know-How or Patent Rights of the other Party, including items owned, controlled or developed by the other Party, or provided by the other Party to the receiving Party at any time pursuant to this Agreement.

9. **CERTAIN FINANCIAL TERMS**

9.1 **Commitment Fee; Loan.** Medinet paid to Argos One Million Dollars ($1,000,000) (the “Commitment Fee”) on December 27, 2013 in consideration of Argos granting the CMO License to Medinet. In addition, Medinet extended a loan of Nine Million Dollars ($9,000,000) (“Loan”) to Argos on December 27, 2013. Medinet and MEDcell hereby agree that MEDcell shall pay Medinet the amount to be separately agreed between Medinet and MEDcell to Medinet in consideration of obtaining the CMO License originally granted to Medinet and purchasing the Loan from Medinet retroactively on December 27, 2013, and Argos hereby acknowledges such arrangement. The Commitment Fee and the Loan proceeds shall be used by Argos for the research and development of the Licensed Product and the Manufacture thereof outside the Territory, for which MEDcell shall receive a direct benefit in the form of data sharing and a manufacturing process. Promptly upon receipt of the proceeds of the Loan, Argos executed and delivered to Medinet an interest-bearing promissory note (“Promissory Note”) in the form of Exhibit A to evidence the Loan. Medinet shall upon receipt of the separately agreed amount from MEDcell deliver Promissory Note to MEDcell, and Argos acknowledges that MEDcell becomes the Holder of Promissory Note thereafter that has the right to receive repayment.

9.2 **Development and Commercialization Consideration.**
9.2.1 If MEDcell exercises the Option, MEDcell shall pay to Argos One Million Dollars ($1,000,000) (the “Upfront Option Fee”) upon exercise.

9.2.2 MEDcell shall pay to Argos [**] Dollars ($[**]) upon receipt of [**].

9.2.3 MEDcell shall pay to Argos [**] Dollars ($[**]) upon receipt of [**].

9.2.4 MEDcell shall pay to Argos [**] Dollars ($[**]) upon receipt of [**].

9.2.5 MEDcell shall pay to Argos [**] Dollars ($[**]) upon receipt of [**].

9.2.6 MEDcell shall pay to Argos [**] Dollars ($[**]) upon receipt of [**].

9.2.7 MEDcell shall pay Argos a royalty on Net Sales of Licensed Product in the Territory by MEDcell or a Related Party at a rate to be negotiated in good faith between the Parties once cost of goods and Net Sales price can be reasonably estimated.

9.2.8 MEDcell shall pay Argos Five Million Dollars ($5,000,000) (the “Milestone Payment”) upon the aggregate of [**] Dollars ($[**]) of Net Sales of the Licensed Product in the Territory by MEDcell, its Related Parties, successors and assigns.

9.2.9 Royalties on Net Sales of the Licensed Product shall continue to be payable until the later of (a) the expiration of the last Valid Claim of the Argos Patent Rights Covering the Manufacture or the Commercialization of the Licensed Product, and (b) the twelfth (12th) anniversary of the First Commercial Sale in the Territory (each such period, a “Royalty Term”). Argos shall continue to be required to pay by itself any royalties Argos owes to a Third Party under an In License without passing such costs to MEDcell.

9.2.10 Unless otherwise agreed by Argos and MEDcell, amounts payable by MEDcell pursuant to 9.2.2-9.2.6 shall be applied first as partial repayment of the principal of the Loan.

9.2.11 If the Loan has not been repaid in full on or before December 31, 2018, then Argos shall grant to MEDcell a non-exclusive, royalty-bearing license to make, use and sell Arcelis products in Japan for the treatment of cancer. Royalties under the license under this section 9.2.11 shall be payable until the expiration of the last Valid Claim of the Argos Patent Rights in the Territory. For the avoidance of doubt, the clinical Data gathered by MEDcell using the Argos Technology under the license under this section 9.2.11 shall belong to MEDcell. The terms of such license, including the royalty rate, shall be negotiated in good faith, with the unpaid principal of the Loan and any accrued interest at the time of the license grant constituting prepaid royalties. For clarification, MEDcell’s right to offset milestones otherwise payable under 9.2.2-9.2.6, MEDcell’s right to offset against future royalties under this Section 9.2.11, and MEDcell’s right to elect repayment of all unpaid principal and unpaid interest under the Promissory Note on December 31, 2018, all of the foregoing at MEDcell’s election, shall constitute the sole sources of repayment of the Loan and MEDcell shall not otherwise demand repayment of or seek to collect the Loan or authorize any third party to do so; provided, however, that upon any default by Argos under the terms of the Promissory Note or this Agreement, MEDcell shall have all available legal and equitable rights and remedies. Any such license shall be treated as a Commercialization License subject to the Revocation Right.
9.3 Payments upon Exercise of the Revocation Right.

9.3.1 In the event Argos exercises the Revocation Right with respect to the Commercialization License only, Argos shall pay to MEDcell within [**] days of the exercise of the Revocation Right an amount equal to the Upfront Option Fee, Fees payable under 9.2.2-9.2.6 and Milestone Payment paid by MEDcell as of the date that the Revocation Right is exercised and also immediately repay the then-outstanding balance of the Loan to MEDcell to the extent not covered by the Fees payable under 9.2.2-9.2.6. In the event Argos exercises the Revocation Right with respect to the CMO License only, Argos shall pay to MEDcell within [**] days of the exercise of the Revocation Right (i) an amount equal to (A) 200% of the Commitment Fee, plus (B) [**]% of the Fees paid under 9.2.2-9.2.6, and the then-outstanding balance of the Loan to MEDcell to the extent not covered by the Fees paid under 9.2.2-9.2.6.

9.3.2 In the event Argos exercises the Revocation Right with respect to the Commercialization License and the CMO License, then (i) if the Revocation Right is exercised by Argos before the [**] of the first to occur of the grant of (A) Regulatory Approval or (B) Conditional Regulatory Approval of the Licensed Product for the Field in the Territory, Argos shall pay to MEDcell within [**] days of the exercise of the Revocation Right an amount equal to 200% of the Commitment Fee, Upfront Option Fee, Fees payable under 9.2.2-9.2.6 and Milestone Payment which have been paid by MEDcell as of the date that the Revocation Right is exercised, and (ii) if the Revocation Right is exercised by Argos thereafter, Argos shall pay to MEDcell within [**] days of the exercise of the Revocation Right an amount equal to 150% of the Commitment Fee, Upfront Option Fee, Fees payable under 9.2.2-9.2.6 and Milestone Payment which have been already paid by MEDcell as of the date that the Revocation Right is exercised. Argos shall also immediately repay the then-outstanding balance of the Loan to MEDcell to the extent not covered by the Fees payable under 9.2.2-9.2.6.

9.4 Necessary Third Party IP. Subject to the applicable provisions of Section 10.5, during the period beginning on MEDcell’s exercise of the Option and ending upon Argos’ exercise of the Revocation Right with respect to the Commercialization License, (i) any royalties and any fees, milestones or other payments under all MEDcell In-Licenses of Necessary Third Party IP shall be borne exclusively by MEDcell, and (ii) any royalties and any fees, milestones or other payments under the Argos In-Licenses shall be borne exclusively by Argos.

9.5 Royalty Adjustments. The royalties payable to Argos pursuant to Section 9.2.7 may be subject to reduction by a portion of the amount paid by MEDcell in royalties in such period under all MEDcell In-Licenses of Necessary Third Party IP that are reasonably allocable to the Development, Manufacture or Commercialization of the Licensed Product in the Field in the Territory.

9.6 Medical Tourism. Medinet and MEDcell and any other Related Party shall not promote the use of Licensed Product for the treatment in the Territory of persons who do not regularly reside in the Territory. For clarification, this shall not prohibit Medinet, MEDcell or a Related Party from supplying Product for use by non-Japanese citizens residing in the Territory, but Medinet, MEDcell and Related Parties shall not, directly or indirectly, encourage or support any business enterprise that encourages persons from outside the Territory to come to the Territory for treatment with Licensed Product, without Argos’ express written consent.
9.7 Reports; Payment of Royalty. MEDcell shall furnish to Argos a written report within [**] days after the end of each Calendar Quarter showing the quantity of Licensed Product sold, the gross sales of Licensed Product, the itemized deductions for Licensed Product included in the calculation of Net Sales, the Net Sales of the Licensed Product during the reporting period, and the royalties payable under this Agreement. In addition, MEDcell shall prepare and deliver to Argos any additional reports as required under the Argos In-Licenses, in each case within a time period sufficiently in advance to enable Argos to comply with its obligations under such Argos In-Licenses. Royalties shown to have accrued by each report shall be due and payable on the date such report is due. MEDcell and its Related Parties shall keep complete and accurate records in sufficient detail to enable the royalties and other payments payable hereunder.

