

ADVANCED CELL TECHNOLOGY, INC.

Form S-3

July 03, 2014

**As filed with the Securities and Exchange Commission on July 3, 2014**

**Registration No. 333-**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM S-3**

**REGISTRATION STATEMENT**

***UNDER***

***THE SECURITIES ACT OF 1933***

**ADVANCED CELL TECHNOLOGY, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

**33 Locke Drive**

**87-0656515**

(State or other  
jurisdiction of

**Marlborough, Massachusetts 01752**

(I.R.S. Employer

**(508) 756-1212**

Identification  
Number)

incorporation or  
organization)

(Address, including zip code, and telephone number, including area code,  
of registrant's principal executive offices)

**Edward Myles**

**Interim President, Chief Operating Officer and Chief Financial Officer**

**Advanced Cell Technology, Inc.**

**33 Locke Drive**

**Marlborough, Massachusetts 01752**

**(508) 756-1212**

(Name, address, including zip code, and telephone number,

including area code, of agent for service)

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*Copies to:*

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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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  Smaller reporting company   
(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

<b>Title of each class of securities to be registered</b>	<b>Amount to be Registered (1)</b>	<b>Proposed maximum offering price per share (2)</b>	<b>Proposed maximum aggregate offering price</b>	<b>Amount of registration fee</b>
Shares of Common Stock, par value \$0.001 per share	260,600,707	\$0.065	\$16,939,045.96	\$2,181.75

The registrant is registering for resale, from time to time, up to 260,600,707 shares of its common stock, par value \$0.001, that the registrant may sell and issue to Lincoln Park Capital Fund, LLC (“Lincoln Park”) pursuant to a Purchase Agreement, dated as of June 27, 2014, by and between Lincoln Park and the registrant. In the event of (1) stock splits, stock dividends, or similar transactions involving the common stock, the number of shares of common stock registered shall, unless otherwise expressly provided, automatically be deemed to cover the additional securities to be offered or issued pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended (the “Securities Act”).

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act (2) of 1933, as amended using the average of the high and low prices as reported on the Over-the-Counter Bulletin Board on June 30, 2014, which was \$0.065 per share.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.**

**The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

SUBJECT TO COMPLETION, DATED July 3, 2014

**PROSPECTUS**

**Advanced Cell Technology, Inc.**

**260,600,707 SHARES  
COMMON STOCK**

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This prospectus relates to the offer and sale of up to 260,600,707 shares of common stock, par value \$0.001, of Advanced Cell Technology, Inc., a Delaware corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the selling stockholder.

The shares of common stock being offered by the selling stockholder have been or may be issued pursuant to the purchase agreement dated June 27, 2014 that we entered into with Lincoln Park. See “The Lincoln Park Transaction” for a description of that agreement and “Selling Stockholder” for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an “underwriter”

within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution”.

Our common stock is currently quoted on the OTCQB, under the symbol “ACTC.” On July 2, 2014, the last reported sales price per share of our common stock on the OTCQB was \$0.07.

**An investment in our common stock involves a high degree of risk. See the heading “Risk Factors” commencing on page 11 of this prospectus for a discussion of these risks and in the sections entitled “Risk Factors” in our most recent annual report on Form 10-K and in any quarterly report on Form 10-Q, as well as in any prospectus supplement related to these specific offerings.**

**We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2014

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## **ABOUT THIS PROSPECTUS**

You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. Neither we nor the selling stockholders have authorized anyone to provide you with additional or different information. If anyone provides you with different or inconsistent information, you should not rely on it. The selling stockholders are not making an offer of these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of that document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

In this prospectus, unless otherwise indicated, “our company,” “we,” “us” or “our” refer to Advanced Cell Technology, Inc., a Delaware corporation, and its consolidated subsidiaries.



## **PROSPECTUS SUMMARY**

*This prospectus summary highlights certain information about our company and other information contained elsewhere in this prospectus or in documents incorporated by reference. This summary does not contain all of the information that you should consider before making an investment decision. You should carefully read the entire prospectus, any prospectus supplement, including the section entitled “Risk Factors” and the documents incorporated by reference into this prospectus, before making an investment decision.*

### **Our Business**

We are a biotechnology company focused on the development and commercialization of human embryonic stem cell (hESC) and adult stem cell technology. Our most advanced products are in clinical trials for the treatment of dry age-related macular degeneration, Stargardt’s macular degeneration and myopic macular degeneration. We are also developing several pre-clinical cell therapies for the treatment of other ocular disorders and for diseases outside the field of ophthalmology, including autoimmune, inflammatory and wound healing-related disorders. We have unique scientific leadership and research competencies which we believe provide opportunities for discovery and innovation in regenerative medicine.

We pursue differentiation approaches to generating transplantable tissues both in-house and through collaborations with other researchers who have particular interests in, and skills related to, cellular differentiation. Our research in this area includes projects focusing on developing many different cell types that may be used to treat a range of diseases across several therapeutic categories. Control of differentiation and the culture and growth of stem and differentiated cells are important current areas of research for us.

### ***Ophthalmology Programs***

We are developing a pipeline of stem cell derived therapeutics which may have use as treatment for degenerative diseases of the eye. In some instances, stem cell derived therapies may repair and replace damaged tissue in the eye, permitting restoration of otherwise lost vision. As our understanding of the underlying pathophysiology of ocular disease increases, we believe we will have additional opportunities to develop other therapeutic products for the ophthalmology market.

### ***Macular Degeneration Programs***

The largest indication involving macular degeneration is “age-related macular degeneration”, or AMD. AMD is the leading cause of blindness and visual impairment in adults over fifty years of age. It is estimated that the clinically detectable AMD patient population in North America and Europe includes about 25-30 million people across the range of disease, from early-stage to late-stage, or legal blindness. AMD represents one of the largest unmet medical needs in medicine today in terms of the lack of useful therapeutics. There is an exponential rise in prevalence and incidence rates with age, with the prevalence rates of late-stage AMD quadrupling every decade of life after the age of 40. Based on population aging trends, a recent article in the *Lancet* has projected that globally the number of people with AMD in 2020 will be about 196 million, increasing to 288 million by 2040.

Retinal pigment epithelium, or RPE, is a single layer of pigmented cells that form part of the blood/ocular barrier. The presence and integrity of the RPE layer is required for normal vision. RPE cells are positioned between the photoreceptor cell layer of the retina and the Bruch’s membrane and choroid, a layer filled with blood vessels. Because the photoreceptors see no direct blood supply, it is the role of the RPE layer to transport nutrients and oxygen to the photoreceptor cells, as well as to supply, recycle, and detoxify products involved with the phototransduction process – the process by which the photoreceptors turn light into a signal to be propagated along the optic nerve to the brain. In particular, the RPE layer serves as the transport layer that maintains the structure of the photoreceptor environment by acting as an intermediary between the nerve layer and blood vessels, supplying small molecules, transporting ions and water from the blood vessels to the photoreceptor layer. The RPE takes up nutrients such as glucose, retinol (Vitamin A), and fatty acids from the blood and delivers these nutrients to photoreceptors. The RPE layer also prevents the buildup of toxic metabolites around the nerve cells by transporting the metabolites to the blood. In addition, the RPE is able to secrete a variety of growth factors helping to maintain the structural integrity and organization of the photoreceptors.

As the name implies, age-related macular degeneration usually affects older adults, with loss of central vision required for reading, driving and other important activities of daily living due to chronic damage of the central retina. It occurs in “dry” (aka “atrophic” or “geographic”) and “wet” (aka “neovascular” or “exudative”) forms. In the case of dry AMD, the disease process appears to begin with loss of RPE cells (cell death) followed by some period of photoreceptor atrophy and inactivity, and after sufficient time, photoreceptor death. For most dry AMD patients, gradual loss of central vision occurs first. Wet AMD is an end-stage manifestation seen in approximately 10 percent of dry AMD patients, with the loss of the RPE layer and its ability to maintain the Bruch’s membrane function as a barrier resulting in failure of the membrane’s integrity and new blood capillaries penetrating into the photoreceptor space with ensuing rapid loss of vision. In addition to AMD, there are nearly 200 other forms of macular degenerative diseases which, even if the underlying causes are different, appear to follow a similar course of RPE loss followed by atrophy, inactivity and ultimately death of the photoreceptor. These include, for example, an inherited juvenile onset form of macular degeneration called Stargardt’s Macular Degeneration, or SMD.

It had been reported in scientific journal articles that a portion of the RPE layer can be transplanted from one part of the eye to the macula to allow rescue of photoreceptor function. In some instances, the investigators demonstrated that photoreceptors appeared present but were not functional, apparently due to the loss of an adjacent functional RPE layer. However, transplantation of a healthy RPE layer to the macula enabled photoreceptor function. Although limited in its potential as a therapeutic modality, RPE translocation is an important proof-of-principle regarding the use of the retinal pigment epithelium as treatment for vision loss secondary to macular degeneration.

Our research has indicated that RPE cells generated from pluripotent stem cell sources, such as an hESC line, could potentially solve the sourcing of transplantable RPE cells for treating macular degenerative conditions. It is likely that the area in which the RPE layer exists will maintain its relative immune-privilege in dry AMD patients, meaning that donor matching is not likely to be a significant limitation so that a single and scalable allogeneic source of RPE cells, one that can be manufactured in culture, might provide a therapeutic solution for the millions of patients affected by this disease. We have created a GMP-compliant hESC master stem cell bank and a GMP protocol for scaled-up manufacturing of human RPE cells from our hESC master bank. Extensive animal testing of the human RPE cells generated in culture has been conducted and has established that when injected into the eyes of test animals as a suspension of cells, the human RPE cells were able to home to areas of damage in the RPE layer, with engraftment and recapitulation of the correct anatomical structure in the back of the eye of the animals. As published in *Stem Cells*, we have also demonstrated that in animal models of macular degeneration, not only did the human RPE cells reform the correct structure, but also that the injection of the cells resulted in preservation of the photoreceptor layer and its function. That is, the injected human RPE cells repaired and restored the function of the RPE layer in animal models of disease.