9.8 Audits.

9.8.1 Upon the written request of Argos delivered at least [**] days in advance, MEDcell and its Related Parties shall permit an independent certified public accounting firm of internationally-recognized standing selected by Argos and reasonably acceptable to MEDcell, at Argos’ expense except as set forth below, to have access during normal business hours to such of the records of MEDcell and its Related Parties as may be reasonably necessary to verify the accuracy of the royalty and other reports hereunder for any year ending not more than [**] years prior to the date of such request for the sole purpose of verifying the basis and accuracy of payments made under this Agreement.

9.8.2 If such accounting firm identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy, together with interest calculated at [**] percent ([**]% per month (or such higher rate as may be required pursuant to any applicable In-License) or the maximum amount permitted by applicable law, from the time of the over-payment or under-payment, within [**] business days of the date Argos delivers to MEDcell such accounting firm’s written report so concluding, or as otherwise agreed by the Parties in writing. Such written report shall be binding upon the Parties. The fees charged by such accounting firm shall be paid by Argos, unless such discrepancy represents an underpayment by MEDcell or its Related Parties of [**] percent ([**]% of the total amounts due hereunder in the audited period, in which case such fees shall be paid by MEDcell.

9.8.3 MEDcell shall comply with all applicable audit requirements in the Argos In-Licenses and shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to make reports to Argos, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Argos’ independent accountant to the same extent required of MEDcell under this Agreement.

9.8.4 Subject to the audit requirements set forth in Argos In-Licenses, Argos shall treat all financial information subject to review under this Section 9.8 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with MEDcell and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.
9.9 Payment Exchange Rate. All payments to be made under this Agreement shall be made in United States dollars and shall be paid by bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by Argos from time to time. In the case of Net Sales made by MEDcell and its Related Parties, the rate of exchange to be used in computing the amount of currency equivalent in United States dollars due shall be the closing telegraphic transfer middle (TTM) rate of Bank of Mitsubishi Tokyo UFJ on the last date of the relevant calculation period of Net Sales.

9.10 Registration. MEDcell will promptly make all filings with and submissions to all governmental or regulatory authorities and obtain and maintain all consents, permits, registrations and authorizations that are necessary or required in order for MEDcell to make timely payments under this Agreement, including, without limitation, any foreign exchange approvals or requirements. MEDcell will promptly provide Argos with evidence thereof upon Argos’ written request.

9.11 Income Tax Withholding. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article 9, MEDcell shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this Article 9. MEDcell shall submit appropriate proof of payment of the withholding taxes to Argos within a reasonable period of time. At the request of Argos, MEDcell shall, at its cost (within a reasonable amount) give Argos such reasonable assistance, which shall include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable Argos to claim exemption from such withholding or other tax imposed or obtain a repayment, reduction or credit and shall upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax.

10. DEVELOPMENT AND COMMERCIALIZATION RESPONSIBILITIES

10.1 Development Responsibilities. Prior to MEDcell’s exercise of the Option, MEDcell shall, on behalf of Argos and at MEDcell’s sole cost and expense, use Commercially Reasonable Efforts to Develop the Licensed Product for the Field in the Territory.

10.1.1 MEDcell shall be entitled to use and reference Argos’ regulatory filings in North America and associated Data including without limitation clinical Data associated with the ADAPT study in connection with MEDcell’s authorized Development and, if MEDcell exercises the Option, the Commercialization of the Licensed Product for the Field in the Territory.

10.1.2 Notwithstanding the foregoing, if (i) MEDcell does not exercise the Option within the Option Period, or (ii) the Development of the Licensed Product for the Field in the Territory, including without limitation Regulatory Approval of the Licensed Product, is not completed by the time Argos exercises the Revocation Right with respect to the Commercialization License only, in either case Argos may take over the responsibility for the Development of the Licensed Product by notifying MEDcell in writing.

10.1.3 If the Development of the Licensed Product for the Field in the Territory, including without limitation Regulatory Approval of the Licensed Product, is not completed by the time Argos exercises the Revocation Right to terminate both the CMO License and Commercialization License, Argos shall take over the responsibility of MEDcell for the Development of the Licensed Product without further notice.
10.1.4 MEDcell shall share with Argos, on a [**] basis, (a) its available Data with respect to the Licensed Product generated during the Commercialization of the Licensed Product. Argos shall be entitled to use such Data in its discretion for all uses outside the Territory, for uses in the Territory for the Field when the Commercialization License is not in effect after the Option Period, and for uses in the Territory outside the Field, including without limitation referencing such Data in any Regulatory Approval submissions by Argos and its Related Parties. For the avoidance of doubt, Argos shall be entitled to Develop, Manufacture and Commercialize Licensed Product to which such MEDcell Data relates without further compensation to or a need for a license from MEDcell. MEDcell shall own the Data it generates and shall be entitled to use such Data for its own internal purposes even if the Revocation Right is exercised.

10.2 Commercialization Diligence. Upon MEDcell’s exercise of the Option, MEDcell will use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Field in the Territory. Without limiting the foregoing, MEDcell and Medinet shall meet Manufacturing, Development and Commercialization milestones negotiated in good faith between the Parties once the cost of goods and Net Sales price of Licensed Product in the Field in the Territory can be reasonably estimated.

10.3 Commercialization Plan. Commencing as of MEDcell’s exercise of the Option, MEDcell shall prepare and deliver to Argos, (a) a Commercialization strategy plan for the following [**] year period, which plan would be updated at least annually, and (b) by no later than each [**], a written plan that describes in detail the Commercialization activities to be undertaken with respect to the Licensed Product in the Territory in the next Calendar Year and the dates by which such activities are targeted to be accomplished (each, a “Commercialization Plan”).

10.4 Reporting Obligations. MEDcell shall prepare and deliver to Argos, by no later than each [**] (for the period ending December 31 of the prior Calendar Year), written reports summarizing MEDcell’s Commercialization activities for the Licensed Product performed to date (or updating such report for activities performed since the last such report submitted hereunder, as applicable). In addition, MEDcell shall provide Argos with written notice of (a) all filings and submissions for Regulatory Approval regarding the Licensed Product in the Territory in a timely manner; (b) all Regulatory Approvals obtained or denied, the filing of any IND for the Licensed Product, and the First Commercial Sale of the Licensed Product in the Territory, within [**] business days of such event; and (c) the initiation of each clinical study of the Licensed Product by or on behalf of MEDcell within [**] business days of such event; provided, however, that in all circumstances, MEDcell shall if possible inform Argos of such event prior to public disclosure of such event by MEDcell. Moreover, MEDcell shall use Commercially Reasonable Efforts to prepare and deliver to Argos any additional reports reasonably requested by Argos to enable it to meet its obligations under the Argos In-Licenses, in each case sufficiently in advance to enable Argos to comply with its obligations under the Argos In-Licenses. MEDcell shall also provide such other information to Argos as Argos may reasonably request and shall keep Argos reasonably informed of MEDcell’s Commercialization activities with respect to the Licensed Product.
10.5 **Sales and Distribution.** MEDcell and its Related Parties shall be responsible for booking sales and shall store and distribute the Licensed Product in the Territory. If MEDcell receives any orders for the Licensed Product outside the Territory or if MEDcell has reason to believe that the Licensed Product is intended to be administered in the Territory to a Person whose primary domicile is outside the Territory, it shall refer such orders to Argos or its designee. Moreover, MEDcell and its Related Parties shall be solely responsible for handling all returns of the Licensed Product, as well as all aspects of the Licensed Product order processing, invoicing and collection, distribution, inventory and receivables, in the Territory.

10.6 **Advertising and Promotional Materials.** MEDcell will be responsible for the creation, preparation, production, reproduction and filing with the applicable Regulatory Authorities, of relevant written sales, promotion and advertising materials relating to the Licensed Product (“Promotional Materials”) for use in the Territory. All such Promotional Materials will be compliant with all applicable laws, rules and regulations, and consistent with the Commercialization Plan for the Territory.

10.7 **Export Monitoring.** MEDcell and its Related Parties will use Commercially Reasonable Efforts to monitor and prevent exports of Licensed Product from the Territory to outside the Territory, using methods commonly used in the industry for such purpose, and shall promptly inform Argos of any such activities, and the actions taken to prevent such activities. MEDcell agrees to take any actions reasonably requested in writing by Argos to prevent such activities to the extent such actions do not breach any applicable law or regulation.

10.8 **Records.** MEDcell will maintain scientific records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of the Development activities with respect to the Licensed Product.

10.9 **Regulatory Matters.**

10.9.1 **Regulatory Filings and Interactions.** Subject to Sections 5.2 and 14.2.3(a), as between the Parties, Argos will own any regulatory documents and applications submitted to the applicable Regulatory Authorities in the Territory with respect to the Licensed Product in the Field unless and until MEDcell exercises the Option, in which case, MEDcell will own such documents and applications. Without limiting the foregoing, MEDcell shall during any period in which it is responsible for the Commercialization of the Licensed Product in the Territory (i) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority, (ii) be responsible for interfacing, corresponding and meeting with each Regulatory Authority, (iii) be responsible for maintaining all regulatory filings, and (iv) apprise the other Party of all material communications from Regulatory Authorities as soon as reasonably possible but in any event within [**] business days. Argos will have the right to reference MEDcell’s and its Related Parties’ INDs and other filings with and submissions to Regulatory Authorities with respect to the Licensed Product for the purpose of conducting its Development activities and to otherwise obtain Regulatory Approval of the Licensed Product outside the Territory. In addition, during any period in which the Commercialization License is not in effect, MEDcell shall deliver to Argos copies of all filings and submissions to Regulatory Authorities, including without limitation Regulatory Approvals, no less than [**] days prior to submission to the Regulatory Authorities. MEDcell shall include in such filings and submissions any comments made by Argos within [**] days of Argos’ receipt of such submissions and filings, except to the extent such comments would cause such submissions or filings to be in violation of applicable laws.
10.9.2 Complaints; Adverse Event Reporting Procedures; Notice of Adverse Events Affecting the Licensed Product. Each Party will maintain a record of any and all complaints it or its Related Parties receive with respect to the Licensed Product. Each Party will notify the other Party in reasonable detail of any such complaints within sufficient time to allow the other Party and its Related Parties to comply with any and all regulatory and other requirements imposed upon them in any jurisdiction in which the Licensed Product is being marketed or tested in clinical studies. Each Party will maintain at its own expense an adverse event database for the Licensed Product, and the other Party will have access to all data in such adverse event database. Notwithstanding the foregoing, each Party will report to the other Party the details around any adverse events and serious adverse events relating to the Licensed Product in its Control within the time periods for such reporting as specified in the Pharmacovigilance Agreement (defined below). Each Party shall be responsible, at its own expense, for obtaining all adverse event information and safety data relating to the Licensed Product from its Related Parties in a timely manner, and for submitting adverse event reports with respect to the Licensed Product to the applicable Regulatory Authorities, with MEDcell having the responsibility for the Territory during the term of the Commercial Licenses and Argos having the responsibility otherwise. Within [**] months after the Effective Date, the Parties will develop and agree in writing upon a pharmacovigilance agreement (“Pharmacovigilance Agreement”) that will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, and any product quality and product complaints involving adverse experiences, related to the Licensed Product, sufficient to enable each Party to comply with its legal and regulatory obligations. In addition, each Party shall promptly notify the other if such Party becomes aware of any information or circumstance that is likely to have a material adverse effect on the Development, Manufacture or Commercialization of the Licensed Product.

10.9.3 Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Licensed Product, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within [**] advise the other Party thereof by telephone, or by email or facsimile together with telephone confirmation. MEDcell or its Related Party, in consultation with Argos, shall decide whether to conduct a recall in the Territory and the manner in which any such recall shall be conducted. Argos or its Related Party shall decide whether to conduct a recall outside of the Territory and the manner in which any such recall shall be conducted. Each Party shall bear the expense of any such recall in its own Territory. Each Party will make available to the other Party all of its pertinent records that may be reasonably requested in order to implement a recall by the other Party.

10.10 Third Parties. MEDcell shall be entitled to utilize the services of Third Party contract research organizations to perform its Development activities under this Agreement; provided, that (a) MEDcell shall ensure that such Third Party operates in a manner consistent with the terms of this Agreement and (b) MEDcell shall remain at all times fully liable for its respective responsibilities. MEDcell shall ensure that any such Third Party agreement shall include confidentiality, non-disclosure and non-use provisions that are substantially similar to those set forth in Article 11 of this Agreement. MEDcell shall provide Argos with a copy of the fully executed agreement and any amendment thereto with any contract research organization together with a relevant extract of English translation, in each case within [**] days of effectiveness.
11. CONFIDENTIALITY AND PUBLICATION

11.1 Nondisclosure Obligation. (a) All Confidential Information disclosed by one Party to another Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to a Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Confidential Information:

(i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure, directly or indirectly, by the disclosing Party, as documented by the receiving Party’s business records;

(ii) is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party or its Related Parties;

(iii) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or

(iv) is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party’s business records.

(b) Notwithstanding the obligations of confidentiality, non-disclosure and non-use set forth above and in Section 11.2 below, a receiving Party may provide Confidential Information disclosed to it, and disclose the existence and terms of this Agreement as may be reasonably required in order to perform its obligations and to exploit its rights under this Agreement, and specifically to (i) Related Parties, and their employees, directors, agents, consultants, advisors and/or other Third Parties for the performance of its obligations hereunder (or for such entities to determine their interest in performing such activities) in accordance with this Agreement in each case who are bound by confidentiality, non-disclosure and non-use obligations substantially similar to those set forth herein; (ii) governmental or other Regulatory Authorities in order to obtain patents or perform its obligations or exploit its rights under this Agreement; provided, that such Confidential Information shall be disclosed only to the extent reasonably necessary to do so, (iii) the extent required by applicable law, including without limitation by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity, (iv) any bona fide actual or prospective underwriters, investors, lenders or other financing sources and any bona fide actual or prospective collaborators or strategic partners and to consultants and advisors of such Party, in each case who are bound by confidentiality, non-disclosure and non-use obligations substantially similar to those set forth herein, and (v) to Third Parties to the extent a Party is required to do so pursuant to the terms of an In-License.
If a Party is required by judicial or administrative process to disclose Confidential Information that is subject to the non-disclosure provisions of this Section 11.1 or Section 11.2, such Party shall promptly inform the disclosing Party of the disclosure that is being sought in order to provide the disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality, non-disclosure and non-use provisions of this Section 11.1 and Section 11.2, and the Party disclosing Confidential Information pursuant to law or court order shall, at the disclosing Party’s expense, take all steps reasonably practical, including without limitation seeking an order of confidentiality, to ensure the continued confidential treatment of such Confidential Information. In addition to the foregoing restrictions on public disclosure, if a Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, such Party shall provide the other Parties with a copy of this Agreement showing any sections as to which the Party proposes to request confidential treatment, will provide the other Parties with an opportunity to comment on any such proposal and to suggest additional portions of the Agreement for confidential treatment, and will take such Party’s reasonable comments into consideration before filing the Agreement.

11.2 Publicity. (a) Except as set forth in Section 11.1 above and clause (b) below, the terms of this Agreement may not be disclosed by a Party, and no Party shall use the name, trademark, trade name or logo of the other Parties or its employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the applicable Party, except as may be required by law or expressly permitted by the terms hereof.

(b) As soon as practicable after the execution of this Agreement, the Parties shall use good faith efforts to agree in writing upon a press release to be issued jointly by the Parties publicizing the execution of this Agreement. After such initial press release, no Party shall issue a press release or public announcement relating to this Agreement without the prior written approval of the other Parties, which approval shall not be unreasonably withheld or delayed, except that a Party may (i) once a press release or other written statement is approved in writing by all Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (ii) issue a press release or public announcement as required, in the reasonable judgment of such Party, by applicable law, including without limitation by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS; INDEMNIFICATION

12.1 Mutual Representations and Warranties, Each Party represents and warrants to the other Parties that as of the Effective Date of this Agreement:

12.1.1 It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement, and to carry out the provisions hereof.

12.1.2 It is duly authorized to execute and deliver this Agreement, and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.