This data, along with safety data we collected on the human RPE cells, or (our RPE Program), formed the basis of several Investigative New Drug, or IND, applications filed and approved by the U.S. Food and Drug Administration, or FDA, and an Investigational Medicinal Product Dossier, or IMPD, approved by the U.K. Medicines and Healthcare Products Regulatory Agency. In the U.S., one of our ongoing clinical trials is a Phase I/II study for treating dry AMD patients by injection of RPE cells made in culture from an hESC line. We are also conducting Phase I/II studies in both the U.S. and the U.K. for the treatment of SMD patients using the RPE cell injections.

We are conducting these three trials in cooperation with leading retinal surgeons at the top eye hospitals in the U.S. and the U.K. including: Jules Stein Eye Institute (UCLA), Wills Eye Institute, Bascom Palmer Eye Institute (University of Miami) and Massachusetts Eye and Ear Infirmary. The U.K. study is being led by investigators at Moorfields Eye Hospital in London. To ensure patient safety, the trials are being overseen by an independent Data Safety and Monitoring Board, or DSMB also comprised of leading retinal surgeons.

The design of the three ongoing trials is similar. Each is an ascending dosage trial, with review of each dosing group by the DSMB, and were originally designed to have enrolled a total of twelve patients in each. The first patients were treated July 2011. Upon reaching the halfway point for all three trials (the dosing of a total of 18 patients) without any adverse events associated with the injection of the RPE cells, approval was granted by the FDA to enroll earlier stage patients in the two U.S. studies.

We believe that the results from the SMD and dry AMD clinical trials, though very preliminary and representing a limited number of patients in an open-label study design, are promising. Preliminary results for the first dry AMD and first SMD patient were published in early 2012 in the *Lancet*. There have been no serious adverse events due to the injected RPE cells, which is the primary endpoint of the Phase 1 aspect of these studies. The trial sites have provided regular follow-up on all of the patients, and have been able to include data relating to the engraftment and persistence of the injected cells as well as impacts on visual acuity. The preliminary data suggest that the injected cells are well tolerated and appear generally to be capable of engrafting at the site of injection, forming the appropriate anatomical monolayer structure around the injected area. Visual acuity improvement was observed to varying degrees in several of these very late-stage patients, a result that was not anticipated in the original design of these studies.

In February 2013, we announced that our clinical partner, the Jules Stein Eye Institute at the University of California, Los Angeles had received approval of its Investigator IND Application to initiate a Phase 1/2 study using our RPE cells to treat myopic macular degeneration, or MMD, a form of macular degeneration that can occur in association with severe forms of myopia. Myopia, or nearsightedness, is the most common eye disorder in the world, and is a significant global public health concern. MMD is an important world-health issue lacking safe and effective treatments. Overall, MMD is reported to be the seventh ranking cause of legal blindness in the United States, the fourth ranking cause in Hong Kong and the second in parts of China and Japan. In June 2014, we announced that Jules Stein Eye Institute has initiated the trial.

MMD seems to be associated with stress on the RPE layer as a consequence to elongation of the eyeball structure in myopic patients. The stress can induce fissures in the RPE layer, leading to RPE cell death and ultimately macular dystrophy and degeneration. We are in the final stages of completing all of the necessary paperwork with Jules Stein Eye Institute and UCLA so that we can begin treating patients in this trial.

As we continue to manage our clinical trials and expand the indications for which our RPE cell therapy is being investigated, we have also begun to take the steps to define our final product formulation, as well as to lay the early ground work to support appropriate pricing and reimbursement programs. We believe that our RPE therapy provides pricing justification across all categories of consideration by Medicare, Medicaid, National Health Service (UK) and private payers. Our SMD program has been granted Orphan Drug status in both the U.S. and Europe, which could accordingly lead to accelerated regulatory approval, potential FDA grant opportunities, and opportunities for early and favorable pricing considerations.

#### *Photoreceptor Progenitor Program*

Photoreceptors mediate the first step in vision, capturing light and turning that into nerve signals to the brain. Rod photoreceptors are active in dim light, while cone photoreceptors are active in bright light and are required for color vision. The photoreceptor atrophy, and subsequent cell death and permanent loss of photoreceptors is seen in later stages of AMD. Loss of photoreceptors is also a consequence to diseases such as diabetes, retinitis pigmentosa, and

elevated intraocular pressure typically associated with glaucoma, and represents additional and significant causes of blindness in developed countries. We recognize the potential value of being able to repair the retina with replacement photoreceptor cells derived from pluripotent stem cell sources such as hESCs. We believe those therapies can provide the basis for new approaches for treating a wide variety of retinal degenerations in diseases where photoreceptors malfunction and/or die, either alone or in combination with our RPE therapy.

We have developed a human photoreceptor progenitor cell. We believe that our photoreceptor progenitor cells are unique with respect to both the markers they express as well as their plasticity, meaning that they can differentiate into both rods and cones, and therefore provide a viable source of new photoreceptors for retinal repair. In addition, our photoreceptor progenitors appear to secrete neuroprotective factors, and have the ability to phagocytose (digest) such materials as the drusen deposits that build up in the eyes of dry AMD patients, and so may provide additional benefits beyond forming new photoreceptors when injected into the subretinal space in the eyes of patients. We will continue our preclinical investigation in animal models, establish appropriate correlation between integration of the transplanted cells and visual function in the animals, and then consider preparation of an IND and/or IMPD application to commence clinical studies with these cells. As part of our evaluation of this program, we will consider, among other things, the data generated from pre-clinical studies, our understanding of the potential market opportunity, and our ability to allocate capital resources to adequately fund the program to the next milestone.

### *Retinal Ganglion Cell Progenitor Program*

In the United States alone, approximately 100,000 people are legally blind from glaucoma. The only proven treatment is drug therapy or surgically lowering the intraocular pressure, but many patients lose vision despite receiving these treatments. In glaucoma, retinal ganglion cells degenerate before photoreceptors are lost. We are currently conducting pre-clinical research and development activities regarding differentiation of stem cells into retinal ganglion cells and demonstration of the ability of those cells to protect against elevated intraocular pressure in glaucoma models. We have succeeded in generating a unique human ganglion progenitor cell which, when injected in animal models of glaucoma, appear to protect against damage and to form new ganglion nerve cells. We will continue our preclinical investigation in animal models, establish appropriate correlation between integration and visual function in the animals, and then consider preparation of an IND and/or IMPD application to commence clinical studies with these cells. As part of our evaluation of this program, we will consider, among other things, the data generated from pre-clinical studies, our understanding of the potential market opportunity, and our ability to allocate capital resources to adequately fund the program to the next milestone.

### *Corneal Endothelial Program*

We have been able to generate sheets of corneal endothelial cells, with Descemet membrane, from hESCs. These endothelial sheets, which resemble fetal cornea in cell density, and thickness and durability of the tissue graft, could serve as the transplanted tissue in DSEK. In culture, our corneal endothelial cells have all the hallmarks, both marker expression and morphology, of native human corneal endothelium. We are testing these cells in several animal models of corneal diseases. We will continue our pre-clinical investigation in animal models, with the goal of establishing that the transplanted tissue functions correctly in the animals, and then consider preparation of an IND and/or IMPD application to commence clinical studies with these cells. As part of our evaluation of this program, we will consider, among other things, the data generated from pre-clinical studies, our understanding of the potential market opportunity, and our ability to allocate capital resources to adequately fund the program to the next milestone.

### *Other Programs*

In addition to our ophthalmology programs we are investing resources into our other programs where we feel that we can leverage our expertise in cellular and developmental biology to generate allogeneic therapies that have the potential to improve health care in other prevalent degenerative diseases and diseases of aging. At the core of our pipeline planning are approaches intended to address large unmet medical needs with allogeneic stem cell-derived therapeutics. The criteria for prioritizing these programs include stem cell capability, competitive landscape within the therapeutic area and severity/prevalence of the therapeutic area. We also utilize a proof-of-concept, or POC, approach in our product development process, testing our candidate therapies in relevant animal models of human disease in order to assess the likelihood of success when it comes time to try those therapies in human patients. Our POC approach allows us to focus only on the most promising projects by verifying the science behind many ideas early in

the development process while terminating those programs with a low probability of success.

### *Mesenchymal Stem Cells*

Pluripotent stem-cell derived mesenchymal stem cells, or MSCs is the most active, of our “other programs”. MSCs regulate immune and inflammatory responses, providing therapeutic potential for treating diseases characterized by the presence of an inflammatory component, which makes them an attractive tool for the cellular treatment of autoimmunity and inflammation. Their underlying molecular mechanisms of action together with their clinical benefit — for example, in autoimmunity — are, in our opinion, being revealed by an increasing number of clinical trials and preclinical studies of MSCs. The immunosuppressive/ immunomodulatory activity of these cells allows MSCs to be transplanted nearly universally, i.e., as an allogeneic cell therapy, without matching between donors and recipients. MSCs’ universality, along with the ability to manufacture and store these cells long-term, present a unique opportunity to produce an "off-the-shelf" cellular drug ready for treatment of diseases in both acute and chronic settings.



The current source of MSCs for therapeutic applications are isolated from cord blood and adult sources such as bone marrow and adipose (fat) tissue. However, once isolated from the source, the MSCs present in these sources do not propagate well in cell culture. Rather, the cells undergo replicative senescence, or “aging,” within only a few passages (i.e., after a limited number of population doublings of cells through cell division). Accordingly, the number of doses of MSCs that can be generated from each donor is limited, and the process using adult MSC sources is consequently high-touch, and therefore riskier.

We believe we have succeeded at creating a differentiated MSC product by producing the cells in culture from a pluripotent stem cell source. Our cell culture process permits us to manufacture large scale quantities of MSC from a renewable stem cell source, potentially eliminating the sourcing issues attendant with relying on adult sources of these cells. The stem-cell-sourced manufacturing process is scalable for global commercialization of MSC therapies, and should prove to be less costly (particularly at commercial scale) when compared to the adult-sourced, and cord blood-sourced, MSC products in development by other companies.

In our preliminary testing of our stem cell-derived MSCs in animal models of autoimmune disease, we have noted another differentiating feature of our cells, relative to other MSCs. The MSCs generated using our proprietary manufacturing approach seem to be more potent with respect to suppressing autoimmune responses in certain diseases models when compared to the equivalent dose of bone marrow MSCs. This potency was dependent on the number of passages in culture our MSCs had been through, with the earlier passage MSCs retaining the greatest potency. This correlates with reports in the scientific literature which suggest that adult MSCs lose potency as they are propagated in culture, and reports indicating that MSC from young adult donors are more potent than MSC from elderly donors. Being derived from embryonic stem cells, the early-passage MSCs we are testing for potential therapeutic uses seem to represent the earliest and most potent stage of biological development for MSCs, a stage that cannot be obtained from adult sources.

We have initiated a number of pre-clinical studies designed to assess the therapeutic value of our MSC's in a number of disease indications, including: lupus, uveitis, sepsis, osteoarthritis and multiple sclerosis, among others. Some of our studies are being carried out in small animal models of disease, such as genetic or induced models. Others are being carried out on larger animals under an approved Investigational New Animal Drug, or INAD, application in place with the U.S. FDA.

Our goal is to conduct preclinical proof-of-concept studies in relevant veterinarian patients and laboratory animal models of disease, and based on those results, advance certain of these MSC discovery programs into IND-enabling pre-clinical studies and perhaps file IND applications, as circumstances dictate. We will evaluate opportunities for strategic partnering relationships, out-licensing or other commercial transactions with large pharmaceutical and biotech companies at various stages in these preclinical programs with an eye towards mitigating our overall cost of these programs.

**Principal Executive Office**

Our executive offices are located at 33 Locke Drive, Marlborough, MA 01752. Our website is located at [www.advancedcell.com](http://www.advancedcell.com), and our telephone number is 508-756-1212. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus, and you should not consider it part of this prospectus or part of any prospectus supplement. Our website address is included in this document as an inactive textual reference only.

## **This Offering**

On June 27, 2014, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from us up to \$30,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on June 27, 2014, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended, or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. As of June 30, 2014, we have issued 10,600,707 shares of our common stock to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement.

Other than 10,600,707 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may sell up to \$30,000,000 of our common stock over the 36-month period. We may, from time to time and at our sole discretion, direct Lincoln Park to purchase up to 3,500,000 shares of our common stock on any such business day, provided that in no event shall Lincoln Park purchase more than \$1,000,000 worth of our common stock on any single business day, plus an additional “accelerated amount” under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the up to 3,500,000 shares that may be sold to Lincoln Park under the Purchase Agreement on any business day will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than 0.03 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, forward or reverse stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day’s notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Previously, in September 2012, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the 2012 Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from us up to \$35,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. As of June 30, 2014, we have issued 536,036,958 shares of common stock to Lincoln Park under the 2012 Purchase Agreement.

The Purchase Agreement provides that we may sell up to \$30,000,000 of our common stock to Lincoln Park, though only 260,600,707 shares of our common stock are being offered under this prospectus, which represents (i)

10,600,707 shares that we issued to Lincoln Park as a commitment fee and (ii) an additional 250,000,000 shares which may be issued to Lincoln Park in the future under the Purchase Agreement. If all of the 260,600,707 shares offered by Lincoln Park under this prospectus were issued and outstanding as of June 30, 2014, such shares would represent approximately 7.33% of the total number of shares of our common stock outstanding and 7.45% of the total number of outstanding shares held by non-affiliates, in each case as of June 30, 2014. If we elect to issue and sell more than the 260,600,707 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Issuer Advanced Cell Technology, Inc.

260,600,707 shares consisting of

Common stock to be offered by the selling stockholder: -10,600,707 commitment shares issued to Lincoln Park, and  
-250,000,000 shares we may sell to Lincoln Park under the Purchase Agreement.

Common stock outstanding as of June 30, 2014: 3,296,586,368 shares, excluding the 10,600,707 commitment shares issued to Lincoln Park on June 27, 2014

Common stock to be outstanding after giving effect to the issuance of 260,600,707 shares under the Purchase Agreement: 3,557,187,075 shares

Use of Proceeds: We will not receive any proceeds from sales of the shares of common stock sold from time to time under this prospectus by Lincoln Park. However, we may receive up to \$30,000,000 under the Purchase Agreement with Lincoln Park. All proceeds that we receive from sales to Lincoln Park under the Purchase Agreement are used for general corporate purposes. See "Use of Proceeds."

Risk Factors: An investment in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 14 for a discussion of certain factors that you should consider when evaluating an investment in our common stock.

Symbol on OTCQB and OTCBB: ACTC

## **RISK FACTORS**

An investment in our company involves a high degree of risk. In addition to the other information included in this prospectus, you should carefully consider the following risk factors described in this prospectus and the risk factors that may be described in any applicable prospectus supplement and the documents incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading “Risk Factors” included in our most recent Annual Report on Form 10-K, as revised or supplemented by our most recent Quarterly Report on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. You should consider these matters in conjunction with the other information included or incorporated by reference in this prospectus. The risks and uncertainties described in this prospectus, any applicable prospectus supplement and the documents incorporated by reference herein are not the only ones facing us. Additional risks and uncertainties that we do not presently know about or that we currently believe are not material may also adversely affect our business. Our business, results of operations or financial condition could be seriously harmed, and the trading price of our common stock may decline due to any of these or other risks.

*This prospectus contains statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements appear in a number of places in this prospectus and include statements regarding the intent, belief or current expectations of our management, directors or officers primarily with respect to our future operating performance. Prospective purchasers of our securities are cautioned that these forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those in the forward-looking statements due to various factors. The accompanying information contained in this prospectus, including the information set forth below, identifies important factors that could cause these differences. See “Special Note Regarding Forward-Looking Statements” on page 35.*

### **Risks Relating to the Purchase Agreement with Lincoln Park**

*The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.*

On June 27, 2014, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$30,000,000 of our common stock. Concurrently with the execution of the Purchase Agreement on June 27, 2014, we issued 10,600,707 shares of our common stock to Lincoln Park as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement. The additional

purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the SEC declared effective the registration statement that this prospectus forms a part.

The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the closing sale price of our common stock is below \$0.03 per share, subject to adjustment as set forth in the Purchase Agreement. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Therefore, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

*We may require additional financing to sustain our operations and without it we may not be able to continue operations.*

As of March 31, 2014, we have an accumulated deficit of \$322,605,844 and a stockholders' deficit of \$20,677,558. We incurred net losses of \$31,022,248, \$34,584,115, and \$55,192,803 for the years ended December 31, 2013, 2012, and 2011, respectively, respectively and a net loss of \$8,689,774 for the three months ended March 31, 2014. We do not currently have sufficient financial resources to fund our operations or those of our subsidiaries. Therefore, we need additional funds to continue these operations.

As of June 27, 2014, we may direct Lincoln Park to purchase up to \$30,000,000 worth of shares of our common stock under the Purchase Agreement over an approximately 36-month period generally in amounts up to 3,500,000 shares of our common stock on any such business day, provided that in no event shall Lincoln Park purchase more than \$1,000,000 worth of our common stock on any single business day, plus an additional "accelerated amount" under certain circumstances. However, Lincoln Park shall not purchase any shares of our common stock on any business day that the closing sale price of our common stock is less than \$0.03 per share, subject to adjustment as set forth in the Purchase Agreement. Assuming a purchase price of \$0.07 per share (the closing sales price of the common stock on July 2, 2014) and the purchase by Lincoln Park of 250,000,000 shares included in this prospectus under the Purchase Agreement, proceeds to us would only be \$17,500,000.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all \$30,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

### **Risks Relating to the Company's Early Stage of Development and Capital Resources**

*Our primary source of liquidity is this financing arrangement with Lincoln Park, and changes in our share price directly affect our ability to fund our operations.*

We currently rely on our share purchase arrangement with Lincoln Park to fund our ongoing operations. Pursuant to the Purchase Agreement with Lincoln Park, the purchase price of such common stock sold to Lincoln Park is based on the prevailing market price of our common stock immediately preceding the time of sales; we control the timing and



amount of any future sales, if any, of common stock. There are no upper limits to the price Lincoln Park may pay to purchase our common stock. The purchase price in most cases is directly derived from the prevailing market price of our common stock on OTCBB. Though the purchase price cannot be less than \$0.03, subject to adjustment as set forth in the Purchase Agreement, this arrangement means that our prevailing share price directly affects the number of shares we need to issue to Lincoln Park at any given time to fund short-term operations. The number of shares issuable under our Certificate of Incorporation and the number of shares to be registered under this prospectus to register the shares sold to Lincoln Park are both limited, and a share price that falls and stays too low would make it difficult or impossible to fund our operations through sales of shares to Lincoln Park due to these limitations.

***Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.***

Our most advanced product candidates are in Phase I/II clinical trials and we don't have any products that are currently in the marketplace. Our potential therapeutic products will require extensive preclinical and clinical testing prior to regulatory approval in the United States and other countries and may additionally require post-authorization outcome studies. We may not be able to obtain regulatory approvals in some cases (see the subsection entitled "Regulatory Risks" below), or commence or continue clinical trials for some of our products, or commercialize any products. Any of our therapeutic and product candidates may prove to have undesirable and unintended side effects or other characteristics that could cause adverse effects on patient safety, efficacy or cost-effectiveness that could prevent or limit their therapeutic use, commercialization or acceptance in the medical community. Any product using any of our technologies may fail to provide the intended therapeutic benefits, or even achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production, or may not be safe for use in humans. In addition, we will need to determine whether any of our potential products can be manufactured in commercial quantities or at an acceptable cost, with or without third-party support. Our efforts may not result in a product that can be or will be marketed successfully. Physicians may not prescribe our products, and patients or third party payors may not accept or reimburse for use of our products. For these reasons we may not be able to generate product revenues.