12.1.3 This Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound, or with its charter or by-laws.
12.1.4 It has not granted, and will not grant, during the Term, any right to any Third Party that would conflict with the rights granted to the other Parties hereunder.

12.1.5 Neither such Party nor any of its Affiliates has been debarred or is subject to debarment and neither such Party nor any of its Affiliates will use in any capacity, in connection with the exercise of its rights and the performance of its obligations under this Agreement, any person or entity that has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or any similar law in any foreign jurisdiction, or that is the subject of a conviction described in such section or similar law in any foreign jurisdiction. Each Party agrees to inform the other Party in writing immediately if it or any person or entity that is performing activities under this Agreement, is debarred or is the subject of a conviction described in Section 306 or similar law in any foreign jurisdiction, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of the notifying Party’s Knowledge, is threatened, relating to the debarment or conviction of the notifying Party or any person or entity used in any capacity by such Party or any of its Affiliates in connection with the performance of its obligations under this Agreement.

12.2 Additional Representations and Warranties of the Parties.

12.2.1 Additional Representations and Warranties of Argos. Argos represents and warrants to Medinet and MEDcell that:

(a) As of the Effective Date, except for any Argos Patent Rights or Argos Know-How Controlled by Argos under an Argos In-License and sublicensed to MEDcell, Argos is the sole and exclusive owner of all right, title and interest in and to the Argos Technology in existence as of the Effective Date in the Territory. As of the Effective Date, to Argos’ Knowledge there are no claims challenging Argos’ Control of the Argos Technology in existence as of the Effective Date in the Territory or making any adverse claim of ownership of the Argos Technology in existence as of the Effective Date in the Territory.

(b) Listed on Schedule D are all the Argos In-Licenses applicable to the Territory existing as of the Effective Date.

(c) As of the Effective Date, (i) each Argos In-License is valid, binding and in full force and effect, (ii) Argos is in compliance in all material respects with its material obligations under each Argos In-License, (iii) to Argos’s Knowledge, each Third Party is in compliance in all materials respects with its material obligations under each Argos In-License and (iv) no party has claimed a breach of, or initiated any dispute resolution proceedings under, any Argos In-License.

(d) As of the Effective Date Argos has not received any written notice from any Third Party asserting or alleging that any Development or Manufacture of the Licensed Product by Argos prior to the Effective Date infringed or misappropriated the Patent Rights or other intellectual property rights of such Third Party.

(e) As of the Effective Date to Argos’ Knowledge, there are no Third Party rights that could interfere with or materially conflict with the grant of rights by Argos to MEDcell under this Agreement.
12.2.2 Additional Representations and Warranties of Medinet and MEDcell. Each of Medinet and MEDcell represents, warrants and covenants to Argos that:

(a) They each have or have the ability to obtain and will maintain as and when necessary the financial and other capabilities reasonably necessary to discharge its obligations under this Agreement.

(b) All Data delivered by Medinet or MEDcell will have been collected in compliance with all applicable laws, and, to Medinet or MEDcell’s Knowledge, respectively, will be true and accurate in all material respects.

(c) They will comply with all laws in the Territory applicable to the exercise of its rights and performance of its obligations hereunder.

12.3 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTIES, AND EACH PARTY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NONINFRINGEMENT. ARGOS HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE LICENSED PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO THE LICENSED PRODUCT WILL BE ACHIEVED.

12.4 Certain Covenants.

12.4.1 Exclusivity. Except as expressly provided in this Agreement, neither MEDcell nor its Affiliates will, alone or with or through a Third Party, during the Term, research, develop, manufacture or commercialize any cell therapy using Argos Technology outside of the scope of this Agreement. For the avoidance of doubt, Medinet and MEDcell shall not be prohibited from generally engaging in the research, development, manufacture or commercialization of the cell therapy (in particular using dendritic cell) as it has been doing for more than 10 years which does not use Argos Technology.

12.4.2 Compliance. MEDcell and its Related Parties shall conduct the Development, Manufacture and Commercialization of the Licensed Product in accordance with all applicable laws, rules and regulations, including without limitation current governmental regulations concerning good laboratory practices, good clinical practices and good manufacturing practices (including but not limited the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)).

12.4.3 Employee Inventions. Prior to performing any activities in connection with this Agreement, MEDcell shall ensure that its and its Affiliates’ employees, agents and consultants have executed valid and binding agreements with it that assign and otherwise effectively vest in them any and all rights that such employees, agents and/or consultants might otherwise have in any invention including but not limited to MEDcell Improvements made by such employees, agents and/or consultants. Should any royalties or other consideration become payable to such employees, agents and/or consultants, MEDcell shall remain solely responsible for making such payments.

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12.5 Indemnification

12.5.1 General Indemnification by MEDcell. MEDcell shall indemnify, hold harmless, and defend Argos, its Affiliates, its Related Parties and the other parties to the Argos In-Licenses, and their respective directors, officers, employees and agents ("Argos Indemnitees") from and against any and all Third Party claims, suits, losses, liabilities, damages, costs, fees and expenses (including reasonable attorneys’ fees) (collectively, “Losses”) to the extent arising out of or resulting from, directly or indirectly, (a) any breach of this Agreement by MEDcell or Medinet, or (b) the negligence or willful misconduct by or of MEDcell, its Related Parties, Medinet, and their respective directors, officers, employees, contractors and agents.

12.5.2 General Indemnification by Argos. Argos shall indemnify, hold harmless, and defend MEDcell, its Affiliates, and their respective directors, officers, employees and agents (“MEDcell Indemnitees”) from and against any and all Losses to the extent arising out of or resulting from, directly or indirectly, (a) any breach of this Agreement by Argos, or (b) the negligence or willful misconduct by or of Argos, its Related Parties, and their respective directors, officers, employees, contractors and agents.

12.5.3 Product Liability. MEDcell shall indemnify, defend and hold harmless the Argos Indemnitees from, against and in respect of any and all Losses arising out of Third Party product liability claims incurred or suffered by the Argos Indemnitees, or any of them, directly relating to Licensed Product to the extent such Losses are attributable to technologies of MEDcell or improper manufacture of Licensed Product by MEDcell. Argos shall indemnify, defend and hold harmless the MEDcell Indemnitees from, against and in respect of any and all Losses arising out of Third Party product liability claims incurred or suffered by the MEDcell Indemnitees, or any of them, directly relating to Licensed Product to the extent such Losses are attributable to Licensed Product properly manufactured and supplied by MEDcell for sale by Argos or an Argos licensee. If MEDcell exercises the Option, then any product liability losses arising from the Development or Commercialization of Licensed Product in the Territory by Medinet and MEDcell which losses are not attributable to the breach or negligence of any Party shall be shared equally by the Parties.

12.5.4 Indemnification Procedure. In the event of any such claim against any MEDcell Indemnitee or Argos Indemnitee (individually, an “Indemnitee”), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnitee shall cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party shall not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party’s written authorization.

12.6 Limitation of Liability. NO PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A PARTY’S WILLFUL MISCONDUCT OR GROSSLY NEGLIGENT BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 11.
12.7 **Insurance.** MEDcell and Medinet shall each obtain and/or maintain insurance during the Term and for a period of at least [**_] years after the last commercial sale of the Licensed Product under this Agreement, with a reputable, solvent insurer in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement. Without limiting the foregoing, such insurance coverage shall include product liability insurance coverage limits of no less than $[**_] per occurrence and in the aggregate.

12.8 **Joint and Several Liability.** Notwithstanding anything in this Agreement to the contrary, MEDcell and Medinet shall be jointly and severally liable for the each other’s obligations under this Agreement.

13. **INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS**

13.1 **Inventorship.** Inventorship for patentable inventions conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with the principles that are used to determine inventorship under the patent laws of the United States.