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

We have limited clinical testing, regulatory, manufacturing, marketing, distribution and sales experience capabilities, which may limit our ability to generate revenues. Due to the early stage of our therapeutic products, including regenerative medical therapies and stem cell therapy-based programs, we have not yet invested significantly in regulatory, manufacturing, marketing, distribution or product sales resources. We cannot assure you that we will be able to invest or develop any of these resources successfully or as expediently as necessary, alone or with strategic partners. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our therapeutic candidates;
- seeking and obtaining regulatory and marketing approvals for therapeutic candidates for which we complete clinical studies;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our therapeutic candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for our therapeutic candidates, if approved;
- launching and commercializing therapeutic candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- obtaining market acceptance of our therapeutic candidates as a viable treatment option;

adequately addressing any competing technological and market developments;

- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new therapeutic candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the therapeutic candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate, including costs related to additional clinical studies, and such costs may exceed our estimates. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. The inability to do so will inhibit or harm our ability to generate revenues or operate profitably.

***We have a history of operating losses and we may not achieve future revenues or operating profits.***

We have generated modest revenue to date from our operations. Historically we have had net operating losses each year since our inception. We have limited current potential sources of income from licensing fees and we do not generate significant revenue from any other source. Additionally, even if we are able to commercialize our technologies or any products or services related to our technologies if approved, it is not certain that they will result in revenue or profitability.

***We have a limited operating history on which investors may evaluate our operations and prospects for profitable operations.***

If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may perhaps lose their entire investment. Our prospects must be considered speculative in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development, particularly in light of the uncertainties relating to the new, competitive and rapidly evolving markets in which we anticipate we will operate. A substantial risk is involved in investing in us because, as an early stage company, we have fewer resources than an established company, our management may be more likely to make mistakes at such an early stage, and we may be

more vulnerable operationally and financially to any mistakes that may be made, as well as to external factors beyond our control. We also have no experience bringing therapeutics candidates through the regulatory approval process to commercialization, and we operate with little budgetary margin for error. To attempt to address these risks, we must, among other things, further develop our technologies, products and services, successfully implement our research, development, marketing and commercialization strategies, respond to competitive developments and attract, retain and motivate qualified personnel. Any failure to achieve any of the forgoing would result in an inability to achieve profitability.

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

As of June 30, 2014, we had 33 full-time employees. As we mature and undertake the activities required to further develop and commercialize our therapeutic candidates, we may expand our full-time employee base and hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

### **Risks Relating to Technology**

*We are dependent on new and unproven technologies.*

Our risks as an early stage company are compounded by our heavy dependence on unproven technologies. If these technologies do not produce satisfactory results in the clinical trial setting and/or are unable to gain regulatory approval, our business may be harmed. We have not shown an ability to bring any therapeutic candidate through the regulatory process to marketing approval. Given the unproven nature of our technology and potential product candidates, the FDA or other regulatory agency may require additional clinical data or manufacturing practices than that required of other conventional therapies. Additionally some of our technologies and potential revenue sources involve ethically sensitive and controversial issues which could become the subject of legislation or regulations materially restricting our development programs, future sales and marketing and other operations and, therefore, harm our financial condition and operating results.

*We may not be able to commercially develop our technologies and proposed product lines, which, in turn, would significantly harm our ability to earn revenues and result in a loss of investment.*

Our ability to commercially develop our technologies may be limited in part by a number of factors including, but not limited to, general economic conditions, the success of our research and pre-clinical and field testing, the availability of collaborative partners willing and able finance our work in pursuing applications of cell therapy technologies, and

technological or other developments in the biomedical field which may render our technologies obsolete or competitively unattractive. We may not pursue one or more commercialization strategies at all if we cannot locate a collaborative partner or entity willing to fund research and development or if we cannot agree to acceptable terms governing a potential development or marketing collaboration. Our decisions regarding the ultimate products and/or services we pursue could have a significant adverse effect on our ability to earn revenue if we misinterpret trends, underestimate development costs and/or pursue wrong products or services. Any of these factors either alone or in concert could materially harm our ability to earn revenues or could result in a loss of any investment in us.

***We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.***

We are engaged in activities in the biotechnology field, which is characterized by extensive research efforts and rapid technological progress. If we fail to anticipate or respond adequately to technological developments, our ability to operate profitably could suffer. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than us. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. We cannot assure you that research and discoveries by other biotechnology, agricultural, pharmaceutical or other companies will not render our technologies or potential products or services uneconomical or result in products superior to those we develop or that any technologies, products or services we develop will be preferred to any existing or newly-developed technologies, products or services.

## **Risks Related to Intellectual Property**

*Certain aspects of our business are dependent upon maintaining licenses with respect to key technology; if we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our markets.*

Several of the patents we utilize are licensed to us by third parties. These licenses are subject to termination under certain circumstances (including, for example, our failure to make minimum royalty payments or to timely achieve spending, development and commercialization benchmarks). The loss of any of such licenses, or the conversion of such licenses to non-exclusive licenses, could harm our operations and/or enhance the prospects of our competitors. Certain of these licenses also contain restrictions, such as limitations on our ability to grant sublicenses that could materially interfere with our ability to generate revenue through the licensing or sale to third parties of important and valuable technologies that we have, for strategic reasons, elected not to pursue directly. The possibility exists that in the future we will require further licenses to complete and/or commercialize our proposed products. We cannot assure you that we will be able to acquire any such licenses on a commercially viable basis.

*Certain parts of our technology are not protectable by patent.*

Certain parts of our know-how and technology are not patentable. To protect our proprietary position in such know-how and technology, we require all employees, consultants, advisors and collaborators to enter into confidentiality and invention ownership agreements with us. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, in the absence of patent protection, competitors who independently develop substantially equivalent technology may harm our business.

*Patent litigation presents an ongoing threat to our business with respect to both outcomes and costs.*

We have previously been involved in patent interference litigation, and it is possible that further litigation or patent office proceedings (such as oppositions, observations and/or reexaminations) over one or more of our own patent filings could arise. We could incur substantial litigation costs or costs associated with patent office proceedings in defending ourselves against suits or other actions brought against us or in suits in which we may assert our patents against others. If the outcome of any such litigation or patent office proceeding is unfavorable, our business could be materially adversely affected. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect its business and prospects. Our competitors may independently develop proprietary technologies and processes that design around the coverage our patents.



Without additional capital, we may not have the resources to adequately defend or pursue such litigation or patent office proceedings. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

***We may not be able to protect our proprietary technology, which could harm our ability to operate profitably.***

The biotechnology and pharmaceutical industries place considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, to a substantial degree, on our ability to obtain and enforce patent protection for our products, preserve any trade secrets and operate without infringing the proprietary rights of others. We cannot assure you that:

- we will succeed in obtaining any patents in a timely manner or at all, or that the breadth or degree of protection of any such patents will protect our interests, or that such patents would even be enforceable;
- the use of our technology will not infringe on the proprietary rights of others;
- patent applications relating to our potential products or technologies will result in the issuance of any patents or that, if issued, such patents will afford adequate protection to us or not be challenged, invalidated or infringed;
- if issued, patents might not be declared as unenforceable or invalid by operation of law;
- patents will not issue to other parties, which may be infringed by our potential products or technologies; and
- we will continue to have the financial resources necessary to prosecute our existing patent applications, pay maintenance fees on patents and patent applications, or file patent applications on new inventions.

We are aware of certain patents that have been granted to others and certain patent applications that have been filed by others with respect to iPS cells and embryonic stem cells, and other stem cell technologies. The fields in which we operate have been characterized by significant efforts by competitors to establish dominant or blocking patent rights to gain a competitive advantage, and by considerable differences of opinion as to the value and legal legitimacy of competitors' purported patent rights and the technologies they actually utilize in their businesses.

***Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products.***

A number of other pharmaceutical, biotechnology and other companies, universities and research institutions have potentially relevant to or required in the manufacturing, storage, sale or use of our expected products. In the case of pending patent application, we cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed patent applications, which in some cases have resulted in issued patents, relating to the generation, formulation and uses of various stem cells, as well as RPE cells, photoreceptor progenitor cells, and mesenchymal stem cells.

If third party patents or patent applications contain claims infringed by us or any strategic partner or other licensee of our products, such as for the manufacturing, storage, sale or use of our expected products, and such patent claims are ultimately determined to be valid and enforceable against us or our licensees, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop some products

commercially. We may be required to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us or our licensees to cease using such technology.

***Changes in U.S. patent law and in patent law in other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings and rulings from the European Patent Office Board of Appeals have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including potentially relating to the patentability of cells and tissues generated from hESC lines. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, and equivalents bodies in other major markets, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***We may not be able to adequately defend against piracy of intellectual property in foreign jurisdictions.***

Considerable research in the areas of stem cells, cell therapeutics and regenerative medicine is being performed in countries outside of the United States, and a number of potential competitors are located in these countries. The laws protecting intellectual property in some of those countries may not provide adequate protection to prevent our competitors from misappropriating our intellectual property. Several of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

## **Regulatory Risks**

***We cannot market our product candidates until we receive regulatory approval; even if we complete the necessary preclinical and clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.***

Development of our products is subject to extensive regulation by governmental authorities in the United States and other countries. The process of obtaining regulatory approval is lengthy, expensive and uncertain. In the United States, the FDA imposes substantial requirements on the introduction of biological products and many medical devices through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years and the time required to do so may vary substantially based upon the type and complexity of the biological product or medical device.

Product candidates that we believe should be classified as medical devices for purposes of the FDA regulatory pathway may be determined by the FDA to be biologic products subject to the satisfaction of significantly more stringent requirements for FDA approval. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our business and cause our stock price to significantly decline.

If we fail to obtain regulatory approval of any of our product candidates for at least one indication, we will not be permitted to market our product candidates and may be forced to cease our operations. Even if our product candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval at all. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on any approved indications. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product

development, clinical studies and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates.

***Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.***

Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Conditions of approval, such as limiting the category of patients who can use the product, may significantly impact our ability to commercialize the product and may make it difficult or impossible for us to market a product profitably. In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices, or GMP, and adherence to commitments made to the FDA in the approval process. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured or manufacturing issues, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

FDA approval of our products may also entail ongoing requirements for post-marketing studies, or limit how or to whom we can sell its products. Even if we obtain regulatory approval, labeling, promotional and manufacturing activities are subject to continual scrutiny by the FDA, state regulatory agencies and, in some circumstances, the Federal Trade Commission. In addition, FDA enforcement policy prohibits the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA's and other third-party payers interpretation of them could materially increase our expenses, impair its ability to effectively market its products, and limit our revenue.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, if our product candidates are approved by the FDA or other regulatory authorities for the treatment of any indications, regulatory labeling may specify that our product candidates may be used in conjunction with other therapies. The occurrence of any of these events or penalties may inhibit our ability to commercialize our product candidates and generate revenues.

***Once obtained, regulatory approvals may be withdrawn and can be expensive to maintain.***

Regulatory approval may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. Regulatory approval may also require costly post-marketing follow-up studies, and failure of our product candidates to demonstrate sufficient efficacy and safety in these studies may result in either withdrawal of marketing approval or severe limitations on permitted product usage. In addition, numerous additional regulatory requirements relating to, among other things, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping will also apply. Furthermore, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Compliance with these

regulatory requirements is time-consuming and requires the expenditure of substantial resources.

If any of our product candidates is approved, we will be required to report certain adverse events involving our products to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning the advertisement and promotional labeling of our products. As a result, even if we obtain necessary regulatory approvals to market our product candidates for any indication, any adverse results, circumstances or events that are subsequently discovered could require that we cease marketing the product for that indication or expend additional money, time and effort to ensure full compliance, which could have an adverse effect on our business or results of operations.

***If our products do not comply with applicable laws and regulations our business will be harmed.***

Any failure by us or by any third parties that may manufacture or market our products, to comply with the law, including statutes and regulations administered by the FDA or other U.S. or foreign regulatory authorities, could result in, among other things, warning letters, fines and other civil penalties, suspension of regulatory approvals and the resulting requirement that we suspend sales of our products, refusal to approve pending applications or supplements to approved applications, export or import restrictions, interruption of production, operating restrictions, closure of the facilities used by us or third parties to manufacture our product candidates, injunctions or criminal prosecution. Any of the foregoing actions could have an adverse effect on our business.

*The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community, and our products may not be accepted in the marketplace.*

If we are successful in obtaining regulatory approval for any of our product candidates, the degree of market acceptance of those products will depend on many factors, including:

- our ability to provide acceptable evidence of, and the perception of patients and the healthcare community, including third party payors, of, the potential advantages of our product candidates relative to existing treatment methods;
- the incidence and severity of any adverse side effects of our product candidates;
- the availability and efficacy of alternative treatments;
  
- the labeling requirements imposed by the FDA and foreign regulatory agencies on our products and related marketing materials, including the scope of approved indications and any safety warnings;
  
- our ability to obtain sufficient third party insurance coverage or reimbursement for our product candidates;
  
- the inclusion of our products on insurance company coverage policies;
  
- the willingness and ability of patients and the healthcare community to adopt new technologies;
  
- public opinion and acceptance of stem cell therapy in general, including media coverage and activism by religious, social or political groups;
  
- the procedure time associated with the use of our product candidates, including time between and frequency of dosage;
  
- our ability to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates with acceptable quality and at an acceptable cost to meet demand; and
  
- internal or external marketing and distribution support for our products.



We cannot predict or guarantee that physicians, patients, healthcare insurers, third party payors or health maintenance organizations, or the healthcare community in general, will accept or utilize any of our product candidates. Failure to achieve market acceptance would limit our ability to generate revenue and would have a material adverse effect on our business. In addition, if any of our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost-effective.

***Restrictions on the use of human embryonic stem cells, the ethical, legal and social implications of stem cell research, and negative public opinion about stem cell therapy may damage public perception of our therapeutic candidates and could prevent us from developing or gaining acceptance for commercially viable products.***

Some of our most important programs involve the use of stem cells that are derived from human embryos. The use of human embryonic stem cells gives rise to ethical, legal and social issues regarding the appropriate derivation of these cells. In the event that our research related to human embryonic stem cells becomes the subject of adverse commentary or publicity or increased scrutiny by governmental or regulatory organizations, our business could be harmed or otherwise substantially impaired, and the market price for our common stock could be significantly harmed. Some political and religious groups have voiced opposition to our technology and practices. We use stem cells derived from human embryos that have been created for *in vitro* fertilization procedures but are no longer desired or suitable for that use and are donated with appropriate informed consent for research use. Many research institutions, including some of our scientific collaborators, have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of research conducted using human embryonic stem cells, thereby impairing our ability to conduct research in this field.

***Governmental regulations and laws could change.***

There can be no assurance that our operations will not be restricted by any future legislative or administrative efforts by politicians or groups opposed to the development of human embryonic stem cell technology or nuclear transfer technology. Additionally, the scope of the Dickey–Wicker Amendment, a 16 year-old ban on U.S. federal funding for activity related to the harm or destruction of an embryo, was recently under review by the federal courts and while it was determined not to preclude funding of human embryonic stem cell research by the federal government, there can be no assurance that it will not be challenged again or the language modified by Congress so as to restrict government funding of human embryonic stem cell research. Judicial review of this or other U.S. federal or state laws, the occurrence and results of which are difficult to predict with any certainty, could result in a more restrictive interpretation of those laws than is previously the case, and may limit or require us to terminate certain of our research and therapeutic programs.

***Because we or our collaborators must obtain regulatory approval to market our products in the United States and other countries, we cannot predict whether or when we will be permitted to commercialize our products.***

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern many of our activities. We are or may become subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. The preclinical testing and clinical trials of the products that we or our collaborators develop are subject to extensive government regulation that may prevent us from creating

commercially viable products from our discoveries. In addition, the sale by us or our collaborators of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising and promoting, selling and marketing, labeling and distributing.

If, and to the extent that, we are unable to comply with these regulations, our ability to earn revenues will be materially and negatively impacted. The regulatory process, particularly in the biotechnology field, is uncertain, can take many years and requires the expenditure of substantial resources. Biological drugs and non-biological drugs are rigorously regulated. In particular, proposed human pharmaceutical therapeutic product candidates are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the United States and similar health authorities in other countries in order to demonstrate safety and efficacy. We may never obtain regulatory approval to market our proposed products.

***Our products may not receive FDA approval, which would prevent us from commercially marketing our products and producing revenues.***

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture and marketing of pharmaceutical products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and varies substantially based upon the type, complexity and novelty of the proposed product. We cannot assure you that FDA approvals for any products developed by us will be granted on a timely basis, if at all. Any such delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of our products and our ability to generate product revenue.

***We may not be able to obtain required approvals in countries other than the United States.***

The requirements governing the conduct of clinical trials and cell culturing as well as the marketing approval process for our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval processes. Some foreign regulatory agencies also must approve prices of the products. 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. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our product candidates in any foreign country. If we fail to comply with these regulatory requirements or fail to obtain and maintain required approvals in any foreign country, we will not be able to sell our product candidates in that country and our ability to generate revenue will be adversely affected.

***The United States federal government maintains certain rights in technology that we develop using federal government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established federal government guidelines.***

Certain of our and our licensors' research have been or are being funded in part by U.S. federal government grants. In connection with certain grants, the federal government retains rights in the technology developed with the grant. These rights could restrict our ability to fully capitalize upon the value of this research.

## **Financial Risks**

***We may not be able to raise the required capital to conduct our operations and develop and commercialize our products.***

We require substantial additional capital resources in order to conduct our operations and develop and commercialize our products and run our facilities. We will need significant additional funds, a collaborative partner, or both, to finance the research and development activities of our therapies and potential products. Accordingly, we are continuing to pursue additional sources of financing. Our future capital requirements will depend upon many factors, including:

- the continued progress and cost of our research and development programs;

- the progression, timing and results of our pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- the costs in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the costs of developing sales, marketing and distribution channels and our ability to sell the therapies/products if developed;
- the costs involved in establishing manufacturing capabilities for commercial quantities of our proposed products;
- competing technological and market developments;

market acceptance of our proposed products;

costs associated with defending any litigation or regulatory investigations, including SEC investigations, investor litigation, or litigation regarding potential infringement by us of third-party intellectual property rights;

the costs for recruiting and retaining employees and consultants; and

the costs for educating and training physicians about our proposed therapies/products.

Additional financing through strategic collaborations, public or private equity financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our shareholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize on our own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs or potential products, any of which could have an adverse effect on our financial condition or business prospects.

### **Risks Related to Third Party Reliance**

*We depend on third parties to assist us in the conduct of our preclinical studies and clinical trials, and any failure of those parties to fulfill their obligations could result in costs and delays and prevent us from obtaining regulatory approval or successfully commercializing our product candidates on a timely basis, if at all.*

We engage consultants and contract research organizations to help design, and to assist us in conducting, our preclinical studies and clinical trials and to collect and analyze data from those studies and trials. The consultants and contract research organizations we engage interact with clinical investigators to enroll patients in our clinical trials. As a result, we depend on these consultants and contract research organizations to perform the studies and trials in accordance with the investigational plan and protocol for each product candidate and in compliance with regulations and standards, commonly referred to as “good clinical practice,” for conducting, recording and reporting results of clinical trials to assure that the data and results are credible and accurate and the trial participants are adequately protected, as required by the FDA and foreign regulatory agencies. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers.

*We depend on our collaborators to help us develop and test our proposed products, and our ability to develop and commercialize products may be impaired or delayed if collaborations are unsuccessful.*

Our strategy for the development, clinical testing and commercialization of our proposed products requires that we enter into collaborations with corporate partners, licensors, licensees and others. We are dependent upon the subsequent success of these other parties in performing their respective responsibilities and the continued cooperation of our partners. Under agreements with collaborators, we may rely significantly on such collaborators to, among other things:

- design and conduct advanced clinical trials in the event that we reach clinical trials;
- fund research and development activities with us;
- pay us royalties or fees upon the achievement of milestones; and
- market with us any commercial products that result from our collaborations.

Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to supporting our research and development activities related to or any diligence obligations on the part of these collaborators under our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. The development and commercialization of potential products will be delayed if collaborators fail to conduct these activities in a timely manner, or at all. In addition, our collaborators could terminate their agreements with us and we may not receive any development or milestone payments. If we do not achieve milestones set forth in the agreements, or if our collaborators breach or terminate their collaborative agreements with us, our business may be materially harmed.

***Our reliance on the activities of our non-employee consultants, research institutions, and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.***

We rely extensively upon and have relationships with scientific consultants at academic and other institutions, some of whom conduct research at our request, and other consultants with expertise in clinical development strategy or other matters. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these consultants and, except as otherwise required by our collaboration and consulting agreements to the extent they exist, can expect only limited amounts of their time to be dedicated to our activities. These research facilities may have commitments to other commercial and non-commercial entities. We have limited control over the operations of these laboratories and can expect only limited amounts of time to be dedicated to our research goals.

### **Preclinical & Clinical Product Development Risks**

***We have limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals.***

Our limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. If we do not succeed in conducting and managing our preclinical development activities or clinical trials or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. In addition, even if we are successful in obtaining necessary regulatory approvals and



bringing one or more product candidates to market, we will be subject to the risk that the marketplace will not accept those products. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

***Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable.***

Our failure to successfully commercialize our product candidates or to become and remain profitable could depress the market price of our common stock and impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

***None of the products that we are currently developing has been approved for marketing by the FDA or any similar regulatory authority in any foreign country, and may never be so approved. Our approach of using cell-based therapy for the treatment of retinal diseases such as Startgardt's disease and dry AMD is risky and unproven and no products using this approach have received regulatory approval in the United States or Europe.***

We believe that no other company has yet been successful in its efforts to obtain regulatory approval in the United States or Europe of a cell-based therapy product for the treatment of retinal disease or degeneration in humans. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials while achieving sufficiently satisfactory results, we will not receive regulatory approval for or be able to commercialize our product candidates.

***Our lead product candidates, our therapeutic Retinal programs for Startgardt's disease and Dry AMD, have been in Phase I Clinical Trials and have not yet received market approval from the FDA or any similar foreign regulatory authority for any indication.***

We cannot market any product candidate until regulatory agencies grant approval or licensure. In order to obtain regulatory approval for the sale of any product candidate, we must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective for each indication under the applicable standards relating to such product candidate. The preclinical studies and clinical trials of any product candidates must comply with the regulations of the FDA and other governmental authorities in the United States and similar agencies in other countries. Our therapeutic Retinal programs may never receive market approval from the FDA or any similar foreign regulatory authority.

In addition, we may experience numerous unforeseen events during, or even if approved for clinical trials, as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:

- The FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our cell culturing processes or facilities unsatisfactory;
- Officials at the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;
- Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;

The FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations; There may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct or continue clinical trials at current or prospective sites;

• We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;

• We may experience difficulties in managing multiple clinical sites;

• Enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays;

• We may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials; and

• Our product candidates may be deemed unsafe or ineffective, or may be perceived as being unsafe or ineffective, by healthcare providers for a particular indication.

Any failure or delay in obtaining regulatory approval will negatively affect our financial results and harm our business.

## **Risks Related to Competition**

*The market for therapeutic stem cell products is highly competitive.*

We expect that our most significant competitors will be fully integrated pharmaceutical companies and more established biotechnology companies. These companies are developing stem cell-based products and they have significantly greater capital resources in research and development, manufacturing, testing, obtaining regulatory approvals and marketing capabilities. Many of these potential competitors are further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent recognition and filings.

*The biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies operating in the fields of regenerative medicine, cell therapy, tissue engineering and tissue regeneration.*

Many of these companies are well-established and possess technical, research and development, financial and sales and marketing resources significantly greater than ours. In addition, certain smaller biotech companies have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies' potential research and development and commercialization advantages. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those we are developing. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before we do.



***In the general area of cell-based therapies (including both allogeneic and autologous cell therapies), we compete with a variety of companies, most of whom are specialty biotechnology companies, such as, Genzyme Corporation, StemCells, Inc., Inc., Viacell, Inc., Biotime, Inc., ISCO, MG Biotherapeutics, Pfizer, GlaxoSmithKline, Novartis, Roche, Cell Cure Neurosciences Ltd., Celgene, Baxter Healthcare, Mesoblast, Osiris Therapeutics and Cytori.***

Each of these companies is well-established and have substantial technical and financial resources compared to us. However, as cell-based products are only just emerging as medical therapies, many of our direct competitors are smaller biotechnology and specialty medical products companies. These smaller companies may become significant competitors through rapid evolution of new technologies. Any of these companies could substantially strengthen their competitive position through strategic alliances or collaborative arrangements with large pharmaceutical or biotechnology companies.

***Our competition includes both public and private organizations and collaborations among academic institutions and large pharmaceutical companies, most of which have significantly greater experience and financial resources than we do.***

Private and public academic and research institutions also compete with us in the research and development of therapeutic products based on human embryonic and adult stem cell technologies. In the past several years, the pharmaceutical industry has selectively entered into collaborations with both public and private organizations to explore the possibilities that stem cell therapies may present for substantive breakthroughs in the fight against disease.

***The biotechnology and pharmaceutical industries are characterized by intense competition. We compete against numerous companies, both domestic and foreign, many of which have substantially greater experience and financial and other resources than we have. Several such enterprises have initiated cell therapy research programs and/or efforts to treat the same diseases targeted by us.***

Companies such as Pfizer, Genzyme Corporation, GlaxoSmithKline, Novartis, Roche, Cell Cure Neurosciences Ltd., Mesoblast, Cytori, StemCells, Inc. and Viacell, Inc., as well as others, many of which have substantially greater resources and experience in our fields than we do, are well situated to effectively compete with us. Any of the world's largest pharmaceutical companies represents a significant actual or potential competitor with vastly greater resources than ours. These companies hold licenses to genetic selection technologies and other technologies that are competitive with our technologies. These and other competitive enterprises have devoted, and will continue to devote, substantial resources to the development of technologies and products in competition with us.

***Many of our competitors have significantly greater experience than we have in the development, pre-clinical testing and human clinical trials of biotechnology and pharmaceutical products, in obtaining FDA and other***

*regulatory approvals of such products and in manufacturing and marketing such products.*

Accordingly our competitors may succeed in obtaining FDA approval for products more rapidly or effectively than we can. Our competitors may also be the first to discover and obtain a valid patent to a particular stem cell technology which may effectively block all others from doing so. It will be important for us or our collaborators to be the first to discover any stem cell technology that we are seeking to discover. Failure to be the first could prevent us from commercializing all of our research and development affected by that discovery. Additionally, if we commence commercial sales of any products, we will also be competing with respect to manufacturing efficiency and sales and marketing capabilities: areas in which we have no experience.

### **General Risks Relating to Our Business**

*We are subject to litigation that will be costly to defend or pursue and uncertain in its outcome.*

Our business may bring us into conflict with our licensees, licensors or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. That litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

A significant adverse determination in any claim against us could adversely affect our operating results or financial condition. The amount we may be required to pay, in cash or in stock, in connection with any Claim may prove to exceed our estimated reserves and, in the case of payment in the form of stock, may prove to be highly dilutive to our stockholders. Should any judgment or settlement occur that exceeds our estimate, or a new claim arise, or if we become aware of additional information that requires us to adjust our estimation of potential exposure, we may need to adjust our overall reserve and, depending on the amount, such adjustment could be material and adversely affect our operating results or financial condition.

***Form 4 filing delays by our Chief Executive Officer have given rise to an investigation by the Securities and Exchange Commission into the delays and our Section 16 compliance procedures, and this investigation may result in penalties and/or sanctions against us.***

As previously disclosed by us, in April 2013, it was determined that Gary Rabin, our Chief Executive Officer, failed to report 27 transactions in which Mr. Rabin sold shares of our common stock that took place between February 7, 2011 and January 10, 2013. Mr. Rabin filed a Form 4 under Section 16 of the Exchange Act on April 15, 2013 reporting the previously unreported sale transactions and correcting the total number of shares of our common stock that Mr. Rabin owned as of the date of filing of the Form 4. Our board of directors initiated an investigation into this matter upon becoming aware of it. We have been advised by the SEC that it is investigating this matter, and we have received requests from the SEC requesting additional information relating to such transactions and our procedures regarding Section 16 filings. We have cooperated with their investigation and supplied information to the SEC in response to its information requests. If the SEC determines that these or other transactions or the failure to report transactions was a violation of the securities laws, such violations could be imputed to us and the SEC could seek to impose remedies against us. We do not know what the outcome of the SEC's investigation may be, and we are unable to estimate the probability of liability or the amount of any penalties that might arise, which may be material to our financial condition. Any action by the SEC could require us to expend significant financial and managerial resources and could also result in further volatility in the market price of our common shares. Nothing set forth in the foregoing statement constitutes an express or implied admission by us of any liability under the Securities Act, the Exchange Act or otherwise.

***We may not be able to obtain third-party patient reimbursement or favorable product pricing, which would reduce our ability to operate profitably.***

Our ability to successfully commercialize some of our proposed products in the human therapeutic field may depend on a significant degree on patient reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health maintenance organizations. We cannot assure you that reimbursement in the United States or foreign countries will be available for any products we may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products with a consequent harm to our business. We cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional



regulations are overly onerous or expensive, or if health care related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon our business model.

***Our products are likely to be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.***

Our products are likely to be significantly more expensive to manufacture than most other drugs currently on the market today. Our present manufacturing processes produce modest quantities of product intended for use in our ongoing research activities, and we have not developed processes, procedures and capability to produce commercial volumes of product. We hope to substantially reduce manufacturing costs through process improvements, development of new science, increases in manufacturing scale and outsourcing to experienced manufacturers. If we are not able to make these or other improvements, and depending on the pricing of the product, our profit margins may be significantly less than that of most drugs on the market today. In addition, we may not be able to charge a high enough price for any cell therapy product we develop, even if they are safe and effective, to make a profit. If we are unable to realize significant profits from our potential product candidates, our business would be materially harmed.