13.2 **Ownership.** Subject to the licenses granted by Argos pursuant to this Agreement, Argos shall own the entire right, title and interest in and to all inventions and discoveries (and Patent Rights claiming patentable inventions therein) first made or discovered solely by employees or consultants of Argos or acquired solely by Argos. Subject to the licenses granted by Medinet or MEDcell pursuant to this Agreement, Medinet or MEDcell shall own the entire right, title and interest in and to all inventions and discoveries (and Patent Rights claiming patentable inventions therein) first made or discovered solely by employees or consultants of Medinet or MEDcell or acquired solely by Medinet or MEDcell. The Parties shall jointly own any inventions and discoveries (and Patent Rights claiming patentable inventions therein) first made or discovered jointly during the Term (“**Joint IP**”).

13.3 **Prosecution and Maintenance of Patent Rights.**

13.3.1 **Argos Technology.** Argos shall file, conduct prosecution, and maintain (including without limitation the defense of any interference or opposition proceedings), all Argos Patent Rights in the Territory, and Argos agrees to use Commercially Reasonable Efforts to prosecute and maintain such Argos Patent Rights in the Territory, in each case for which Argos controls the prosecution.

13.3.2 **MEDcell Technology.** MEDcell shall file, conduct prosecution, and maintain (including without limitation the defense of any interference or opposition proceedings), all Patent Rights comprising MEDcell Improvements in the Territory. MEDcell agrees to use Commercially Reasonable Efforts to prosecute and maintain the MEDcell Improvements in the Territory.

13.3.3 **Joint IP.** Argos and MEDcell shall, subject to mutual agreement by both parties, file, conduct prosecution, and maintain (including without limitation the defense of any interference or opposition proceedings), all relevant Patent Rights comprising Joint IP, in the names of both Argos and MEDcell. Both Argos and MEDcell shall reasonably cooperate and use Commercially Reasonable Efforts to prosecute and maintain the said Joint IP in the Territory. The cost to prosecute and maintain the said Joint IP shall be shared between the parties equally.
13.3.4 Cooperation. Each Party hereby agrees to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to Patent Rights.

13.3.5 Patent Expenses. The patent filing, prosecution and maintenance expenses incurred after the Effective Date with respect to Patent Rights (“Patent Expenses”) shall be borne by each Party filing, prosecuting and maintaining such Patent Rights under this Section 13.3; provided, however, that both Argos and MEDcell shall share the costs to prosecute and maintain the relevant Joint IP equally pursuant to Section 13.3.3.

13.4 Third Party Infringement.

13.4.1 Notices. Each Party shall promptly report in writing to the other Party during the Term any (a) known or suspected infringement of any Argos Technology, Medinet Improvements or Joint IP or (b) unauthorized use or misappropriation of any Confidential Information, Argos Technology, Medinet Improvements or Joint IP by a Third Party of which it becomes aware, and shall provide the other Party with all available evidence supporting such infringement, or unauthorized use or misappropriation.

13.4.2 Rights to Enforce.

(a) MEDcell’s First Right. MEDcell shall have the sole and exclusive right (but not obligation) to initiate an infringement or other appropriate suit anywhere in the world against any Third Party who at any time has infringed, or is suspected of infringing, any MEDcell Improvements, or MEDcell Know-How. Notwithstanding the foregoing, in the event such infringement, suspected infringement, or unauthorized use is by an Argos Related Party, the Parties shall discuss in good faith a resolution to the foregoing prior to engaging in litigation. MEDcell will consider in good faith any request from Argos to initiate an infringement or other appropriate suit against any Third Party with respect to matters described in this Section 13.4.2(a) occurring outside the Territory and in the Territory during the term of the Commercial License; provided, however, that MEDcell shall not be required to initiate any such suit. Argos shall not be entitled to initiate any such suit without the prior written consent of MEDcell.

(b) Argos’s First Right. Argos shall have the sole and exclusive right (but not obligation) to initiate an infringement or other appropriate suit anywhere in the world against any Third Party who at any time has infringed, or is suspected of infringing, any Argos Patent Rights, or of using without proper authorization any Know-How comprising Argos Patent Rights, or Argos Know-How. Notwithstanding the foregoing, in the event such infringement, suspected infringement, or unauthorized use is by a MEDcell or Related Party, the Parties shall discuss in good faith a resolution to the foregoing prior to engaging in litigation. Argos will consider in good faith any request from MEDcell to initiate an infringement or other appropriate suit against any Third Party with respect to matters described in this Section 13.4.2(b) occurring outside the Territory and in the Territory during the term of the Commercial License; provided, however, that Argos shall not be required to initiate any such suit. MEDcell shall not be entitled to initiate any such suit without the prior written consent of Argos.
(c) **Procedures; Expenses and Recoveries.** The Party having the right to initiate any infringement suit under Section 13.4.2(a) or (b) above shall have the sole and exclusive right to select counsel for any such suit and shall pay all expenses of the suit, including but not limited to attorneys’ fees and court costs and reimbursement of the other Party’s reasonable out-of-pocket expense in rendering assistance requested by the initiating Party. If required under applicable law in order for the initiating Party to initiate and/or maintain such suit, or if either Party is unable to initiate or prosecute such suit solely in its own name or it is otherwise advisable to obtain an effective legal remedy, in each case, the other Party shall join as a party to the suit and will execute and cause its Affiliates to execute all documents necessary for the initiating Party to initiate litigation to prosecute and maintain such action. In addition, at the initiating Party’s request, the other Party shall provide reasonable assistance to the initiating Party in connection with an infringement suit at no charge to the initiating Party except for reimbursement by the initiating Party of reasonable out-of-pocket expenses incurred in rendering such assistance. The non-initiating Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit, any damages, license fees, royalties or other compensation (including but not limited to any amount received in settlement of such litigation) ("Recoveries"), such amounts shall be allocated in all cases as follows regardless of which Party brings the enforcement action:

(a) first, to reimburse each Party for all expenses of the suit incurred by such Party, including but not limited to attorneys’ fees and disbursements, travel costs, court costs and other litigation expenses;

(b) second, (i) if such suit is related to the Argos Technology in the Territory and is attributable to a time period in which the Commercial License is in effect, then MEDcell shall be entitled to receive that portion of the remaining Recoveries reasonably attributable to Net Sales of the Licensed Product in the Territory in the Field (as determined by a court of competent jurisdiction in a final, non-appealable decision); provided, that the Recoveries reasonably attributable to Net Sales of Licensed Product to which MEDcell is entitled after reimbursement of expenses shall be treated as Net Sales for purposes of this Agreement and Argos shall be entitled to receive royalties on such constructive Net Sales pursuant to the terms of Section 9.2.2 as if such Net Sales had occurred during the time period of the infringement, and (ii) if such suit is related to Medinet Improvements in the Territory for any period in which the Commercial License is not in effect, then Argos shall be entitled to receive that portion of the remaining Recoveries reasonably attributable to Net Sales of the Licensed Product in the Territory (as determined by a court of competent jurisdiction in a final, non-appealable decision); and

(c) the Party initiating the suit shall be entitled to [**] percent ([**]%), and the non-initiating Party shall be entitled to [**] percent ([**]%), of the balance of the Recoveries.

13.5 **Claimed Infringement.**
13.5.1 **Notice.** In the event that after the Effective Date a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of their respective Affiliates or Sublicensees, claiming infringement of its patent rights or unauthorized use or misappropriation of its know-how, based upon an assertion or claim arising out of the Development, Manufacture or Commercialization of the Licensed Product (“**Infringement Claim**”) in the Field, such Party shall promptly notify the other Parties of the claim or the commencement of such action, suit or proceeding, enclosing a copy of the claim and all papers served. Each Party agrees to make available to the other Parties its advice and counsel regarding the technical merits of any such claim at no cost to the other Parties and to offer reasonable assistance to the other Parties at no cost to the other Parties.

13.5.2 **Responsibility.** MEDcell shall assume full responsibility for any Infringement Claims brought against any Party or its Affiliates or Sublicensees arising out of the Development or Commercialization of the Licensed Product in, or Manufacture of Licensed Product for, the Territory in the Field by MEDcell or its Related Parties. All liabilities, damages, costs and expenses arising out of such Third Party Infringement Claims shall be borne by MEDcell. Argos shall assume full responsibility for any Infringement Claims brought against a Party or its Affiliates or Sublicensees arising out of the Commercialization of the Licensed Product, or Manufacture of Licensed Product for, outside the Territory or outside the Field in the Territory by Argos or its Related Parties. All liabilities, damages, costs and expenses arising out of such Third Party Infringement Claims shall be borne by Argos.

13.5.3 **Procedure.** Each Party shall have the sole and exclusive right to select counsel for any Infringement Claim that it defends; provided, that it shall consult with the other Parties with respect to selection of counsel for such defense. Each Party will keep the other Party informed, and shall from time to time consult with the other Parties regarding the status of any such claims and shall provide the other Parties with copies of all documents filed in any suit brought in connection with such claims. The other Parties shall also have the right to participate and be represented in any such claim or related suit, at its own expense. No Party shall settle any claims or suits involving rights of another Party without obtaining the prior written consent of such other Parties, which consent shall not be unreasonably withheld or delayed.

13.5.4 **Other Infringement Resolutions.** In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the types described in Sections 13.4 and 13.5 of this Agreement (e.g., actions seeking declaratory judgments and revocation proceedings), the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute (including but not limited to the sharing in and allocating the payment or receipt of damages, license fees, royalties and other compensation) shall apply.

13.6 **Patent Certification.** To the extent required by law or permitted by law, the Parties shall use Commercially Reasonable Efforts to maintain with the applicable Regulatory Authorities during the Term correct and complete listings of applicable Patent Rights for the Licensed Product.

13.7 **Trademarks.**

13.8.1 Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos. To the extent permitted by local law, upon Argos’ request, MEDcell and its Related Parties shall include Argos’ (or its designee’s) name with equal prominence, or as close thereto as permitted by local law, on all Licensed Product promotional materials related to the Licensed Product in the Territory.
13.8.2 MEDcell will develop and propose, and Argos shall review and comment on for approval by MEDcell, one or more trademarks for the Licensed Product (the “Licensed Product Trademarks”) for use by MEDcell and its Related Parties throughout the Territory. Any Licensed Product Trademark(s) (other than the Argos Trademarks) that are used by MEDcell to promote and sell the Licensed Product in the Territory are hereinafter referred to as the “MEDcell Trademarks”. Argos (or its Related Parties, as appropriate) shall own all rights to the trademarks developed and/or used by Argos with respect to the Commercialization of the Licensed Product outside the Territory (the “Argos Trademarks”), and all goodwill associated therewith. MEDcell (or its Related Parties, as appropriate) shall own all rights to MEDcell Trademarks and all goodwill associated therewith. Argos shall also own rights to any Internet domain names incorporating the applicable Argos Trademarks or any variation or part of such Argos Trademarks used as its URL address or any part of such address; and MEDcell shall also own rights to any Internet domain names incorporating the applicable MEDcell Trademarks or any variation or part of such MEDcell Trademarks used as its URL address or any part of such address.

13.8.3 If MEDcell Trademarks are used to promote and sell the Licensed Product in the Territory then MEDcell will use Commercially Reasonable Efforts to establish, maintain and enforce the MEDcell Trademarks in the Territory during the Term, at its expense. If MEDcell requests a license to Argos Trademarks in writing to promote and sell the Licensed Product in the Territory, then Argos shall grant MEDcell an exclusive license to use such Argos Trademarks to Commercialize the Licensed Product in the Territory in the Field on terms and conditions to be negotiated by the Parties in good faith. Argos shall be entitled to no additional compensation for the grant of such license other than the reimbursement in full of Argos’ costs and expenses of establishing, maintaining and enforcing such Argos Trademarks in the Territory. If MEDcell Trademarks are used to promote and sell the Licensed Product outside the Territory, then MEDcell shall grant Argos an exclusive license to use such MEDcell Trademarks to Commercialize the Licensed Product outside the Territory on terms and conditions to be negotiated by the Parties in good faith. MEDcell shall be entitled to no additional compensation for the grant of such license other than the reimbursement in full of MEDcell’s costs and expenses of establishing, maintaining and enforcing such MEDcell Trademarks outside the Territory.

13.8.4 In the event either Party becomes aware of any infringement of any Licensed Product Trademark or Argos Trademark by a Third Party, such Party shall promptly notify the other Party and the Parties shall consult with each other and jointly determine the best way to prevent such infringement, including, without limitation, by the institution of legal proceedings against such Third Party.

14. TERM AND TERMINATION

14.1 Term. This Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Section 14.2 below, this Agreement shall continue in effect until (i) Argos’ exercise of the Revocation Right with respect to the CMO License and, if MEDcell has exercised the Option, the Commercialization License, or (ii) to the extent Argos does not exercise such Revocation Right with respect to the CMO License and, if MEDcell has exercised the Option, the Commercialization License, the later of (A) the expiration of the Royalty Term, if applicable, and (B) the expiration or earlier termination of the Supply Agreement (“Term”).
14.2 Termination Rights.

14.2.1 Termination for Cause. This Agreement may be terminated at any time during the Term:

(a) upon written notice by either Argos or MEDcell if the other Party is in breach of its material obligations hereunder and has not cured such breach within [**] business days in the case of a payment breach, or [**] days in the case of all other breaches, after written notice requesting cure of the breach; or

(b) by Argos or MEDcell upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings of the other Party, or in the case of Argos as the terminating Party, MediNet, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the case of Argos as the terminating Party, MediNet; provided, however, that in the event of any involuntary bankruptcy or receivership proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within sixty (60) days after the filing thereof.

14.2.2 Challenges of Patent Rights. In the event that MEDcell or any of its Related Parties (a) commences or participates in any action or proceeding (including, without limitation, any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any of the Argos Patent Rights licensed to MEDcell under this Agreement, or any claim thereof or (b) actively assists any other person or entity in bringing or prosecuting any action or proceeding (including, without limitation, any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any of such Argos Patent Rights or any claim thereof, then (i) MEDcell shall give notice thereof to Argos within [**] days of taking such action and (ii) Argos will have the right, in its sole discretion, to give notice to MEDcell that either (A) the licenses granted to MEDcell with respect to all or any portion of the Argos Technology under this Agreement will terminate in [**] days following such notice (or such longer period as Argos may designate in such notice), and, unless MEDcell or Related Parties cease all participation with respect to all such challenge(s) (including withdrawing any challenge within its control) within such [**]day period, such licenses will so terminate, or (B) the royalty rate determined in accordance with Section 9.2.2 shall be doubled until such time as MEDcell or Related Parties cease all participation with respect to all such challenge(s) (including withdrawing any challenge within its control). In the event that Argos elects to terminate the licenses but is not permitted to do so under applicable law, then the Parties agree to construe this provision as to permit Argos to terminate the licenses to that portion of such Argos Technology with respect to which Argos has the legal right to do so.
14.2.3 Effect of Termination.