***Our current source of revenues depends on the stability and performance of our sub-licensees.***

Our ability to collect royalties on product sales from our sub-licensees will depend on the financial and operational success of the companies operating under a sublicense. Revenues from those licensees will depend upon the financial and operational success of those third parties. We cannot assure you that these licensees will be successful in obtaining requisite financing or in developing and successfully marketing their products. These licensees may experience unanticipated obstacles including regulatory hurdles, and scientific or technical challenges, which could have the effect of reducing their ability to generate revenues and pay us royalties.

***We depend on key personnel for our continued operations and future success, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.***

Because of the specialized nature of our business, we are highly dependent on our ability to identify, hire, train and retain highly qualified scientific and technical personnel for the research and development activities we conduct or sponsor. The loss of one or more certain key executive officers, or scientific officers, would be significantly detrimental to us. In addition, recruiting and retaining qualified scientific personnel to perform research and development work is critical to our success. Our anticipated growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing, will require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities, and there can be no assurance that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise would adversely affect our business.

***Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.***

Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify, however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles, and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

*We have limited product liability insurance, which may leave us vulnerable to future claims we will be unable to satisfy.*

The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims, and we cannot assure you that substantial product liability claims will not be asserted against us. We have limited product liability insurance. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. We cannot assure you that adequate insurance coverage will be available in the future on acceptable terms, if at all, or that, if available, we will be able to maintain any such insurance at sufficient levels of coverage or that any such insurance will provide adequate protection against potential liabilities. Whether or not a product liability insurance policy is maintained in the future, any product liability claim could harm our business or financial condition.

*We presently have members of management and other key employees located in various locations throughout the country which adds complexities to the operation of the business.*

Presently, we have members of management and other key employees located in both California and Massachusetts, which adds complexities to the operation of our business.

### **Risks Relating to Our Common Stock**

*Stock prices for biotechnology companies have historically tended to be very volatile.*

Stock prices and trading volumes for many biotechnology companies fluctuate widely for a number of reasons, including but not limited to the following factors (some of which may be unrelated to their businesses or results of operations):

- clinical trial results;
- the amount of cash resources and ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by companies or their competitors;
- entering into or terminating strategic relationships;
- changes in government regulation;
- disputes concerning patents or proprietary rights;
- changes in revenues or expense levels;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
- reports by securities analysts;
- activities of various interest groups or organizations;
- media coverage; and
- status of the investment markets.

This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock and the return on your investment.

***A significant number of shares of our common stock have become available for sale and their sale could depress the price of our common stock.***

Substantially all of our common stock is freely tradable in the equity markets.

We may also sell a substantial number of additional shares of our common stock in connection with a private placement or public offering of shares of our common stock (or other series or class of capital stock to be designated in the future). The terms of any such transactions would likely require us to register the resale of any shares of capital stock issued or issuable in the transaction.

Sales of a substantial number of shares of our common stock under any of the circumstances described above could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate.

***We do not intend to pay cash dividends on our common stock in the foreseeable future.***

Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Furthermore, we may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

***Our common stock is subject to “penny stock” regulations and restrictions on initial and secondary broker-dealer sales.***

The SEC has adopted regulations which generally define “penny stock” to be any listed, trading equity security that has a market price less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exemptions. Penny stocks are subject to certain additional oversight and regulatory requirements. Brokers and dealers affecting transactions in our common stock in many circumstances must obtain the written consent of a customer prior to purchasing our common stock, must obtain information from the customer and must provide disclosures to the customer. These requirements may restrict the ability of broker-dealers to sell our common stock and may affect your ability to sell your shares of our common stock in the secondary market.

*As an issuer of “penny stock,” the protection provided by the federal securities laws relating to forward looking statements does not apply to us.*

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Statements in this prospectus and in the documents incorporated by reference in this prospectus contain forward-looking statements that involve risks and uncertainties. We use words such as “may,” “assumes,” “forecasts,” “positions,” “predicts,” “strategy,” “expects,” “estimates,” “anticipates,” “believes,” “projects,” “intends,” “plans,” “budgets,” “continue” and variations thereof, and other statements contained in this prospectus, regarding matters that are not historical facts and are forward-looking statements. Because these statements involve risks and uncertainties, as well as certain assumptions, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to those risks identified under “Risk Factors” and from time to time in our other filings with the SEC. The information in this prospectus or any prospectus supplement speaks only as of the date of that document and the information incorporated herein by reference speaks only as of the date of the document incorporated by reference. Except as required by law, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Forward-looking statements include our plans and objectives for future operations, including plans and objectives relating to our products and our future economic performance. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions, future business decisions, and the time and money required to successfully complete development and commercialization of our technologies, all of which are difficult or impossible to predict accurately and many of which are beyond our control. Although we believe that the assumptions underlying the forward-looking statements contained herein are reasonable, any of those assumptions could prove inaccurate and, therefore, we cannot assure you that the results contemplated in any of the forward-looking statements contained herein will be realized. Based on the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of any such statement should not be regarded as a representation by us or any other person that our objectives or plans will be achieved.

## **USE OF PROCEEDS**

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. However, we may receive gross proceeds of up to \$30,000,000 under the Purchase Agreement over an approximately 36-month period beginning July 2014, assuming that we sell the full amount to Lincoln Park under the agreement and other estimated fees and expenses. See “Plan of Distribution” elsewhere in this prospectus for more information.

All proceeds that we receive under the Purchase Agreement will be used to fund our clinical activities, including the conclusion of our phase 1 AMD and SMD trials and initiation of phase 1 MMD trials and phase 2 AMD and SMD clinical trials, the advancement of our pre-clinical studies in other ocular indications and other programs, and for general corporate purposes. The amounts and timing of our actual expenditures will depend on numerous factors, including the status of our product sales and marketing efforts, the amount of proceeds actually raised from sales under the Purchase Agreement, and the amount of cash generated through our existing strategic collaborations and any additional strategic collaborations into which we may enter. Accordingly, our management will have significant flexibility in applying any net proceeds that we receive pursuant to the Purchase Agreement

## **DETERMINATION OF OFFERING PRICE**

The selling stockholders may offer and sell the shares of common stock covered by this prospectus at prevailing market prices or privately negotiated prices. See “Plan of Distribution.”



## THE SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Lincoln Park, of shares of common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement, as described in greater detail below. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on June 27, 2014, concurrently with our execution of the Purchase Agreement and in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the selling stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have sold or may sell to Lincoln Park under the Purchase Agreement. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

The following table presents information regarding the selling stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholder, and reflects its holdings as of June 30, 2014. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 3,296,586,368 shares of our common stock actually outstanding as of June 30, 2014, excluding the 10,600,707 commitment shares issued to Lincoln Park on June 27, 2014.

Selling Stockholder	Shares Beneficially Owned Prior to the Offering		Maximum Shares Offered Hereby	Shares Beneficially Owned After the Offering <sup>(1)</sup>
	Number	Percentage		
Lincoln Park Capital Fund, LLC <sup>(2)</sup>	10,600,707	*	260,600,707	7.3%

\* Less than 1%

(1) Based on 3,557,187,075 outstanding shares of our common stock as of June 30, 2014.

(2) Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Cope

and Scheinfeld have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Lincoln Park Capital, LLC is not a licensed broker dealer or an affiliate of a licensed broker dealer.

## **The Lincoln Park Transaction**

### General

On June 27, 2014, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$30,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

As of June 30, 2014, we have issued 10,600,707 shares of our common stock to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement.

We may sell up to \$30,000,000 worth of our common stock under the Purchase Agreement over the approximately 36-month period. We may, from time to time and at our sole discretion but no more frequently than every other business day, direct Lincoln Park to purchase up to 3,500,000 shares of our common stock on any such business day, provided that in no event shall Lincoln Park purchase more than \$1,000,000 worth of our common stock on any single business day, plus an additional “accelerated amount” under certain circumstances, at a purchase price per share based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount.

### Purchase of Shares Under the Purchase Agreement

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 3,500,000 shares of our common stock on any such business day, provided that in no event shall Lincoln Park purchase more than \$1,000,000 worth of our common stock on any single business day. Such purchases are hereinafter referred to as “Regular Purchases”. The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice, to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, not to exceed the lesser of:

30% of the aggregate shares of our common stock traded during normal trading hours on the purchase date; and  
two times the number of purchase shares purchased pursuant to the corresponding Regular Purchase.

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

97% of the volume weighted average price during (i) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the Purchase Agreement, or (ii) the portion of the trading day of the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum; or  
the closing sale price of our common stock on the purchase date.

In the case of both Regular Purchases and Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

### Minimum Purchase Price

Under the Purchase Agreement, we have set a floor price of \$0.03 per share. Lincoln Park shall not purchase any shares of our common stock on any day that the closing sale price of our common stock is below the floor price. The floor price will be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction and, effective upon the consummation of any such event, the floor price will be the lower of (i) the adjusted price and (ii) \$1.00.

### Events of Default

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- suspension by our principal market of our common stock from trading for a period of three consecutive business days;
- the de-listing of our common stock from our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Global Market, the NASDAQ Global Select Market, the NASDAQ Capital Market, the NYSE Amex or the OTC Bulletin Board (or nationally recognized successor thereto);
- the transfer agent's failure for five business days to issue to Lincoln Park shares of our common stock which Lincoln Park is entitled to receive under the Purchase Agreement;
- any breach of the representations or warranties or covenants contained in the Purchase Agreement or any related agreement which has or which could have a material adverse effect on us subject to a cure period of five business days;
-

any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; and  
if at any time we are not eligible to transfer our common stock electronically or a material adverse change in our business, financial condition, operations or prospects has occurred.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park's control, shares of our common stock cannot be sold by us or purchased by Lincoln Park under the Purchase Agreement.

#### Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

#### No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

#### **Effect of Performance of the Purchase Agreement on Our Stockholders**

All 260,600,707 shares of our common stock registered in this offering which may be sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Lincoln Park may ultimately purchase all, some or none of the shares of common stock registered in this offering that Lincoln Park has not previously purchased. Lincoln Park may sell all, some or none of the shares it has purchased or will purchase under the Purchase Agreement. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$30,000,000 of our common stock, exclusive of the 10,600,707 shares issued to Lincoln Park as a

commitment fee. Depending on the price per share at which we sell our common stock to Lincoln Park, we may be authorized to issue and sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus. If we choose to do so, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement registered in this offering at varying purchase prices:



<b>Assumed Average Purchase Price Per Share</b>	<b>Number of Registered Shares to be Issued if Full Purchase(1)(2)</b>	<b>Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (3)</b>	<b>Proceeds from the Sale of Shares to Lincoln Park Under the \$30,000,000 Purchase Agreement</b>
\$0.03 <sup>(4)</sup>	250,000,000	7.02%	\$7,500,000
\$0.07 <sup>(5)</sup>	250,000,000	7.02%	\$17,500,000
\$0.10	250,000,000	7.02%	\$25,000,000
\$0.20	150,000,000	4.33%	\$30,000,000

Although the Purchase Agreement provides that we may sell up to \$30,000,000 of our common stock to Lincoln Park, we are only registering 260,600,707 shares under this prospectus (inclusive of the 10,600,707 shares issued (1) to Lincoln Park as a commitment fee), which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering.

(2) The number of registered shares to be issued excludes the 10,600,707 commitment shares because no proceeds will be attributable to such commitment shares.

The denominator is based on 3,296,586,368 shares outstanding as of June 30, 2014, adjusted to include the 10,600,707 shares issued to Lincoln Park as commitment shares in connection with this offering and the number of shares set forth in the adjacent column which we would have sold to Lincoln Park at the applicable assumed average purchase price per share. The numerator does not include the 10,600,707 shares issued to Lincoln Park as (3) commitment shares in connection with this offering, and is based on the number of shares registered in this offering to be issued under the Purchase Agreement at the applicable assumed purchase price per share set forth in the adjacent column. The number of shares in such column does not include shares that may be issued to Lincoln Park under the Purchase Agreement which are not registered in this offering.

Under the Purchase Agreement, we may not sell and Lincoln Park may not purchase any shares on a day in which (4) the closing sale price of our common stock is below \$0.03, as may be adjusted in accordance with the Purchase Agreement.

(5) The closing sale price of our shares on July 2, 2014.

## PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be affected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions. In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by

this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the expenses incident to the registration, offering, and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

Our common stock is quoted on the OTCQB and OTCBB under the symbol "ACTC".

## **LEGAL MATTERS**

The validity of the shares offered hereby has been passed upon for us by Goodwin Procter LLP, Boston, Massachusetts.

## **EXPERTS**

The consolidated financial statements and the effectiveness of internal control over financial reporting incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2013, have been audited by SingerLewak LLP, an independent registered public accounting firm, as stated in their report incorporated by reference herein, and have been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

**LIMITATION ON LIABILITY AND DISCLOSURE OF COMMISSION POSITION ON  
INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our directors and officers are indemnified by our bylaws against amounts actually and necessarily incurred by them in connection with the defense of any action, suit or proceeding in which they are a party by reason of being or having been directors or officers of the Company. Our certificate of incorporation provides that none of our directors or officers shall be personally liable for damages for breach of any fiduciary duty as a director or officer involving any act or omission of any such director or officer. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to such directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by us of expenses incurred or paid by such director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

## **WHERE YOU CAN FIND MORE INFORMATION**

This prospectus and any subsequent prospectus supplements do not contain all of the information in the registration statement. We have omitted from this prospectus some parts of the registration statement as permitted by the rules and regulations of the SEC. Statements in this prospectus concerning any document we have filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified in their entirety by reference to these filings. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any documents that we have filed with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the operation of the Public Reference Room. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information that we file electronically with the SEC, including us. The SEC's Internet site can be found at <http://www.sec.gov>. In addition, we make available on or through our Internet site copies of these reports as soon as reasonably practicable after we electronically file or furnished them to the SEC. Our Internet site can be found at <http://www.advancedcell.com>. Our website is not a part of this prospectus.

## INFORMATION INCORPORATED BY REFERENCE

We have elected to incorporate certain information by reference into this prospectus. By incorporating by reference, we can disclose important information to you by referring you to other documents we have filed or will file with the SEC. The information incorporated by reference is deemed to be part of this prospectus, except for information incorporated by reference that is superseded by information contained in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any statements in the prospectus or any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents set forth below that we have previously filed with the SEC:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as amended;
- Our Quarterly Report on Form 10-Q for the fiscal quarters ended March 31, 2014;
- Our Current Reports on Form 8-K as filed on January 22, 2014, March 10, 2014, April 21, 2014, May 5, 2014, May 29, 2014, June 6, 2014, June 24, 2014 and July 3, 2014; and
- The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on May 28, 2003.

We also incorporate by reference all documents we file in the future pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of the initial filing of the post-effective amendment to the registration statement that contains this prospectus and prior to the termination of the offering (except in each case the information contained in such document to the extent “furnish” and not “filed”).

You may obtain copies of these documents on the website maintained by the SEC at <http://www.sec.gov>, or from us without charge (other than exhibits to such documents, unless such exhibits are specifically incorporated by reference into such documents) by writing us at Corporate Secretary, Advanced Cell Technology, Inc., 33 Locke Drive, Marlborough, Massachusetts 01752 or visiting our website at [www.advancedcell.com](http://www.advancedcell.com).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or deemed to be incorporated by reference herein modifies or supersedes that statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.



**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth our costs and expenses in connection with the registration for resale of our common stock as described in this registration statement. All of the amounts shown are estimates except the Commission Registration Fee.

	AMOUNT
Commission Registration Fee	\$ 2,182
Legal Fees and Expenses	10,000
Accounting Fees and Expenses	8,000
Miscellaneous Expenses	2,000
Total	\$ 22,182

**Item 15. Indemnification of Directors and Officers.**

Section 145 of the Delaware General Corporation Law authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact of their prior or current service to the corporation as a director or officer, in accordance with the provisions of Section 145, which are sufficiently broad to permit indemnification under certain circumstances for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"). The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

Our directors and officers are indemnified by our bylaws against amounts actually and necessarily incurred by them in connection with the defense of any action, suit or proceeding in which they are a party by reason of being or having

been our directors or officers. Our certificate of incorporation provides that none of our directors or officers shall be personally liable for damages for breach of any fiduciary duty as a director or officer involving any act or omission of any such director or officer. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to such directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by us of expenses incurred or paid by such director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**Item 16. Exhibits.**

See Index of Exhibits immediately following the signature page of this registration statement.

**Item 17. Undertakings.**

a. The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - i. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

- ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
- iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

i. Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

ii. Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

5. That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

- iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

b. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

c. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has duly caused this Registration Statement to be signed on its behalf by the undersigned, and certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the city of Marlborough, Commonwealth of Massachusetts, on July 3, 2014.

ADVANCED CELL TECHNOLOGY, INC.,  
a Delaware corporation

By: /s/ Edward Myles

Edward Myles

Interim President, Chief Operating Officer and Chief Financial Officer

## POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each individual whose signature appears below hereby severally constitutes and appoints Edward Myles as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any registration statement that is to be effective upon filing pursuant to Rule 462(b) of the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

/s/ Edward Myles

Edward Myles

July 3,  
2014

Interim President, Chief Operating Officer and Chief Financial Officer (Principal Executive, Financial and Accounting Officer)

/s/ Robert Langer

Robert Langer

Director

July 3,  
2014

/s/ Zohar Loshitzer  
Zohar Loshitzer            July 3, 2014  
Director

/s/ Gregory D. Perry  
Gregory D. Perry         July 3, 2014  
Director

/s/ Alan C. Shapiro  
Alan C. Shapiro           July 3, 2014  
Director

/s/ Michael T. Heffernan  
Michael T. Heffernan     July 3, 2014  
Director and Chairman



## INDEX OF EXHIBITS

The following documents are filed as exhibits to this registration statement:

Exhibit Number	Description
4.1	Certificate of Incorporation of the Registrant dated November 17, 2005 (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on November 21, 2005 and incorporated by reference herein).
4.2	Certificate of Amendment to Certificate of Incorporation dated October 13, 2006 (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K on October 13, 2006 and incorporated herein by reference).
4.3	Certificate of the Powers, Designations, Preferences and Rights of the Series A-1 Convertible Preferred Stock dated March 5, 2009 (previously filed as Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed on July 20, 2009 and incorporated herein by reference).
4.4	Certificate of Amendment to Certificate of Incorporation dated September 15, 2009 (previously filed as Exhibit 3.15 to the Registrant's Registration Statement on Form S-1 filed November 18, 2009 and incorporated herein by reference).
4.5	Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock dated November 3, 2009 (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on November 12, 2009 and incorporated by reference herein).
4.6	Certificate of Designations of Preferences, Rights and Limitations of Series C Preferred Stock dated December 30, 2010 (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 3, 2011 and incorporated herein by reference).
4.7	Certificate of Amendment to Certificate of Incorporation dated January 24, 2012 (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 30, 2012 and incorporated herein by reference).
4.8	Certificate of Amendment to Certificate of Incorporation dated October 24, 2013 (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 24, 2013 and incorporated herein by reference).

- 4.9 Bylaws of the Registrant (previously filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on November 21, 2005 and incorporated by reference herein).
- 4.10 Amendment No. 1 to Bylaws of the Registrant (previously filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on November 30, 2007 and incorporated by reference herein).
- 4.11 Specimen Stock Certificate (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on November 21, 2005 and incorporated by reference herein).
- 5.1 \* Opinion of Goodwin Procter LLP.  
Purchase Agreement, dated as of June 27, 2014, between the Registrant and Lincoln Park (previously filed as
- 10.1 Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 3, 2014 and incorporated herein by reference).
- 10.2 Registration Rights Agreement, dated as of June 27, 2014, between the Registrant and Lincoln Park (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 3, 2014 and incorporated herein by reference).
- 23.1\* Consent of SingerLewak LLP, an independent registered public accounting firm.
- 23.2 \* Consent of Goodwin Procter LLP (included in Exhibit 5.1).
- 24.1 \* Powers of Attorney (included on signature pages).

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\* Filed herewith.