(a) Termination by Argos. Without limiting any other legal or equitable remedies that Argos may have, if Argos terminates this Agreement in accordance with Section 14.2.1 or 14.2.2, then (i) notwithstanding anything in Section 12.4.1 to the contrary, MEDcell’s and its Affiliates obligations under Section 12.4.1 shall survive for a period of [**]** years after the effective date of termination, (ii) the license grant to Argos in Section 6.3 shall, solely with respect to licensable subject matter in existence on the effective date of termination, survive and shall become non-exclusive and be fully-paid, perpetual and include an unrestricted right to grant sublicenses, (iii) MEDcell shall as promptly as practicable, and to the extent not prohibited by law or practically not impossible, transfer and assign to Argos or Argos’ designee at Argos’ cost (A) possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including without limitation all Regulatory Approvals and pricing and reimbursement approvals) relating to the Development, Manufacture or Commercialization of the Licensed Product and all Licensed Product Trademarks and execute any and all documents and carry out any other actions as may be requested by Argos to assist Argos with all regulatory filings with the applicable Regulatory Authorities required in connection with the termination of this Agreement to ensure that all Regulatory Approvals in the Territory can be transferred or issued to Argos or Argos’ designee, (B) copies of all data, reports, records and materials in MEDcell’s possession or Control relating to the Licensed Product, including without limitation customer lists and customer contact information and all adverse event data in MEDcell’s possession or Control, and (C) all records and materials in MEDcell’s and its Related Parties’ possession or Control containing Confidential Information of Argos, (iv) as promptly as practicable appoint Argos or Argos’ designee as MEDcell’s and/or MEDcell’s Related Parties’ agent for all Licensed Product-related matters involving Regulatory Authorities in the Territory until all Regulatory Approvals and other regulatory filings have been transferred to Argos or its designee, to the extent not prohibited by law or practically not impossible, (v) if the effective date of termination is after First Commercial Sale, then MEDcell shall as promptly as practicable appoint Argos as its exclusive distributor of the Licensed Product in the Territory and grant Argos the right to appoint sub-distributors, until such time as all Regulatory Approvals in the Territory have been transferred to Argos or its designee, (vi) if MEDcell or its Related Parties are Manufacturing Licensed Product and the Supply Agreement is not then in effect, at Argos’ option, to the extent not prohibited by law or practically not impossible, supply the Licensed Product to Argos in the Territory on commercially reasonable terms (but any event, no less favorable than those on which MEDcell supplied the Licensed Product prior to such termination to the applicable distributor(s) in the Territory) until such time as all Regulatory Approvals in the Territory have been transferred to Argos or its designee, Argos has obtained all necessary manufacturing approvals and Argos has procured or developed its own source of Licensed Product supply, (vii) if Argos so requests, MEDcell shall transfer and cause its Related Parties to transfer to Argos any Third Party agreements relating to the Development, Manufacture or Commercialization of the Licensed Product to which MEDcell or a Related Party is a party, subject to any required consents of such Third Party, which MEDcell shall use Commercially Reasonable Efforts to obtain promptly, and (viii) unless otherwise agreed by Argos in writing, all Sublicense Agreements shall automatically terminate. The license granted and other transfers to be effected pursuant to this Section 14.2.3(a) shall be royalty-free, fully paid and perpetual. MEDcell shall execute and cause Related Parties to execute all documents and take all such further actions as may be reasonably requested by Argos in order to give effect to the foregoing clauses (i) through (viii).
(b) **Termination by MEDcell for Cause.** Without limiting any other legal or equitable remedies that MEDcell may have (including a claim for damages), if MEDcell terminates this Agreement in accordance with Section 14.2.1(a) or (b), then the licenses granted to Argos under this Agreement shall terminate and, provided that Argos has not exercised the Revocation Right with respect to the Commercialization License and MEDcell has made the First Commercial Sale of Licensed Product in the Territory, MEDcell shall have an option to continue the business by sending a written notice to Argos and if MEDcell exercises its option then the licenses granted to MEDcell under this Agreement with respect to the Licensed Product shall continue in full force and effect; provided, that MEDcell continues to use Commercially Reasonable Efforts to Manufacture, Commercialize the Licensed Product and comply with its obligations under Sections 10.1 and 10.2, pay all amounts that become due to Argos pursuant to Article 9 as a result of such Commercialization and comply in all respects with the requirements of each Argos In-License.

(c) **Termination upon Bankruptcy of a Party.** If this Agreement is terminated by a Party (the “Non-Bankrupt Party”) pursuant to Section 14.2.1(b) due to the rejection of this Agreement by or on behalf of another Party (the “Bankrupt Party”) under Section 365 of the United States Bankruptcy Code (the “Code”) or an equivalent type of provision under a relevant law applicable to the Party in question, all licenses and rights to licenses granted under or pursuant to this Agreement by the Bankrupt Party to the Non-Bankrupt Parties are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to “intellectual property” as defined under Section 101(35A) of the Code. The Parties agree that the Non-Bankrupt Parties, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against the Bankrupt Party under the Code, the Non-Bankrupt Parties shall be entitled to a complete duplicate of, or complete access to (as the Non-Bankrupt Party deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to the Non-Bankrupt Parties (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by the Non-Bankrupt Parties, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party upon written request therefor by the Non-Bankrupt Parties. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Parties may have arising under the Code or other applicable law. The parties intend for the substance of this Section 14.2(c) to apply worldwide, even if the Code does not expressly apply to the Bankrupt Party or to the Non-Bankrupt Parties.

14.3 **Effect of Expiration or Termination; Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for the Licensed Product sold prior to such expiration or termination. The provisions of Articles 11, 14 and 15, and Sections 9.7, 9.8, 10.4, 10.9.2, 10.9.3, 12.3, 12.5, 12.6, 12.7, 13.4, 13.5 and 13.6 shall survive any expiration or termination of this Agreement. Except as set forth in this Article 14, upon termination or expiration of this Agreement all other rights and obligations of the Parties under this Agreement cease.
15. **MISCELLANEOUS**

15.1 **Assignment.** Except as provided in this Section 15.1, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by a Party without the consent of the other Parties. However, a Party may, without the other Parties' consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or to a party that acquires, by merger, sale of assets or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates. The assigning Party shall remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned. An assignment to an Affiliate shall terminate, and all rights so assigned shall revert to the assigning Party, if and when such Affiliate ceases to be an Affiliate of the assigning Party.

15.2 **Governing Law.** This Agreement shall be construed and the respective rights of the Parties determined in accordance with the substantive laws of the State of New York, notwithstanding any provisions of New York law governing conflicts of laws to the contrary, and the patent laws of the relevant jurisdiction without reference to any rules of conflict of laws. **SUBJECT TO SECTION 15.11, THE PARTIES HEREBY IRREVOCABLY CONSENTS TO THE NONEXCLUSIVE JURISDICTION AND VENUE OF ANY STATE OR FEDERAL COURT SITTING IN NEW YORK COUNTY OVER ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, AND THE PARTIES HEREBY IRREVOCABLY AGREES THAT ALL CLAIMS IN RESPECT OF SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH STATE OR FEDERAL COURT.**

15.3 **Entire Agreement; Amendments.** This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof, and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral. This Agreement (including the Schedules hereto) may be amended, or any term hereof modified, only by a written instrument duly-executed by authorized representatives of both Parties hereto.

15.4 **Severability.** If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

15.5 **Headings.** The captions to the Articles and Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

15.6 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

15.7 **No Implied Waivers; Rights Cumulative.** No failure on the part of Argos, Medinet or MEDcell to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.
15.8 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile, sent by email, sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Argos, to: Argos Therapeutics, Inc.
4233 Technology Drive
Durham, NC 27704
Attention: President
Facsimile: 919 287-6336
Email: jabbey@argostherapeutics.com

With a copy to: Hutchison PLLC
3110 Edwards Mill Road, Suite 300
Raleigh, NC 27612
Attention: William N. Wofford
Facsimile No.: (866) 479-7550
Email: bwofford@hutchlaw.com

If to Medinet, to: Medinet Co., Ltd.
Shin-Yokohama Square Bldg.
14F, 2-3-12 Shin-Yokohama,
Kohoku-ku, Yokohama, Kanagawa, 222-0033 JAPAN

If to MEDcell, to: MEDcell Co., Ltd.
2-8 Tamagawa-dai Setagaya-ku
Tokyo, 158-0096 JAPAN

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile or email on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on receipt if sent by overnight courier; and/or (c) on receipt if sent by mail.

15.9 **Compliance with Export Regulations.** No Party shall export any technology licensed to it under this Agreement except in compliance with all applicable export laws and regulations.
15.10  **Force Majeure.** No Party shall be held liable or be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including without limitation embargoes, war, acts of war (whether war be declared or not), insurrections, terrorism, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Parties. The affected Party shall notify the other Parties of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

15.11  **Dispute Resolution.**

15.11.1  **Disputes.** The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from, or related to, this Agreement or to the breach hereof (collectively, “**Dispute**”). In particular, the Chief Executive Officers of the Parties shall attempt to resolve all Disputes. In the event that the Chief Executive Officers cannot reach an agreement regarding a Dispute, and a Party wishes to pursue the matter, each such Dispute that is not an “Excluded Claim” shall be finally resolved by binding arbitration under the then-current Rules of Arbitration of the International Chamber of Commerce (“**ICC**”) by three (3) arbitrators appointed in accordance with the said Rules and Section 15.11.2 below, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. As used in this Section 15.11, the term “**Excluded Claim**” shall mean a dispute that concerns the validity or infringement of a patent, trademark or copyright.

15.11.2  **Arbitration.** The arbitration shall be conducted by a panel of three (3) persons experienced in the pharmaceutical business who are independent of the Parties and neutral with respect to the Dispute presented for arbitration. Within [*]* days after initiation of arbitration, each of MEDcell and Argos shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [*]* days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC International Court of Arbitration. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English.

A Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. A Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees, and the Party that does not prevail in the arbitration proceeding shall pay the arbitrators’ and any administrative fees of arbitration. Except to the extent necessary to confirm an award or as may be required by law, no Party or an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(a) The Parties agree that any payments made pursuant to this Agreement pending resolution of the Dispute shall be refunded promptly if an arbitrator or court determines that such payments are not due.
(b) The Parties hereby agree that any disputed performance or suspended performances pending the resolution of the arbitration that the arbitrators determine to be required to be performed by a Party must be completed within a reasonable time period following the final decision of the arbitrator.

(c) The Parties hereby agree that any monetary payment to be made by a Party pursuant to a decision of the arbitrators shall be made in United States dollars, free of any tax or other deduction. The Parties further agree that the decision of the arbitrators shall be the sole, exclusive and binding remedy between them regarding determination of the matters presented to the arbitrator.

15.12 Independent Contractors. It is expressly agreed that Argos and Medinet and MEDcell shall be independent contractors and that the relationship between Argos and Medinet and MEDcell shall not constitute a partnership, joint venture or agency. Argos shall not have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on Medinet or MEDcell, without the prior written consent of Medinet or MEDcell, and Medinet or MEDcell shall not have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on Argos without the prior written consent of Argos.

15.13 Counterparts. The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15.14 Binding Effect; No Third Party Beneficiaries. As of the Effective Date, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective permitted successors and permitted assigns. Except as expressly set forth in this Agreement, no person or entity other than the Parties and their respective Affiliates and permitted assignees hereunder shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[THE REMAINDER OF THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK]
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

MEDCELL CO., LTD.

BY: /s/ Kunihiku Suzuki
NAME: Kunihiku Suzuki
TITLE: President

ARGOS THERAPEUTICS, INC.

BY: /s/ Jeffrey D. Abbey
NAME: Jeffrey D. Abbey
TITLE: President and CEO

MEDINET CO., LTD.

BY: /s/ Kunihiku Suzuki
NAME: Kunihiku Suzuki
TITLE: President and CEO
Arcelis is Argos’ proprietary active immunotherapy technology platform for generating fully personalized RNA-loaded dendritic cell immunotherapies. Argos uses the Arcelis platform to manufacture AGS-003, which is initially being developed for the treatment of mRCC, and AGS-004, which is being developed for the treatment of HIV.

The Arcelis platform is focused on dendritic cells that present antigens to the attention of the immune system and are critical to the human immune system’s recognition of the presence of proteins derived from cancer cells or virus-infected cells. Dendritic cells are capable of internalizing cancer protein antigens or virus protein antigens and displaying fragments of these protein antigens on their surface as small peptides. The dendritic cells then present these peptide antigens to T-cells capable of binding to these peptide antigens and producing a large complement of molecular factors that, in the case of cancer, lead to direct cancer cell death and, in the case of infectious disease, kill virus-infected cells to control the spread of infectious pathogens.

The following graphic illustrates the processes comprising our Arcelis platform:

As shown in the graphic above, the Arcelis platform requires two components derived from the particular patient to be treated, specifically:

- a disease sample from the patient — tumor cells in the case of cancer or a blood sample containing virus in the case of infectious disease — which is generally collected at the time of diagnosis or initial treatment, and

- dendritic cells derived from the patient’s monocytes, a particular type of white blood cell, which are obtained from the patient through a laboratory procedure called leukapheresis that occurs after diagnosis and at least four weeks prior to the initiation of our immunotherapy.
The tumor cells, or the blood sample containing the virus, and the leukapheresis product are shipped separately following collection from the clinical site to a centralized manufacturing facility where we use standard methods to isolate the patient’s mRNA, which is a key component of the genetic code, from the disease sample and amplify the mRNA. In parallel, we take the monocytes from the leukapheresis product and culture them using a proprietary process to create matured dendritic cells. Argos then immerses the matured dendritic cells in a solution of the patient’s isolated mRNA and a synthetic RNA that encodes a protein known as CD40 ligand, or CD40L, and apply a brief electric pulse to the solution, in a process referred to as electroporation. This process enables the patient’s isolated mRNA and the CD40L protein to pass into, or load, the dendritic cells. Argos then further cultures the mRNA-loaded dendritic cells so that these cells allow for antigen expression from the patient’s mRNA and presentation in the form of peptides on the surface of the dendritic cells. These mature, loaded dendritic cells are formulated into the patient’s plasma that was collected during the leukapheresis to become the Arcelis-based drug product. Argos then vials, freezes and ships the drug product to the clinic, which thaws the drug product and administers it to the patient by intradermal injection.

Upon injection into the skin of the patient, the antigen-loaded dendritic cells in the drug product migrate to the lymph nodes near the site of the injection. It is at these lymph nodes that the drug product comes into contact with T-cells. Argos believes that through this interaction the loaded dendritic cells orchestrate the differentiation, expansion and education, of antigen-specific T-cells. A unique property of the dendritic cells is that they result in the generation of CD8+ central and effector memory T-cells. Once activated and expanded, these T-cells are able to seek out and kill cancer or virus-infected cells that express the identical antigens as those displayed on the surface of the dendritic cells. Because the generation of these T-cells is dependent on secretion of IL-12 from the dendritic cells, measurement of IL-12 is a marker for potency of AGS-003 and potentially other Arcelis-based products.
SCHEDULE B

ARGOS PATENT RIGHTS

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**]
SCHEDULE C

AUTOMATED SYSTEMS

Argos Automated Systems were designed as works for hire by Invetech in collaboration with Argos.

The Automated Nucleic Acid Processing System includes systems, devices and components thereof, as well as related methods for automated processing of samples in a closed container, including automated isolation, purification, amplification, processing and packaging of nucleic acids. Examples of the Argos Automated Nucleic Acid Processing System are described in PCT Publication [**]. Uses of this System include isolation of RNA from tumor lysates, RT-PCR, in vitro transcription and related nucleic acid purification and packaging steps.

The Automated Cell Processing Systems are held as trade secret, with the exception of a centrifuge bowl described in International Patent Application [**] and medicament devices described in International Patent Application [**]. These System and components thereof automate many aspects of cell processing, differentiation, electroporation, and packaging. Uses of these System include automated differentiation of monocytes into mature RNA-loaded dendritic cells.
SCHEDULE D

ARGOS IN-LICENSES

2. License Agreement between University of Antwerp, Gerold Shuler and Argos dated April 1, 2012.
4. License Agreement between Argos (f/k/a Merix Bioscience, Inc.) and Duke University dated January 10, 2000, as amended.
<table>
<thead>
<tr>
<th>Name</th>
<th>Jurisdiction</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC Bio Corp.</td>
<td>Nova Scotia, Canada</td>
</tr>
</tbody>
</table>
We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-195223) of Argos Therapeutics, Inc. of our report dated March 31, 2015 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
March 31, 2015
CERTIFICATIONS

I, Jeffrey D. Abbey, certify that:

1. I have reviewed this Annual Report on Form 10-K of Argos Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2015

By: /s/ JEFFREY D. ABBEY

Jeffrey D. Abbey
President and Chief Executive Officer
(Principal Executive Officer)
CERTIFICATIONS

I, Lori R. Harrelson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Argos Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting;

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2015

By: /s/ LORI R. HARRELSON
Lori R. Harrelson
Vice President of Finance
(Principal Financial Officer)
CERTIFICATIONS PURSUANT TO 18 U.S.C. 1350

The undersigned, the Chief Executive Officer and the Vice President of Finance (principal financial officer) of Argos Therapeutics, Inc. (the “Company”), each hereby certifies that, to his/her knowledge on the date hereof:

(a) the Annual Report on Form 10-K of the Company for the period ended December 31, 2014 filed on the date hereof with the Securities and Exchange Commission (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ JEFFREY D. ABBEY
Jeffrey D. Abbey
Chief Executive Officer
March 31, 2015

By: /s/ LORI R. HARRELSON
Lori R. Harrelson
Vice President of Finance
(principal financial officer)
March 31, 2015